First-Quarter 2021 Earnings Conference Call Prepared Remarks
May 4, 2021

[Slide 4: Opening Remarks – Albert Bourla]

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

I couldn't be prouder of the way Pfizer has started 2021. During the first quarter:

- We delivered strong financial results. Even excluding the revenue provided from our COVID-19 vaccine, our revenues grew 8% operationally. And this 8% growth includes a negative 5% impact from pricing.
- We continued to accelerate production and shipments of our COVID-19 vaccine – in many cases exceeding our contractual obligations for delivery timelines.
- And we achieved several important clinical, regulatory and commercial milestones.

[Slide 5: Q1 2021 Revenues: Key Growth Drivers]

Let me start with commentary on some of our biggest growth drivers in the quarter.

The **Pfizer-BioNTech COVID-19 Vaccine** contributed 3.5 billion dollars in global revenues during the first quarter. As of May 3, 2021, Pfizer, along with its partner BioNTech, has shipped approximately 430 million doses of the vaccine to 91 countries and territories around the world. I will share some thoughts on the sustainability of this revenue stream later in my remarks.

Eliquis has continued to deliver a strong performance, with revenues up 25% operationally to 1.6 billion dollars in the first quarter. In the U.S., Eliquis sales growth was driven mainly by strong volume growth.

Vyndaqel and **Vyndamax** generated revenues of 453 million dollars, representing operational growth of 88%. Our disease education efforts in the U.S. continued to support appropriate diagnosis, increasing the estimated diagnosis rate to almost 24% at quarter end, up from 21% at the end of 2020. At the end of the quarter, more than 23,500 patients have been diagnosed, more than 17,000 patients have received a prescription and more than 10,500 patients have received the drug, including patients who receive the drug at no cost through our patient assistance programs. While there are still regional differences in cardiology activity and elective diagnostic procedures due to COVID-19 guidelines … on a national basis, diagnosis

rates in the U.S. have now recovered and exceed pre-COVID levels as compared with the first quarter of 2020. We also have seen strong growth from Japan and from developed Europe, which is the largest contributor to our revenues outside the U.S.

Xeljanz also performed well, with global revenues up 18% operationally to 538 million dollars. The growth was primarily driven by 16% growth in the U.S. and 14% operational growth in international developed markets. The underlying prescription demand in the U.S. grew 9% compared with the first quarter of 2020, outpacing the advanced therapy market by 3 percentage points. We have invested in formulary access in the U.S., which has played a vital role in enabling this volume growth.

In the U.S., **Ibrance** revenues declined 7% compared with the year-ago quarter. Total prescription volume is relatively stable, and we continue to be the leading product in the CDK class by a wide margin with an 84% of total patient share in first-line use. However, we saw increased enrollment this quarter in our Patient Assistance Program, which provides Ibrance free of charge to certain low-income patients. We believe this increase is due to COVID-19-related economic hardships that are affecting particularly the demographics of the Ibrance patient population, and we do expect this to normalize over time as the economic impact from the pandemic subsides.

[Slide 6: Updates on BNT162b2]

As of mid-April, we had contracted for approximately 1.6 billion doses of our COVID-19 vaccine expected to be delivered in 2021. As a result, based on the contracts signed through mid-April, we are increasing our revenue guidance and now expect revenues of approximately 26 billion dollars from the vaccine in 2021. We also are in ongoing discussions with multiple countries around the world about their needs, and we expect these discussions to lead to additional supply agreements.

Based on what we've seen, we believe that a durable demand for our COVID-19 vaccine – similar to that of the flu vaccines – is a likely outcome.

We want to be a long-term partner to health authorities around the world in their ongoing efforts to combat COVID-19, including their planning of an ongoing pandemic vaccination approach that is fit-for-purpose to local requirements. To that end, together with our partner, BioNTech, we expect to have the capacity to manufacture at least 3 billion doses in 2022.

