



## Third-Quarter 2021 Earnings Conference Call Prepared Remarks November 2, 2021

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

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

**[Slide 5: Q3 2021 Key Highlights]**

Thank you, Chris. Hello, everyone.

I am happy to report that Pfizer generated another solid performance in the third quarter, recording 130% operational revenue growth compared with the third quarter of 2020. Even excluding direct sales and alliance revenues provided by our COVID-19 vaccine, we generated 7% operational revenue growth compared with the prior-year quarter. We also are raising our 2021 total company guidance for both revenues and adjusted EPS.

While we are proud of our financial performance, we are even more proud of what these financial results represent in terms of the positive impact we are having on human lives around the world.

In the first nine months of 2021, our innovative medicines and vaccines reached nearly a billion people. Excluding our COVID-19 vaccine, we reached nearly 300 million people during that time. These are humbling numbers for all of us at Pfizer.

At the same time, we delivered to our shareholders the 331st consecutive quarterly dividend.

We also continued to advance our R&D pipeline. Some key milestones include the first COVID-19 vaccine authorized for emergency use in the U.S. for children 5 to 11 years of age; the first patient dosed in our large Phase 3 RENOIR study for our RSV bivalent vaccine candidate; and the initiation of Phase 2/3 studies for both IV and oral protease inhibitor candidates for COVID-19.

**[Slide 6: Q3 2021 Revenues: Comirnaty]**

Let me start with commentary on some of our key growth drivers in the quarter - the biggest of which was **Comirnaty**, which contributed \$13 billion in global revenues during the third quarter. To date, we have produced 2.6 billion doses and shipped 2 billion doses to 152 countries or territories. So far, 75% of our

Comirnaty revenues have been generated outside the U.S., and we continue to sign agreements with governments around the world. We also remain on track to produce 3 billion doses this year, of which at least one billion will go to middle- and low-income countries.

In addition, our weekly market share of COVID-19 vaccines administered continues to increase.

- In the U.S. our four-week average market share increased from about 56% in April to about 74% as of October 31; and in the EU it went from about 70% to about 80% during the same time period.
- These market share increases are primarily the result of our booster being the first to receive emergency use authorization and our two-dose series being preferred by some countries around the world for use in certain younger populations.

We also continue to follow the science to help ensure we stay ahead of the virus. Let me speak to two examples:

- First, top-line results from our Phase 3 randomized, controlled trial demonstrated that a booster dose administered to individuals 16 years of age and older who previously received the Pfizer-BioNTech primary two-dose series restored vaccine protection against COVID-19 to the high levels achieved after the second dose.
- Second, the U.S. Food and Drug Administration (FDA) has authorized our COVID-19 vaccine for emergency use for children 5 through 11 years of age, the first and only vaccine to receive such authorization. For this age group, the vaccine is to be administered in a two-dose regimen of 10- $\mu$ g doses given 21 days apart. The 10  $\mu$ g dose level was carefully selected based on safety, tolerability and immunogenicity data.

Last week we announced that the U.S. government exercised its final purchase option under the existing U.S. supply agreement to purchase 50 million additional doses of Comirnaty. This brings the total number of pediatric doses purchased by the U.S. government to 115 million, which is enough to vaccinate every U.S. child. Overall, the U.S. has now purchased a total of 600 million doses across all age ranges under this supply agreement.

#### **[Slide 7: Q3 2021 Revenues: Other Key Growth Drivers]**

Now let's take a look at some of the quarter's other key growth drivers.

**Eliquis** has continued to deliver strong performance, with global revenues up 19% operationally to \$1.3 billion in the third quarter. In the U.S., sales growth for Eliquis was driven mainly by a 16% growth in prescription volume.

**Vyndaqel** and **Vyndamax** revenues were up 42% operationally to \$501 million globally. Our disease education efforts in the U.S. continued to support increases in appropriate diagnosis, while the main driver

of growth in Japan has been the successful establishment of several referral networks in select areas resulting in new patient starts.

**Ibrance** revenues outside of the U.S. were up 9% operationally to \$500 million. This growth was driven by accelerating demand as the delays in diagnosis and treatment initiations caused by COVID-19 show signs of recovery across several international markets. Global revenues for Ibrance were up only 1% operationally, as the international growth was largely offset by a 3% decline in the U.S. The U.S. decline was driven by an increase in the proportion of patients accessing Ibrance through our Patient Assistance Program.

