Fourth-Quarter and Full-Year 2021 Earnings Conference Call Prepared Remarks
February 8, 2022

[Slide 4: Opening Remarks – Albert Bourla]

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

[Slide 5: FY 2021 Key Highlights]

2021 was a watershed year for Pfizer. A year in which we set all-time highs in all major areas of focus for Pfizer.

- We reached an estimated 1.4 billion patients with our medicines and vaccines. That’s more than one out of every six people on Earth. Never before has Pfizer’s patient impact been so wide-reaching.
- We improved our ranking from fourth to second among large biopharma companies in the PatientView Global Survey.
- According to Morning Consult, 61% of Americans have a favorable view of Pfizer, which is up 33 points since January 2020.
- Just last week, Fortune ranked us fourth on its annual World’s Most Admired Companies list – the highest ranking we have ever achieved.
- Ninety-five percent of our colleagues said in an internal survey that they are proud to work for Pfizer, which ranks among the best in corporate America.
- We increased our investments in Research & Development (R&D) from $8.9 billion in 2020 to $10.5 billion in 2021.
- We initiated 13 pivotal clinical studies – the highest number ever for Pfizer.
- Lastly, we grew revenues by 92% operationally to $81.3 billion and Adjusted Diluted EPS by 92% operationally to $4.42.

Our successes in leading the fight against COVID-19 have not only made a positive difference in the world; I believe they have fundamentally changed our company and our culture forever. Colleagues across Pfizer are inspired by what we have achieved and more determined than ever to be part of the next potentially game-changing breakthrough. To that end, we are applying the “lightspeed” principles developed for our
COVID-19 work to our other therapeutic areas to make sure we continue to move at the speed of science for the benefit of patients.

[Slide 6: FY 2022 Total Company Guidance]

As a result, we believe we can do even better with each of these metrics in 2022. Our full-year 2022 financial guidance, for example, includes for the first time ever a forecasted revenue midpoint that is $100 billion and an Adjusted Diluted EPS midpoint of $6.45.


While Comirnaty is having a significant positive impact on Pfizer’s financial performance, it’s the tremendous impact that COVID-19 vaccines have had on society that is most important. In the U.S. alone, the COVID-19 vaccination program is estimated to have saved more than one million lives and prevented more than ten million hospitalizations, according to a December 2021 Commonwealth Fund report.

The economic impact is equally astounding. According to a December 2021 Heartland Forward report, the rapid deployment and wide availability of COVID-19 vaccines in the U.S. created an estimated economic savings of $438 billion in 2021, which amounted to U.S. GDP being 2.3% higher than it otherwise would have been.

I’m proud to say that Pfizer contributed significantly to these benefits given that approximately 6 out of 10 doses administered in the U.S. as of February 6, 2022, were Comirnaty.

This is the value of our science … what our culture has enabled … and what drives our people.

Now I would like to speak to three factors that will help drive our growth going forward:

- the long-term outlook for COVID-19 and why we believe we are well positioned to continue to lead the battle against this disease;
- our thoughtful capital allocation strategy and why we believe it can help drive our growth in the second part of the decade; and
- how our commitment to ESG principles is designed to create sustainable growth for Pfizer and deliver meaningful value to patients.

[Slide 8: Long-term Expectations for COVID-19]

Let me start with the COVID-19 pandemic.

Our scientists continue to monitor the SARS-CoV-2 virus and believe it is unlikely that it will be fully eradicated in the foreseeable future. They believe this for several reasons:
The global distribution of the virus makes it difficult to contain. The virus has shown an ability to mutate often, making it difficult to stay ahead of it. And the data appear to show that natural infections do not lead to the type of durable protection needed to prevent all transmissions and viral mutation. As a result, people can become reinfected by the same or different strains over time.

[Slide 9: Tools to Help Manage Pandemic and Move into Endemic Phase]

That said, we now have the tools – in the form of vaccines and treatments – that we believe will help enable us to not only better manage the pandemic, but also help countries move into an endemic phase. In other words, we believe these tools will help allow us to go back to normality and spend time with family and friends, travel, attend indoor dining and concerts, and enjoy many other activities while lowering the risk of overburdening hospitals and healthcare systems around the world.

[Slide 10: Bringing These Tools to the World]

All of us at Pfizer are extremely proud of the role we have continued to play in bringing these tools to the world.