We are in discussions with a number of countries around the world for multi-year contracts for the potential supply of COVID-19 vaccine doses during 2022 and beyond. In fact, we recently signed an agreement with the U.K. to supply 60 million additional doses in 2021, and with Israel to supply millions of doses in 2022 – enough for the government to boost every eligible citizen, subject to local guidelines – with the option to purchase millions of additional doses for additional boosters. We also have reached an agreement with the

Canada to supply up to 125 million doses in 2022 and 2023, with options to supply up to 60 million additional doses in 2024.

It is our hope that the Pfizer-BioNTech vaccine will continue to have a global impact by helping to get the devastating pandemic under control and helping economies around the world not only open – but stay open – creating a scenario in which Pfizer can continue to be both a leader and a beneficiary. To realize this goal, we are continuing to lead with strong science – not only to maximize the impact of our COVID-19 vaccine in preventing disease, but also with the work we are doing to develop two potential novel protease inhibitors – one administered intravenously and one administered orally.

[Slide 7: Key Near-term Potential Milestones for COVID-19 Vaccine Program (2021)]

As you can see on the accompanying slide, we have many clinical studies ongoing and expect to have multiple readouts and submissions throughout the remainder of the year. Let me touch on a few.

First, while we are currently distributing our vaccine in the U.S. under an Emergency Use Authorization (EUA), we expect to submit this month a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking full approval for our COVID-19 vaccine for individuals 16 years of age and older.

Second, we are evaluating the safety and immunogenicity of a third dose of the existing formulation of our COVID-19 vaccine to understand the effect of a booster on immunity against the SARS-CoV-2 variants in circulation. Additionally, we have started an evaluation of an updated, prototype variant version of our vaccine that encodes the spike protein of the lineage B.1.351 SARS-CoV-2 variant, which includes the mutation E484K, first identified in South Africa. This study is designed to establish a regulatory pathway to update the current vaccine to address any future variant of potential concern in approximately 100 days, if needed. We expect to have immunogenicity data for both studies in early July.

Third, we are continuing our efforts to evaluate the Pfizer-BioNTech COVID-19 vaccine in additional populations.

- We expect to hear back shortly from the FDA on our application for expanded Emergency Use Authorization for our COVID-19 vaccine to include individuals 12 to 15 years of age.
- The Pfizer-BioNTech pediatric study evaluating the safety and efficacy of our COVID-19 vaccine in children six months to 11 years of age is ongoing. We expect to have definitive readouts and submit for an EUA for two cohorts, including children 2-5 years of age and 5-11 years of age, in September. The readout and submission for the cohort of children six months to two years old are expected in the fourth quarter.
- We also expect to have Phase 2 safety data from our ongoing study in pregnant women by late July/early August.

Fourth, we are making progress with improving the stability of our COVID-19 vaccine.

- On Friday, we submitted new stability data to the FDA, and we believe we could soon receive an update to the EUA Prescribing Information allowing the vaccine to be stored at standard refrigerator temperatures (2°C to 8°C) for up to four weeks.
- We also are working on a ready-to-use formulation that, subject to generating supportive stability data and obtaining regulatory approval, could potentially be stored at standard refrigerator temperatures for up to 10 weeks, and up to six months at -50°C to -70°C. If successful, we expect to have the data to support this formulation in August.

Fifth, as we move closer to a potential approval for our investigational 20-valent pneumococcal conjugate vaccine for adults – which, if approved, may be launched during an ongoing pandemic – we plan to begin this month a study of co-administration of the Pfizer-BioNTech COVID-19 vaccine with the 20-valent pneumococcal conjugate vaccine.

[Slide 8: Two Protease Inhibitor Antiviral Candidates]

Moving to COVID-19 treatments, we have early studies ongoing for two protease inhibitor antiviral candidates: one administered intravenously and one orally. We expect to begin our Phase 2/3 study for the intravenously administered compound in May and for the orally administered compound in July.

With regard to our oral protease inhibitor, we are planning to evaluate its safety and efficacy through three development pathways.