We continue to be pleased with the performance of our **Oncology biosimilars portfolio**, which is now the largest in the industry, with six biosimilars approved in the U.S. for patients living with cancer. Global revenues from this portfolio grew 51% operationally during the quarter to \$398 million. This growth was primarily driven by continued strong results from our U.S. therapeutic monoclonal antibody launches. In International Developed Markets, Oncology biosimilars contributed 29% operational growth, driven by new launches of Zirabev and continued growth of Trazimera.

#### **[Slide 8: Q3 2021 Revenues: Managing Through Challenges]**

With such a broad portfolio of life-changing and life-saving products, it would be uncommon to not have a few challenges.

U.S. revenues for our **Pevnar family (Pevnar/Prevenar 13 & 20)**, for example, were down 2%, primarily due to a 36% decline in the adult indication due to the ongoing prioritization of primary and booster vaccination campaigns for COVID-19 and a later start to the flu season compared with last year. Other contributing factors were the continued impact of the lower remaining unvaccinated eligible adult population and the June 2019 change to the Advisory Committee on Immunization Practices (ACIP) recommendation for the Pevnar 13 adult indication to shared clinical decision-making.

Just two weeks ago, ACIP voted to recommend Pevnar 20™ for routine use to help protect adults against invasive disease and pneumonia caused by the 20 *Streptococcus pneumoniae* serotypes in the vaccine. Specifically, the ACIP voted to recommend Pevnar 20 for adults ages 65 and older and adults ages 19 to 64 with certain risk conditions, without the need to be followed by PPSV-23 vaccination. This recommendation recognizes for the first time the significance of helping protect more populations under age 65 with co-morbid and immunocompromising conditions who are at increased risk of disease against these 20 disease-causing serotypes. This new one-dose regimen option, once endorsed by the CDC Director, also will help simplify long-standing adult pneumococcal recommendations. As a reminder, Pevnar 20 is the only vaccine the FDA has approved not only for invasive pneumococcal disease but also for pneumonia.

In September, I'm sure many of you saw that the FDA issued a Drug Safety Communication related to its completed review of the Xeljanz ORAL Surveillance trial. We are in continuing dialogue with the FDA about its assessment and the resulting, final content in the Xeljanz label.

With this important step taken, we hope we are a step closer to having an update regarding the new drug application (NDA) for abrocitinib in atopic dermatitis and the supplemental NDA for Xeljanz in ankylosing spondylitis, both of which are currently under FDA review.

In terms of **Xeljanz** in its currently approved indications in the U.S., we believe that Xeljanz prescribing behavior will adjust in the coming months based on the FDA's update, resulting in an initial correction in the short term. But based on the trends we have observed and the broad application of Xeljanz across its approved indications, we believe Xeljanz has the potential to return to growth again once a final U.S. label is issued, and physicians have adjusted their prescribing habits accordingly as we go into 2022 and beyond.

**Cibinqo (abrocitinib)** received marketing authorization for the treatment of moderate to severe atopic dermatitis (AD) in adults and adolescents aged 12 years and over from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and the Japanese Ministry of Health, Labour and Welfare (MHLW) in both doses. It also received a positive opinion in adults from The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). We are hopeful this momentum will continue. We have applications currently filed for review with regulators around the globe, including in the U.S. and Australia.

Overall, we remain confident in the importance of the JAK inhibitor class for appropriate patients with inflammatory diseases, and we are pursuing a variety of options for advancing additional JAK inhibitor assets within our pipeline. For example, Pfizer has granted an exclusive license to brepocitinib and TYK2, both in Phase 2 development, to a new company formed in collaboration with a partner that has a proven track record in late-stage Inflammation & Immunology drug development. The new company will direct all future development decisions, while Pfizer will have a 25% stake and retain certain ex-US commercial rights for brepocitinib and TYK2. This transaction will enable the allocation of resources to advance development of brepocitinib and TYK2 while allowing Pfizer to focus on diversifying its pipeline.