- Throughout 2021, we continued our efforts to bring our COVID-19 vaccine to more populations and to further ramp up our manufacturing and distribution capabilities. As a result, the market share of our Comirnaty vaccine has continued to grow, representing 70% of all doses distributed across the U.S. and EU as of February 5.
- When it comes to Paxlovid, we expect to produce six million treatment courses during the first quarter of 2022. Overall, we expect to produce 30 million courses in the first half of 2022 and 120 million courses for the full year, depending on the global need. Having recently received a conditional marketing authorization from the European Medicines Agency (EMA), Paxlovid has now received emergency or conditional authorization for use with certain populations in approximately 40 countries so far. We are in discussions with governments around the world and expect that as the number of authorizations increase, so will the number of contracts for this treatment, which could truly be a game changer.

[Slide 11: Maintaining Leadership in COVID-19]

At Pfizer, we are keenly aware of our responsibility to continue to invest in R&D to maintain our leadership in providing these tools and other meaningful solutions to the world. That's why we continue to develop and test different versions of our vaccine to potentially address variants of concern as they emerge, and why we are currently working on a new omicron-based vaccine candidate and on a bivalent COVID-19 vaccine candidate. It’s also why just two months after receiving Emergency Use Authorization (EUA) from the U.S.
Food & Drug Administration (FDA) for Paxlovid, we are already working on a potential next-generation oral COVID-19 treatment.

Going forward, we are confident in our ability to maintain this leadership position because of our significant investments in R&D combined with our ability to move at the speed of science without compromising quality or safety; the strong credibility we have earned with governments, healthcare providers and consumers combined with our extensive global field presence; and our unparalleled capabilities for high-quality manufacturing at scale.

[Slide 12: Pfizer’s Capital Allocation Strategy (1 of 2)]

The second thing I wanted to touch on is how we think about our capital allocation and to repeat once more our strategy.

We feel that the entirety of our business continues to demonstrate a robust topline growth trajectory through 2025. Consensus estimates are beginning to slowly recognize this momentum.

However, consensus estimates currently show our topline shrinking from 2025-2030. This is inconsistent with our own plans. Our goal is to continue to be a growth company from 2025-2030, despite the impact of LOEs expected during that period.

Our confidence in this is underpinned by the momentum of our business, the durability of our COVID-19 offerings as I just described, the underestimated strength of our internal pipeline, and, of course, by our ability to deploy capital into growth-focused business development to access external science.

[Slide 13: Pfizer’s Capital Allocation Strategy (2 of 2)]

We leverage business development opportunities to advance our business strategies and objectives. The strength of our balance sheet and cash flows allows us to pursue new business development opportunities going forward that could add at least $25 billion of risk-adjusted revenues to our 2030 topline expectations. We expect to do this while still maintaining our growing dividend, as well as flexibility for other uses of our cash.

The focus of our business development efforts will continue to be on compelling external science in the form of both later-stage assets, as well as earlier medical innovations, that have the potential to be breakthroughs for patients. Our focus will largely be in the therapeutic areas and platforms where we have the scientific skills and acumen to add substantial value and select the most successful targets. In addition, we feel that we have distinctive attributes such as world-class excellence in clinical development and unsurpassed manufacturing and commercial capabilities at scale that make us a very attractive partner across a variety of deal arrangements. We believe the opportunities to deliver on this approach exist, and I will be personally focusing on its execution.
I want to emphasize that despite our significant capital flexibility, we will never lower the scientific and financial standards we apply in our business development. As we pursue these opportunities, we will continue to be highly disciplined in our evaluation and prioritization processes.

Since 2019, we have already invested almost $25 billion in business development transactions adding more than $13 billion in consensus 2030 revenue. I would point out that the $13 billion of consensus currently includes nothing for the Trillium assets, the Biohaven collaboration, or the recently announced mRNA deals, all of which have substantial potential. I see this pace of business development accelerating going forward, and I am confident it will be an important driver in ensuring Pfizer as a growth company in the back-half of this decade.

One highly visible example of our approach to business development is the recent investments we are making in mRNA technology and collaborations.

[Slide 14: Pfizer’s mRNA Strategy Roadmap]

mRNA has emerged as a versatile technology, with potential applications across many infectious diseases, cancer, rare genetic disorders and even autoimmune diseases. Although mRNA is not the holy grail, we believe the technology has the potential to have a game-changing impact on global health, which is why we have developed a robust mRNA strategy and are aggressively building our platform.

While the pandemic has demonstrated that it’s not that easy to deliver mRNA vaccines at scale, Pfizer has emerged as a leader in this space. With decades of experience on our side, we’ve developed what is arguably the most efficient clinical development and vaccine manufacturing capabilities the world has ever seen. We also have rapidly scaled and built out new capabilities in record time by hiring nearly 2,400 new colleagues in these functions in a nine-month timeframe. Going forward, we plan to continue to invest to capitalize on the leadership we have built in terms of both mRNA R&D and manufacturing.