- We are studying it compared to a placebo to confirm whether it is efficacious against COVID-19.
- We are studying it against monoclonal antibodies to assess relative efficacy against current circulating strains. Mutations of spike protein may lead to diminished efficacy of presently available monoclonal antibodies, and our intent is to bring about a therapy with durable efficacy through a different mechanism of action and conservation of the 3CL protein.
- We are studying it in unvaccinated household contacts exposed to someone infected with COVID-19 to evaluate if it prevents close contacts from contracting COVID-19. It has been well established with flu antiviral drugs that administering them to close contacts of subjects who have flu reduces the chance of them also getting flu by more than 80%. Though SARS CoV-2 is a different virus than flu, we are hopeful the principle will be the same: If we administer the investigational treatment to those who are at risk from close contact, does it prevent them from getting sick.

As you can see on our timeline, if things go well, we could potentially apply for approvals before the end of the year.

The intravenously administered protease inhibitor is being studied in in-patient Phase 1b studies in the U.S., Spain, Belgium and Brazil. We expect to begin a Phase 2/3 study, in which the IV compound will be tested against the current standard of care, this quarter.

With the current unmet global medical need for anti-virals, we are constantly assessing how we can accelerate the development of these potential treatments.

[Slide 9: mRNA Flu Vaccine]

Pfizer has emerged as a leader in mRNA development, and we are exploring a wide range of opportunities for the technology.

We are making rapid progress with our potential flu mRNA program, and we aim to maintain mRNA leadership with two potential game-changing mRNA approaches to a flu vaccine expected to enter the clinic in the third quarter of 2021.

We will test multiple constructs in Phase 1/2 to facilitate swift selection of an optimal tetravalent flu product dose regimen. We aim to develop initially a tetravalent flu vaccine using the modified mRNA platform. Pending the generation of favorable immune and tolerability Phase 1/2 data, a potential rapid progression to Phase 3 is possible, given our large-scale pharmaceutical science and manufacturing capabilities.

We also are exploring the potential to address other infectious diseases that we plan to discuss in the near future.

In addition to prophylactic vaccines for infectious diseases, we believe mRNA has the potential to address a wide range of therapeutic areas, including cancer and genetic disease. As you have seen, today we have increased our 2021 R&D guidance to reflect our plans to increase our mRNA capabilities, build momentum in our targeted areas of interest, and deliver on mRNA's breakthrough potential for the benefit of people worldwide. You can expect to hear more about our plans and potential applications in the coming weeks.

[Slide 10: Selected Pipeline Updates (1 of 3)]

Now let's turn to Pfizer's R&D pipeline, which continues to be one of our great strengths. Our pipeline currently includes 99 potential new therapies or indications. That's 99 potential opportunities to change the lives of patients around the world.

I will now provide an update on some of these exciting candidates.

In **Vaccines** …

- As referenced earlier, the FDA is reviewing the Biologic License Application for our investigational 20-valent pneumococcal conjugate vaccine for adults 18 years of age and older with a PDUFA date

in June of 2021. Among pneumococcal conjugate vaccines on the market or in late stage development, if approved, we believe it could provide the most comprehensive coverage against pneumococcal pneumonia disease in adults.

In **Internal Medicine** …

- In December 2020, we entered into a collaboration with Myovant Sciences to commercialize Relugolix combination therapy for uterine fibroids and endometriosis, pending FDA approval, as well as Relugolix for advanced prostate cancer. We are excited about the prospect of soon commercializing this product for its potential indication of uterine fibroids, if approved, and the FDA has a PDUFA date of June 1, 2021. An estimated five million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated three million women are inadequately treated by current therapy and require further treatment. We are also working on our planned FDA submission for the endometriosis indication, which we hope to submit this year. An estimated six million women in the U.S. suffer from symptoms of endometriosis, and an estimated one million women are inadequately treated by current therapy and require further treatment.