#### **[Slide 9: Bolstering the Pipeline with Recent Business Development Opportunities]**

Another way in which we are continuing to bolster our pipeline is through strategic business development agreements. This slide highlights ten such agreements we have entered into in recent years, spanning four different therapeutic areas.

- To further build on our strength in cancer research we acquired Array Biopharma. The team in Boulder, Colorado, has become a center of excellence for targeted therapies in not only cancers but other diseases as well – with an expected 1-2 new compounds entering the clinic each year.
- Leveraging our strengths in gene therapy, we entered into a collaboration with Vivet Therapeutics for a potential gene therapy for Wilson Disease, a rare, genetic disorder that can cause severe hepatic damage, neurological symptoms, and potentially death.
- Our acquisition of Therachon builds on our Rare Disease team's 30-year commitment to develop innovative medicines that address significant unmet medical needs of people with rare diseases.
- Regarding our worldwide exclusive licensing agreement with Akcea, we believe our expertise and breadth of experience in cardiovascular and metabolic diseases makes us well suited to accelerate clinical development of AKCEA-ANGPTL3-LRx, an investigational antisense therapy being developed to treat patients with certain cardiovascular and metabolic diseases.
- We are excited about our collaboration with Valneva to develop and commercialize Valneva's Lyme disease vaccine candidate, VLA15, the only active Lyme disease vaccine program in clinical development today.
- Of course, our collaboration with BioNTech on a COVID-19 vaccine led to the first mRNA vaccine ever approved, and this relationship was born out of our companies' initial collaboration to develop an improved flu vaccine based on mRNA tech.
- Building on our strengths in prostate cancer and women's health, we have entered into an agreement with Myovant to jointly develop and commercialize Orgovyx™ (relugolix) in advanced prostate cancer and relugolix combination tablet in women's health in the U.S. and Canada.
- Our global collaboration with Arvinas to develop and commercialize ARV-471, an investigational oral PROTAC® estrogen receptor protein degrader, builds on our metastatic breast cancer franchise, allowing us to potentially go into earlier non-metastatic patients and add to efficacy of Ibrance in a metastatic setting.
- Trillium's CD47/SIRP-alpha focused technology has the potential to be as foundational in cancer immunotherapy as PD-1 / PD-L1s have been. We look forward to that acquisition closing later this year or in the first half of 2022.

With three approvals, four EUAs and multiple submissions and readouts, these transactions are already bearing fruit and positioning us to reach even more patients.

**[Slide 10: Welcome to Aamir Malik]**

Before I close, I want to welcome to the call Aamir Malik, who joined us in August as Executive Vice President and Chief Business Innovation Officer. Aamir came to us from McKinsey, where during his 25-year career he has developed growth strategies, guided mergers and acquisitions, and implemented large-

scale programs to improve patients' lives and transform performance for life science companies. This includes working closely with Pfizer on several strategic initiatives. I have known Aamir for more than 15 years, and I am certain he will be an incredible addition to Pfizer as we look to the next era of innovation.

**[Slide 11: Looking Ahead]**

Looking ahead, we continue to focus on driving operational excellence across the organization and pursuing the kinds of first-in-class science that will define the New Pfizer.

Given our third quarter performance and our current expectations for the near-term, we continue to expect a revenue CAGR of at least 6%, on a risk-adjusted basis, through the end of 2025 and double-digit growth on the bottom line.

I would remind you that these projections do not include any potential impact from Comirnaty, recent or subsequent business development activities, or potential future mRNA programs. Rather, we remain very confident in our ability to achieve these growth rates because of the strength of our current product portfolio and R&D pipeline.

Now I'll turn it over to Mikael to speak more about our R&D efforts and then Frank will provide financial details on the quarter and our outlook for the remainder of 2021.

**[Slide 12: Scientific Updates – Mikael Dolsten]**

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

Thank you, Albert. I appreciate the chance to share updates from Pfizer's robust R&D pipeline.

**[Slide 13: Pfizer Continues to Sustain High End-to-End Clinical Success Rates]**

As a measure of the transformation that we have instituted in our R&D organization, we track our average clinical success rates against peers. In every phase and end-to-end, we achieved greater success rates than peer average in 2020, and have continued to sustain those high rates in 2021.