[Slide 15: Four Recent Agreements that Will Help Advance our mRNA Strategy]

In addition to these internal investments and improvements, we’re also making external investments to build out our capabilities in this space. For example, Pfizer recently has entered into four important business development deals to help advance our mRNA strategy.

- We are expanding our collaboration with BioNTech to use the existing platform to co-develop an mRNA vaccine candidate for Herpes Zoster Virus to protect against shingles.
- Our agreement with Beam Therapeutics expands our mRNA efforts to another core therapeutic area for Pfizer – rare disease – with a four-year research collaboration for three targets for rare genetic diseases of the liver, muscle and central nervous system. We believe this will give us the potential to use mRNA to treat diseases – not just help prevent them.
• Our agreement with Acuitas gives us the ability to collaborate with – and license – their proprietary lipid nanoparticle (LNP) technology for up to ten targets for mRNA vaccines and therapies. We believe this will give us greater independence in this space.

• And we have signed a strategic collaboration and licensing agreement with Codex DNA, a leader in the development of automated solutions for on-demand synthesis of genes and mRNA, potentially allowing enzymatic assembly of DNA at the front-end of the mRNA production process. This could possibly reduce the time to produce a new vaccine from 3 months down to 2 months. If successful, this would be an important differentiator when developing a vaccine for the flu, for example, as it would allow us to select a strain much closer to the start of any flu season.

These deals represent only four pieces of a much bigger strategic puzzle. As we continue executing on our mRNA strategy, you should expect to see more targeted activity in this area.

[Slide 16: Bolstering the Pipeline with Recent Business Development Opportunities]

Of course, our business development activity in the last quarter went beyond executing on our mRNA strategy. This is an update of the slide I showed you last quarter, and I would like to highlight a few of the other recent deals.

The acquisition of Trillium builds on our strong track record of leadership in Oncology, enhancing our hematology portfolio as we strive to improve outcomes for people living with blood cancers around the globe.

Our strategic collaboration with Biohaven leverages our leading commercial capabilities in pain and women’s health with Biohaven's groundbreaking oral CGRP receptor antagonist - the only one approved in the U.S. for both acute and preventative treatment of migraine - to potentially bring a valuable new treatment option to patients living with this debilitating neurological disease outside the U.S.

Through the proposed acquisition of Arena we plan to leverage Pfizer’s leading research and global development capabilities to accelerate the clinical development of etrasimod for patients with immuno-inflammatory diseases.

[Slide 17: Pfizer’s ESG Strategy: Creating Value for Multiple Stakeholders (1 of 2)]

Now, I'd like to share some details about Pfizer’s enhanced ESG strategy. The strategy is focused on six areas where we see opportunities to create a meaningful and measurable impact over the next decade: product innovation; equitable access and pricing; product quality and safety; diversity, equity and inclusion; climate change; and business ethics.

[Slide 18: Pfizer’s ESG Strategy: Creating Value for Multiple Stakeholders (2 of 2)]
Each quarter going forward, I will provide examples of how we are embedding ESG into all core areas of our business. This quarter, I will highlight our efforts to:

- improve clinical trial diversity,
- improve diversity within our colleague base, and
- help ensure equitable access to our COVID-19 vaccine and treatment.

Last year, Pfizer published an industry-first retrospective analysis of demographic data of U.S. participants in 213 of our interventional clinical trials that initiated enrollment from 2011 through 2020. The analysis demonstrated that overall trial participation of Black or African American individuals was at the U.S. census level (14.3% vs. 13.4%), participation of Hispanic or Latino individuals was below U.S. census (15.9% vs. 18.5%), and female participation was at U.S. census (51.1% vs. 50.8%).

We published this analysis to be transparent and for it to serve as a baseline as we measure progress in this area. We believe that diversity in trials is a matter of equity and good science and are taking decisive steps designed to improve diversity in our trials. Our goal is to achieve racially and ethnically diverse participation at or above U.S. census or disease prevalence levels (as appropriate) in all our trials.

The second item I want to highlight is the significant progress we are making in diversifying our colleague base, particularly at more senior-level positions. In the last three years, for example, we have increased the percentage of women at the vice president level and above globally from 32% to 42%. Over that same timeframe, we have increased the percentage of minorities at the vice president level and above in the U.S. from 19% to 25%.

The third item I wanted to highlight is the progress we are making to help ensure our COVID-19 vaccine and oral treatment are accessible by everyone everywhere. I am thrilled to say that we remain on track to meet or exceed our goal of delivering at least two billion doses of our vaccine to low- and middle-income countries by the end of 2022 – having just met our goal of delivering the first one billion by the end of 2021. I also want to highlight two data points about our two billion-dose commitment.