[Slide 11: Selected Pipeline Updates (2 of 3)]

In **Inflammation & Immunology** …

- Alopecia areata is an immune disease that causes hair loss and has no approved treatments in the U.S. and Europe. The Phase 2b/3 pivotal clinical trial to evaluate our JAK3/TEC inhibitor ritlecitinib in alopecia areata is expected to read out late in the third quarter of 2021. If approved, ritlecitinib has the potential to transform the lives of certain patients with this condition.
- The FDA has extended the priority review period for our New Drug Application for abrocitinib for the treatment of adults and adolescents with moderate to severe atopic dermatitis. The PDUFA date has been extended three months to early third quarter 2021, as the FDA has requested additional information and will require additional time to review these data. We believe in the efficacy and safety profile of abrocitinib, which was demonstrated in a robust Phase 3 clinical trial program of more than 2,800 patients. We look forward to working with the FDA and other regulators around the world over the coming months to potentially help bring this important option to patients.
- It is important to note that each JAK inhibitor is unique and potential risks identified in one molecule do not necessarily implicate other molecules. We continue to remain confident in the importance of the JAK inhibitor class for appropriate patients with inflammatory diseases given the role of JAK pathways in inflammatory processes. Patient safety is of utmost importance and we continue to monitor all compounds in our portfolio to identify signals both in development as well as after regulatory approval.

In **Oncology** …

- We continue to evaluate talazoparib in three studies in prostate cancer. The first is TALAPRO-1, a Phase 2 study in 2L+ patients with DDR mutations, which recently had a positive readout as a monotherapy, providing the key proof of concept to move forward in prostate cancer combinations studies. The second is TALAPRO-2, a Phase 3 study in 1L metastatic castration-resistant prostate cancer (or mCRPC) in an unselected population for which the Primary Completion Date is expected in the second half of 2021. And finally, TALAPRO-3, which is beginning soon and will study talazoparib in combination with enzalutamide in DDR-deficient metastatic castration-sensitive prostate cancer (or mCSPC).
- In February 2021, we announced that the first participant has been dosed in the registration-enabling Phase 2 MagnetisMM-3 study (NCT04649359) of elranatamab, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody, in patients with relapsed/refractory multiple myeloma. New enrollment in the study has been paused while we provide additional information to the FDA regarding three cases of peripheral neuropathy observed in the ongoing Phase 1 MagnetisMM-1 study (NCT03269136). Patients who are deriving clinical benefit from elranatamab may continue treatment.

[Slide 12: Selected Pipeline Updates (3 of 3)]

In **Rare Disease** …

- Our Phase 3 lead-in study of the gene therapy fidanacogene elaparvovec in hemophilia B has now been fully enrolled with more than 40 patients. We remain on course to complete dosing and expect to conduct a planned interim analysis for a potential data readout in 2021.
- We also continue to progress our hemophilia A Gene Therapy, girocotocogene fitelparvovec, which was developed in collaboration with Sangamo Therapeutics. We anticipate presenting two-year Phase 1/2 data in the fourth quarter of 2021. Additionally, we are pleased to report that our lead-in study for our Phase 3 AFFINE study is in hemophilia A now fully enrolled, which could lead to a pivotal readout in 2022.
- For our gene therapy candidate for Duchenne muscular dystrophy (DMD), we now have an approved generic name, fordadistrogene movaparvovec, and we are progressing our Phase 3 trial, CIFFREO. To date, we have opened 15 trial sites in 8 countries (Italy, Spain, Israel, the UK, South Korea, Japan, Russia and Canada). In the U.S., we are actively working with the FDA to address outstanding questions related to our Investigational New Drug Application, including technical aspects of our potency assay matrix, so that we can begin enrolling patients in Phase 3 U.S. study sites. While we have high confidence in our current quality control overall and with the potency assay matrix, which has been accepted in countries outside of the U.S., the FDA has additional

technical requests that we are working to address as quickly as possible. We understand the sense of urgency among many families in the U.S. who were hoping for sites to open soon. While we cannot speculate at this time as to when sites may open in the U.S., we do not expect a resolution in the first half of 2021. We are working with a sense of urgency and hope to reach alignment with the FDA as soon as possible. In the interim, we will continue to progress our trial globally and enroll patients at other sites, which we believe will allow our program to remain on track to potentially enable approvals around the world, including the U.S.