**[Slide 14: Key Portfolio Updates Q3 2021 Earnings Call]**

Today, I will provide updates from our Vaccines, Rare Disease and Inflammation and Immunology portfolios, and on our oral protease inhibitor. In several cases, I will reference publicly available data on other agents so that you can understand our enthusiasm about what we are seeing in our development programs. Of course, head-to-head clinical trials would be necessary to support any comparative claims.

**[Slide 15: COMIRNATY Induced Robust Efficacy in Children 5-11 yrs. Phase 2/3 Study]**

Last Friday, the FDA granted Emergency Use Authorization for 5 through 11 year olds, and the CDC's Advisory Committee on Immunization Practices is meeting today to discuss recommendations.

On the left, we show the comparable immune response observed with 10µg dosing in children 5 through 11 as 30µg dosing in 16 to 25 year olds.

On the right, we show 90.7% vaccine efficacy observed. This too is comparable to what we've seen in older populations.

**[Slide 16: Fever & Chills Milder in 5-11yrs. (10µg) than Adolescent & Adults (30µg)]**

The rate and severity of fever and chills after the first and second doses were less in the younger children than either adolescents or adults.

We believe that vaccinating younger children is one important step in making our way through this pandemic.

Looking ahead, we expect initial pivotal data from the studies in 2 to less than 5-year olds this quarter, and in 6 month to less than two year olds next quarter, with full data readouts to follow.

**[Slide 17: Improved Handling Conditions for 5-11 yr. versus 12+ yr.]**

On the right we show improved handling conditions that have been approved for vials to dose 5 through 11 year olds.

Of note are the smaller pack sizes and the ability to refrigerate for up to 10 weeks.

We plan to submit data to regulators for potential approval of similar handling conditions for vials used to dose the 12 and older population.

**[Slide 18: 3rd Booster Dose Restores High Levels of Vaccine Effectiveness]**

We are the first manufacturer to report phase 3 clinical efficacy data on a third dose boost and, to the best of our knowledge, are the only company with an ongoing pivotal efficacy study.

In a study of participants 16 and older, shown on top, a booster demonstrated a relative vaccine efficacy of 95.6% compared to the original two dose schedule during a period in which Delta was the prevalent strain, affirming the protective impact of the early immunological data which led to the EUA.

It's projected that the third dose boost vaccine efficacy is even higher compared to the unvaccinated population, potentially above 98%. This assumes that vaccine efficacy for those vaccinated with two doses versus unvaccinated is above 55% at this time point.

We observed consistent efficacy in younger and older adults. While the majority of cases were in the older age group as would be expected, we recorded a relative vaccine efficacy of 100% in individuals aged 16 to 30 years.

Data from Israel, shown at the bottom and published by Professor Marc Lipsitch of Harvard and others in Lancet, showed that a third dose protected individuals against severe COVID-19-related outcomes.

We plan to monitor the participants in our clinical study, and at an appropriate time consider a randomized fourth dose booster study to document the impact of additional and possibly annual repeat vaccinations. This will be supplemented with real world evidence studies.

**[Slide 19: Guidelines Favoring COMIRNATY in Certain Populations]**

Countries have started to recognize the favorable risk/benefit profile of our vaccine. In each country shown here, our vaccine is recommended or the only one permitted in younger populations and, in the case of France, not restricted for boosting. News over the weekend from another manufacturer suggests that their vaccine may not be available in the near-term for younger populations.

We are encouraged by these science-driven decisions which have helped make COMIRNATY one of the most-used COVID-19 vaccines globally.

**[Slide 20: Pfizer Gene Therapy: Program Updates]**

Next, gene therapy.

In hemophilia A, we have temporarily and voluntarily paused screening and dosing in our Phase 3 study evaluating Factor VIII gene therapy, which we're developing with Sangamo, in order to implement a protocol amendment following the observance of Factor VIII levels greater than 150% in some trial participants.

To date, no patient has experienced a thrombotic event and some patients are being treated with oral anticoagulants to reduce the risk of thrombosis.

We are committed to resuming dosing as quickly as possible once a protocol amendment, which is intended to provide guidelines for clinical management of elevated Factor VIII levels, is implemented.

Separately, based on recent interactions with the FDA, Pfizer no longer plans to conduct an interim analysis of the Phase 3 data from our hemophilia A and B gene therapy programs. We anticipate pivotal data readouts to be based on full analyses on at least 50 study participants for the hemophilia A program and 40 participants for the hemophilia B program.



This will push out the timing of readouts of those trials compared to our previous expectations. For hemophilia A, we are working to evaluate the impact of both the FDA feedback as well as the protocol amendment on timelines and will share an update at the appropriate time. For hemophilia B, we anticipate a readout in the first quarter of 2023.

We continue to collect long-term follow-up data in our Phase 1b DMD study, in which 19 ambulatory boys in the US have been treated, and plan to present the one-year dataset at a scientific meeting.

We recently shared information on muscle weakness (presumed myositis), in some cases with myocarditis, in three participants in the Phase 3 ambulatory trial with a specific subset of dystrophin truncation mutations.

They were treated with higher doses of steroids and all improved within a few weeks, were discharged from the hospital and have recovered or are still recovering.

The data monitoring committee has confirmed that immunologic assessments performed in the trial support the hypothesis that an immune response against the mini-dystrophin protein caused these cases.

This type of reaction is a risk potentially inherent to any gene replacement therapy, and similar severe adverse events reported in other programs support the notion that this is a class effect.

We have proposed a protocol change to exclude patients with any mutation affecting exons 9 through 13, inclusive, or a deletion that affects both exon 29 and exon 30.

A few sites have resumed new patient activities and we anticipate that nearly all ex-US trial sites will have restarted clinical activity by the end of this month.

These mutations are estimated to represent less than 15% of patients with DMD. We recognize the devastating impact that DMD has on these boys and their families and plan to include patients with some of these excluded mutations in future studies.

In addition, we continue to work with the FDA to address outstanding IND questions related to the Phase 3 study, including technical aspects of our potency assay matrix. We have made considerable progress with development of the CMC assay as per FDA guidance and are now in an active phase of filing this update. While we cannot speculate as to when sites may open, we are working to reach alignment with the FDA as soon as possible.

In addition, we have 12 pre-clinical gene therapy programs and are anticipating approximately one to two First in Human study starts each year.

**[Slide 21: High Potency PDE4+ (PF-07038124) Atopic Dermatitis & Psoriasis]**

We'll now turn to a high potency PDE4+ immune modulator we are exploring in atopic dermatitis and psoriasis.

Topical delivered high potency PDE4+ inhibition may offer a differentiated efficacious and safety profile compared to other mechanisms of action whether used orally or topically.

PDE4+ inhibition could provide both rapid and deep responses versus other agents, with the potential for further improvement at higher doses.

Even at a significantly lower dose, we observed promising clinical efficacy compared to what we have seen with PDE4 topicals in other trials.

We expect to initiate Phase 2b studies in both diseases in 2022, exploring higher doses.

**[Slide 22: High Potency (Hi Po) PDE4+ Atopic Dermatitis Phase 2a Study *Significant Reduction in Eczema Area Severity at Low Dose*]**

On the left, we show in vitro potency at a low dose versus roflumilast and crisaborole. Our asset demonstrated approximately 240-fold greater inhibition of IL-4 and approximately 25-fold greater inhibition of IL-13 versus roflumilast.

On the right, we observed clinically significant improvement in Eczema Area Severity versus comparators in other studies, with a 45% reduction from baseline at week 6.

Our asset showed stronger or similar efficacy at week 6 as compared to reported data from another study at week 8 with the recently approved topical JAK 1/2 inhibitor ruxolitinib.

There was no stinging observed at the application site.

**[Slide 23: High Potency (Hi Po) PDE4+ Psoriasis Phase 2a Study *Significant Reduction in Psoriasis Area Severity at Low Dose*]**

On the left, we saw an approximately 80% reduction in IL-23 versus activated skin plus vehicle in an in vitro skin model. This displays a relevant mechanism of action for high potency PDE4+ in psoriasis.

On the right, in patients, we saw significant clinical improvement in Psoriasis Area and Severity versus a comparator in a separate study, with a 4.5 point reduction from baseline at week 6.