[Slide 13: Our Engagement in a Key Policy Issue: Affordable Access]

Now I would like to address a key policy issue in which we continue to be actively engaged: affordable access.

We expect the Biden Administration will soon announce a "human capital" component to their infrastructure package that will include health provisions. Pfizer is mobilizing to work with the Administration, as well as lawmakers in both political parties, on meaningful solutions for patient access. Specifically, there are three key areas where we would like to see Congress and the Administration focus: rebate reform, capping beneficiary cost-sharing in Medicare Part D, and incentivizing the uptake of biosimilars.

At the state level, we have focused our efforts on meaningful solutions to directly address patient affordability challenges. This includes legislation to require 100 percent of negotiated rebates to be passed through to consumers at the pharmacy counter. We have also worked with state policymakers to advance legislation in several states ensuring that patient assistance provided by manufacturers will count towards the patient's deductible and out of pocket maximums.

Looking Ahead

Looking ahead, we remain focused on being nimble and investing in our R&D organization, so we can build on the strong improvement in the clinical success rates we have seen over the past five years and potentially translate that success into strong commercial launches that benefit patients.

Excluding any impact from our COVID-19 vaccine, we are on track and continue to expect a revenue CAGR of at least 6%, on a risk-adjusted basis, through the end of 2025, as well as double-digit growth on the bottom line.

We remain very confident in our ability to achieve these growth rates because of the strength of both our current product portfolio and our R&D pipeline. At the same time, we will continue to pursue business development opportunities with the potential to further enhance our long-term growth prospects. Just last week, for example, Pfizer acquired Amplyx Pharmaceuticals, a privately held company dedicated to the development of therapies for debilitating and life-threatening diseases that affect people with compromised

immune systems. Amplyx's lead compound is a novel investigational asset under development for the treatment of invasive fungal infections.

Thank you.

[Slide 14: Financial Review – Frank D'Amelio]

Frank D'Amelio – ***Pfizer Inc. – Chief Financial Officer, Executive Vice President, Global Supply***

[Slide 15: Quarterly Income Statement Highlights]

I know you've seen our release so let me provide a few highlights regarding the financials.

Clearly the COVID-19 vaccine has had a dramatic positive impact on our year-over-year results and Albert has addressed the key points on the COVID-19 vaccine landscape.

Looking at the income statement, revenue and Adjusted cost of sales were significantly impacted by COVID-19 vaccine sales and the associated 50% gross profit split with BioNTech, which we recognize on the cost of sales line.

Revenue increased 42% operationally in the first quarter of 2021 driven by COVID-19 vaccine sales and solid performance from a number of our other key growth drivers. The Adjusted cost of sales increase shown here reduced gross margin by 10 percentage points compared to the first quarter of 2020, which primarily reflects the impact of the COVID-19 vaccine gross profit split which accounted for approximately 8 percentage points, and to a much smaller extent, product mix.

Looking at the business excluding the COVID-19 vaccine contribution, we saw a continuation of solid revenue growth for the business in the quarter which nicely supports our projected revenue CAGR of at least 6% through the end of 2025. As a reminder this growth projection continues to exclude any contribution from the COVID-19 vaccine.

In addition, compared with the prior-year quarter, first-quarter 2021 revenues were favorably impacted by approximately $400 million as a result of first-quarter 2021 having three additional selling days in the U.S. and four additional selling days in international markets. This increase in selling days will be offset in fourth-quarter 2021, resulting in essentially the same number of selling days in full-year 2021 as full-year 2020.

However, the favorable impact on quarter-over-quarter comparisons in first-quarter 2021 from selling days was partially offset by the non-recurrence of favorable revenue impacts related to COVID-19 on first-quarter 2020, including increased demand for certain products of approximately $150 million and additional wholesaler inventories of approximately $100 million.

Given these factors, the net favorable impact on first-quarter 2021 revenues was approximately $150 million or approximately 1.5 percentage points of operational growth, which in effect reduces a strong 8% operational growth rate to about 7%.