**[Slide 24: TL1A Inhibitor (PF-06480605) Ulcerative Colitis]**

Let's turn to a TL1A inhibitor, which targets a newly identified member of the TNF superfamily, being explored for ulcerative colitis.

In a Phase 2a study, we saw promising endoscopic improvement.

Based on the benefit/risk profile seen, there is potential for TL1A inhibition to be used earlier in the treatment paradigm.

Phase 2b studies in inflammatory bowel disease are ongoing, with estimated primary completion in the fourth quarter of 2022.

**[Slide 25: TL1A Inhibitor Ulcerative Colitis Phase 2a Study Improvement in Mayo Score & Potential for Biomarker-Driven Patient Selection to Improve Efficacy]**

On the left, our TL1A inhibitor demonstrated greater endoscopic improvement than what tofacitinib demonstrated in a similar trial, with 34% of patients responding at week 14.

We matched the populations based on the characteristics of those enrolled in our TL1A study using propensity score matching. The week 14 data for tofacitinib is interpolated based on week 8 data of the induction study and month 12 data from the maintenance and open label studies.

On the right, a post-hoc analysis found that 48% of patients who had biomarkers achieved endoscopic improvement versus 13% of patients who were biomarker-negative.

Approximately 70% of patients are positive for this biomarker and we believe a precision medicine approach utilizing key biomarkers may enhance patient selection and improve patient outcomes.

**[Slide 26: Interferon Beta (IFN- $\beta$ ) Inhibitor (PF-06823859) Dermatomyositis]**

Next is an interferon beta inhibitor, a potential breakthrough therapy for dermatomyositis, that we developed in a research collaboration with Mass General Brigham. This is a disease with very limited treatment options.

In an ongoing Phase 2 clinical trial, we have observed significant reduction in clinical disease activity in skin compared to placebo.

We anticipate a readout of the full Phase 2 study in the first quarter of 2022.

**[Slide 27: Interferon Beta (IFN- $\beta$ ) Inhibitor: Phase 2 (Part 1) A Potential Breakthrough Therapy for Dermatomyositis Patients]**

On the left, treatment demonstrated an 83.6% decrease in gene signature scores from baseline at week 12, compared to 11.8% with placebo.

On the right, treatment also showed significant decrease in clinical disease activity at week 12 compared to placebo.

**[Slide 28: Oral Protease Inhibitor Candidate Targets 3 Patient Populations]**

An important step in addressing the pandemic will be the availability of effective out-patient treatments for people who acquire COVID-19.

A robust program to study the breadth of both treatment and prevention in high risk, standard risk and household contact populations is well underway.

Projected pivotal readouts start potentially this quarter and extend through mid-2022.

**[Slide 29: Recent and Potential Upcoming Milestones *Select Examples*]**

Finally, our recent milestones are a reflection of those high clinical success rates that I shared at the beginning, and we look forward to continuing the momentum in 2022.

Select milestones expected in the fourth quarter include:

- a pivotal data readout for our C. difficile vaccine candidate,
- a proof of concept readout for vupanorsen for severe hypertriglyceridemia and cardiovascular risk reduction, and
- a proof of concept readout for danuglipron for diabetes.

Milestones expected in the first half of 2022 include:

- Phase 3 results for our RSV adult and maternal vaccine candidates,
- a potential pivotal Phase 2 readout for elranatamab in relapsed/refractory multiple myeloma,
- a proof of concept readout for our mRNA flu vaccine candidate,
- a phase 2b proof of concept readout for the potential Lyme disease vaccine on which we are collaborating with Valneva,
- a proof of concept readout for ROBO2-Fc for focal segmental glomerulosclerosis,
- a proof of concept readout for danuglipron for obesity, and
- Phase 3 results of Talzena and Xtandi in first-line metastatic castration-resistant prostate cancer.

In addition, we expect continued active business development to further augment the clinical portfolio.

Thank you for your attention and I look forward to your questions. Now, let me turn it over to Frank.

**[Slide 30: Financial Review – Frank D’Amelio]**

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

### [Slide 31: Quarterly Income Statement Highlights]

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

The COVID-19 vaccine once again had a significant positive impact on our quarterly results and Albert has already addressed the key points on the COVID-19 landscape.

Turning to the income statement. Revenue increased 130% operationally in the third quarter of 2021 driven by COVID-19 vaccine sales and strong performance from a number of our other key growth drivers.

And looking at the revenue growth excluding the COVID-19 vaccine contribution from direct sales and alliance revenues, as Albert said earlier, we saw a continuation of solid performance from the business again this quarter, delivering 7% operational revenue growth despite a negative 5% impact from price, getting us to a robust volume growth of 12% for the business excluding the COVID-19 vaccine contribution. The 12% volume growth is in spite of an approximately 2% negative impact to growth from the Chantix recall and distribution pause. This supports our projected revenue CAGR of at least 6% from 2020 through the end of 2025. Of course, there will be some variability in quarterly growth rates due to a variety of factors, but we continue to expect at least a 6% CAGR through 2025.

There was no impact from the number of selling days in the quarter as compared to the year ago period like we saw in our first quarter where we had more selling days compared to the year ago period. I'd remind you that the offset to this imbalance will be seen in the fourth quarter results where we will have fewer selling days as compared to the year ago quarter. For the full year this results in essentially the same number of selling days in 2021 as 2020. I'll come back to this in a little bit when I discuss the updated guidance.

The Adjusted cost of sales increase shown here reduced this quarter's gross margin by approximately 22 percentage points compared to the third quarter of 2020, which is almost entirely driven by the impact of the COVID-19 vaccine.

Adjusted SI&A expenses increased primarily due to a level of promotional spend and sales force activity more similar to pre-pandemic levels.

The increase in Adjusted R&D expense this quarter was primarily driven by increased investments in COVID-19 related programs as well as other programs within our pipeline.

The growth rate for reported diluted EPS was +445%, while Adjusted diluted EPS grew +129% for the quarter.

Foreign exchange movements resulted in a 4% benefit to revenue as well as a 4% benefit, or \$0.02, to Adjusted diluted EPS.

### **[Slide 32: 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 on the projected COVID-19 vaccine contribution and the business without the COVID-19 vaccine.

Our revenue guidance has increased and we now expect total company revenue to be in a range of \$81.0 to \$82.0 billion, increasing by \$2.5 billion at the midpoint, with the COVID-19 vaccine revenue for the year now expected to be approximately \$36 billion, an increase of approximately \$2.5 billion compared to our prior guidance. The projected COVID-19 vaccine revenue as a percentage of total company revenue at the midpoint has increased to 44% as compared to 42% in our previous 2021 guidance. I'll come back to that in a minute.

We also adjusted our cost and expense guidance, mostly to reflect actual performance to date. Let me give you some more detail.

For Adjusted cost of sales, the range has decreased to between 39.1% to 39.6%.

On Adjusted SI&A, we have tightened the range and now expect \$11.6 to \$12.1 billion, a decrease of \$150 million at the midpoint.

In addition, we increased our Adjusted R&D guidance range to \$10.4 to \$10.9 billion, an increase of \$400 million at the midpoint, to reflect anticipated incremental spending on COVID-19 and mRNA-based projects.

We are keeping our assumption for the effective tax rate for the year flat compared to prior guidance at Approximately 16.0%.

This yields an increased Adjusted diluted EPS range of \$4.13 to \$4.18 or 84% growth at the midpoint compared to 2020, including an expected 4% benefit from foreign exchange.

### **[Slide 33: Assumptions Related to Comirnaty 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 discussed earlier, the Pfizer BioNTech COVID-19 vaccine collaboration construct is a 50/50 gross profit split.

Pfizer books 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 the China region.

We continue to expect that we can manufacture 3 billion doses in total by the end of 2021.

The \$2.5 billion increase in expected COVID revenues to \$36 billion primarily represents the impact of contracts signed since mid-July, which was the cutoff for our prior guidance. This assumes deliveries of approximately 2.3 billion doses in fiscal year 2021, compared to prior guidance of deliveries of 2.1 billion doses, and our production assumption of 3 billion doses during calendar year 2021. This difference of 700 million doses represents doses which will be delivered in fiscal year 2022.

To refresh your memory, our cost of sales for the COVID-19 vaccine revenue includes manufacturing and distribution costs, applicable royalty expenses, and 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 20's as a percentage of revenue. This margin level also includes the anticipated spending on additional mRNA programs and spending on the COVID-19 protease inhibitor antiviral programs.