Reported diluted EPS for the quarter was up 44% compared to the year-ago quarter, while Adjusted diluted EPS grew 47% for the quarter.

Foreign exchange movements resulted in a 3% positive benefit to revenue and a 1% benefit to Adjusted diluted EPS.

[Slide 16: 2021 Financial Guidance]

Let's move to our revised 2021 guidance.

We've again provided total-company guidance, which includes the business with the COVID-19 vaccine, and then we've provided some additional sub-ledger detail on our assumptions regarding the projected COVID-19 vaccine contribution so you can also see our projection for the business without the COVID-19 vaccine.

To start, the adjustments we've made to our total company guidance are almost entirely due to the anticipated impact of the COVID-19 vaccine and R&D spending on incremental COVID-19 programs and non-COVID-19 mRNA programs along with a small increase in the revenue outlook for the business excluding the COVID-19 vaccine,

For Adjusted cost of sales, the ranges have increased to 38-39%, which incorporates the incremental anticipated COVID-19 vaccine revenue which has a significantly higher cost of sales due to the gross margin split with BioNTech as compared to the rest of the business. The projected COVID-19 vaccine revenue as a percentage of total company revenue has increased to 36% as compared to 25% in our initial 2021 guidance.

On Adjusted SI&A, we have maintained our initial guidance of $11-12 billion.

In addition, we increased our Adjusted R&D guidance range to $9.8 to $10.3 billion to incorporate anticipated spending on incremental COVID-19 related programs and other mRNA-based projects that are not part of the BioNTech collaboration.

Working this through with a projected 15 percent effective tax rate yields an increased Adjusted diluted EPS range of $3.55 to $3.65, or 59% growth at the midpoint compared to 2020 including an expected 4% benefit from foreign exchange.

[Slide 17: Assumptions Related to BNT162b2 within 2021 Financial Guidance]

Let me quickly remind you of some assumptions and context on the projected COVID-19 vaccine contribution and our collaboration agreement:

As referenced earlier, the Pfizer BioNTech COVID-19 vaccine collaboration construct is a 50/50 gross margin split.

Pfizer will book the vast majority of the global collaboration revenue, except for Germany and Turkey where we receive a profit share from BioNTech, and we do not participate in China.

We now expect that we can manufacture up to 2.5 billion doses in 2021 subject to continuous process improvements, expansion at current facilities and adding new suppliers and contract manufacturers.

As of mid-April, we have contracted for approximately 1.6 billion vaccine doses to be delivered in 2021 and still have contracts for potential additional doses under review.

Based on the approximately 1.6 billion doses, we are now forecasting approximately $26 billion in COVID-19 vaccine revenue this year. We continue to have three pricing tiers for government contracts depending on the relative wealth of nations.

Our cost of sales for the COVID-19 vaccine revenue continues to include manufacturing and distribution costs, applicable royalty expense as well as a payment to BioNTech representing the 50% gross profit split.

We continue to expect that the Adjusted income before tax margin for the COVID-19 vaccine contribution to be in the high 20s as a percentage of revenue. This margin level also includes the anticipated spending on additional mRNA programs. As I noted earlier, the COVID-19 vaccine is now projected to account for 36% of total revenue for 2021, up from 25% in our initial guidance for the year.

Let me add that If we contract for delivery of additional doses during the year, we will provide a guidance update in our subsequent earnings releases.

[Slide 18: Selected 2021 Financial Guidance Ranges Excluding BNT162b2]

If we remove the projected COVID-19 vaccine contribution from both periods, you will see that we slightly increased the 2021 revenue guidance range to be between $44.6 and $46.6 billion, so representing approximately 6 percent operational revenue growth at the midpoint.

In terms of Adjusted diluted EPS, we continue to project a range of $2.50 - $2.60, which represents approximately 11% operational growth at the midpoint. These growth rates are all consistent with how we've been publicly positioning the business post-the Upjohn separation.