**[Slide 34: Selected 2021 Financial Guidance Ranges Excluding Comirnaty]**

If we remove the projected COVID-19 vaccine contribution from both periods, you will see that we slightly decreased the 2021 revenue range to \$45 to \$46 billion, so representing approximately 6 percent operational revenue growth at the midpoint. The decrease in guidance at the mid-point largely reflects the impact from the Chantix recall and pause in shipments.

In terms of Adjusted diluted EPS without the contribution from the COVID-19 vaccine, we have increased the range to be between \$2.60 and \$2.65 for the year which represents approximately 12% 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 may notice that the implied Q4 guidance suggests non-COVID-19 operational revenue to decline by 1%, especially as compared to the revenue growth that we've seen year-to-date of 8%. Let me walk you through the drivers of this.

The largest driver of the decline is a difference in number of selling days compared to the comparable quarter in 2020. You will remember my discussion of extra selling days in Q1 when we had three more selling days in the US and four more selling days in the international markets, and I talked then about how Q4 would largely offset that impact, leaving 2021 as a whole with approximately the same number of selling days as 2020. So, in Q4, we will now have four fewer selling days each in domestic and international as compared to Q4 2020. This is expected to decrease sales by approximately \$600 million or have a negative impact to the growth rate of 6% for the company, excluding COVID vaccine sales.

We expect the Chantix sales to be zero in Q4 due to the recall and pause in shipments, representing another 2% headwind to growth.

**[Slide 35: 2022 Outlook for Potential Comirnaty Sales]**

While it is not our normal practice to discuss 2022 outlook during the Q3 conference call, I wanted to make a brief comment related to potential Comirnaty sales next year as we have noticed some estimates of those sales to be very high. While we have capacity to produce 4 billion doses in 2022, at this point we expect to recognize revenues for 1.7 billion doses in 2022, representing COVID vaccine direct sales and alliance revenues of approximately \$29 billion. We continue to engage with governments regarding potential further orders for 2022, including doses for which certain governments have the option to order and take deliveries in 2022.

**[Slide 36: Capital Allocation Framework]**

And going forward we will continue to be prudent in our capital allocation activities with the opportunities for deployment shown here on this slide.

**[Slide 37: Key Takeaways]**

In summary a strong quarter and first nine months of the year, based on continued strong performance for our growth drivers. We have increased our revenue and EPS guidance for the remainder of the year, mainly driven by increased expectations for Comirnaty sales. Our pipeline continues to advance, and we have invested to support that advance. We look forward to an expected closing of the Trillium acquisition as soon as this quarter or in the first half of 2022, subject to the satisfaction of the closing conditions.

With that, 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 2, 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, 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) 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:

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; 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 or indications from regulators on a timely basis or at all; regulatory decisions impacting labeling, 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 any potential 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 diseases and conditions similar to those treated 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 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 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 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 and clinical data (including the Phase 2/3 data for Comirnaty), 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 Comirnaty 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, potential treatments for COVID-19 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 in pediatric populations, applications for a potential booster dose and/or biologics license and/or EUA applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when any drug applications and/or EUA applications for any potential indications for any potential treatments for COVID-19 may be filed in any jurisdictions; whether and when any applications that may be pending or filed for Comirnaty (including the potential submissions for pediatric populations, a potential booster dose or any other requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program or potential treatments for COVID-19 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; risks related to the availability of raw materials to manufacture or test any such products; challenges related to our vaccine's 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 or potential treatment 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 or government customers, 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, including uncertainties related to regulator-directed risk evaluations and assessments;*
- *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 or interruption of our information technology systems and infrastructure;*
- any business disruption, theft of confidential or proprietary information, extortion or integrity compromise resulting from a cyberattack;*
- 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 or being restricted from enforcing 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 November 2, 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.*

*Emergency uses of the Pfizer-BioNTech COVID-19 Vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. COMIRNATY is licensed by FDA for individuals 16 years of age and older. In addition, COMIRNATY is under EUA for individuals ages 12 through 15, a third dose for certain immunocompromised individuals 12 years of age and older, and a booster dose for certain individuals 18 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheet at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).*

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

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