You likely saw our announcement that we have maintained our dividend payment for the second quarter at its current level despite Viatris announcing their expected dividend payment. For those continuing to own

Viatris shares this effectively represents an increase in dividend income and our Board felt that the strength of our business supported maintaining our dividend.

For the foreseeable future, we expect our Board to continue to support annual dividend increases at approximately this year's level. Obviously, we have no say as to what Viatris does with its future dividend.

[Slide 19: Key Takeaways]

In summary, a tremendous start to 2021, the COVID-19 vaccine continues to benefit millions of people around the world and the business is on track for anticipated solid top- and bottom line growth. We remain focused on advancing our pipeline, supporting in-market brands and looking to deploy capital responsibly with a focus on initiatives that can solidify our long-term revenue and earnings growth outlook.

Disclosure Notice: *This material represents prepared remarks for Pfizer Inc.'s earnings conference call and is not an official transcript. Except where otherwise noted, the information contained in these prepared remarks is as of May 4, 2021. 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 and prospects; expectations for our product pipeline, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, clinical trial results and other developing data that become available, 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 (BNT162b2) and our investigational protease inhibitors; 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" 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:

<u>Risks Related to Our Business, Industry and Operations, and Business Development:</u>

- *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, as well as 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;

- *our ability to successfully address comments received from regulatory authorities such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency, or obtain approval from regulators on a timely basis or at all; regulatory decisions impacting labeling, manufacturing processes, safety and/or other matters; 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 any potential actions by regulatory authorities based on analysis of ORAL Surveillance or other data;*
- *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 diseases and conditions similar to those treated by our in-line drugs and drug 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 or our third-party suppliers' facilities; and legal or regulatory actions;*
- *the impact of public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic) on our business, operations and financial condition and results, including, among others, the impact of COVID-19 on our sales and operations, including impacts on our employees, manufacturing, supply chain, 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 potential treatments for COVID-19, 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 or clinical data (including the Phase 3 data for BNT162b2), including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations following commercialization; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine 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 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 a Biologics License Application (BLA) for BNT162b2 may be filed in the U.S. and whether and when other biologics license and/or emergency use authorization (EUA) applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including a potential BLA in the U.S. or any requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine'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, 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; risks related to the availability of raw materials to manufacture or test any such products; challenges related to our vaccine's ultra-low temperature formulation, two-dose 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 new variant-specific 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 or potential treatment for COVID-19; 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 potential approved treatment, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine 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 vaccine confidence or awareness; trade restrictions; 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, which account for a substantial portion of our revenues;*
- *the impact of the increased presence of counterfeit medicines 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 JVs 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 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, civil unrest or military action;*
- *the impact of product recalls, withdrawals and other unusual items;*
- *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 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 political unrest, 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, changes in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations, including, among others, any potential changes to the existing tax law by the current U.S. Presidential administration and Congress increasing the corporate tax rate and/or the tax rate on foreign earnings;*

Risks Related to Intellectual Property, Technology and Security:

- *any significant breakdown, infiltration or interruption of our information technology systems and infrastructure;*

- *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, including against claims of invalidity that could result in loss of exclusivity, unasserted intellectual property claims 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 intellectual property related to our products, including our vaccine to help prevent COVID-19 and potential treatments for COVID-19.*

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, 2020 and in our subsequent reports on Form 10-Q, in each case including in the sections thereof captioned "Forward-Looking Information and Factors That May Affect Future Results" and "Item 1A. Risk Factors," and in our subsequent reports on Form 8-K.

These prepared remarks include discussion of certain financial measures that were not prepared in accordance with generally accepted accounting principles (GAAP). Reconciliations of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Company's Current Report on Form 8-K dated May 4, 2021.

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 (BNT162b2) has not been approved or licensed by the FDA, but has been authorized for emergency use by the FDA under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see the EUA Fact Sheet for Healthcare Providers

Administering Vaccine (Vaccination Providers) including full EUA prescribing information available at www.cvdvaccine.com.

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

# # # # #