- One billion of these doses are being provided to the poorest countries completely free of charge thanks to our agreement with the U.S. government. Pfizer is providing these doses to the U.S. government at a not-for-profit price, and the government is then providing them to the poorest countries for free.
- Also, the one billion doses we delivered in 2021 represented 37% of all doses we delivered last year.

In terms of our oral COVID-19 treatment, we have signed a voluntary license agreement with the Medicines Patent Pool (MPP), which we hope will lead to expanded access pending country regulatory authorization.
or approval, in 95 low- and middle-income countries that account for approximately 53% of the world’s population.

Lastly, I’m pleased to announce that the Compensation Committee of our Board of Directors has been reviewing methods for linking executive compensation with ESG performance, which we expect to begin this year.

For details regarding the impact of our ESG strategy had on our business in 2021, please keep an eye out for Pfizer’s 2021 ESG Report, which will be published online in mid-March.

[Slide 19: An Outstanding Year Made Possible by Outstanding People]

In summary, 2021 was an outstanding year for Pfizer, and we look forward to continuing to apply the lessons learned from COVID to deliver breakthroughs for patients across all our therapeutic areas. We remain focused on being nimble, investing in our R&D organization and exploring dynamic partnerships that will enable us to fully realize the power of our science.

None of this is possible without the contributions of our amazingly purpose-driven colleagues, who continue to rise to the challenge of addressing the world’s most devastating diseases. In 2021, our colleagues exceeded expectations. Therefore, we will once again use a part of the bonus pool that the Board approved for bonus-eligible colleagues to provide a one-time, special COVID-19 Circumstances Bonus (CCB) to our non-bonus eligible colleagues to reward them for their hard work and to help them cover personal, family and living expenses incurred because of the COVID-19 pandemic.

With that, I will turn it over to Mikael to update you on our R&D efforts. After Mikael, Frank will provide financial details on the fourth quarter and our outlook for 2022.

[Slide 20: Scientific Updates – Mikael Dolsten]

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

Thank you, Albert. I’m delighted to share updates from this quarter as we continue to deliver first-in-class science.

[Slide 21: Advancing Breakthroughs at the Speed of Science]

Today, I will share updates from our COVID-19 programs and select other assets in our pipeline.

[Slide 22: PAXLOVID: Preclinical Data on SARS-CoV-2 Variants]

Let’s start with PAXLOVID.
As the COVID-19 pandemic continues to burden public health, we have advanced the science on our novel oral antiviral therapeutic.

Importantly, we see consistent, potent antiviral activity in vitro against all current variants of concern, including both Delta and Omicron.

This would be expected from how the compound was designed. On the left, you can see a crystal structure showing how tightly nirmatrelvir binds into the active site of the Omicron variant.

History has told us from the HIV protease field that the closer the therapeutic is designed to mimic the substrate, the harder it is for resistance to emerge. That combined with the essential nature of the protease, the short duration of treatment and the co-dosing with ritonavir to drug exposures that are over five to six times the amount of compound needed to kill the virus in an in vitro assay, suggests there is a reduced risk for resistance.

[Slide 23: External in vitro Data on Key Therapeutics Against Variants]

External data support our findings. Nirmatrelvir maintains in vitro potency in the low nanomolar range, as you can see in these graphs that include other authorized or approved therapeutics.

On the left is in vitro data from a study done in collaboration with the Icahn School of Medicine at Mount Sinai. Nirmatrelvir demonstrated potent antiviral activity as measured by IC50 – a measure of drug efficacy indicating the concentration needed to inhibit infection by half.

This is consistent with findings from the Rega Institute at KU Leuven in Belgium, shown on the right.

[Slide 24: PAXLOVID: Target Populations for Clinical Studies]

We anticipate a New Drug Application decision by the FDA in the high-risk population in the second half of 2022, pivotal readouts of our household contact and standard risk studies in the second quarter and second half of 2022, respectively, and a study start in children aged 6 to 18 years old in the first quarter of 2022.

In the standard risk study, we are expanding enrollment by 750 non-hospitalized patients with symptomatic COVID-19, and vaccinated, standard-risk patients may also be eligible, provided their last SARS-CoV-2 vaccine dose was received at least 12 months prior to screening.

This expansion will allow us to further evaluate the secondary endpoint seen in the interim analysis, which showed a 70% reduction in hospitalization and no deaths compared to placebo.

[Slide 25: NextGen SARS-CoV-2 Antiviral Oral Candidate]
We also are advancing work on a potential next generation SARS-CoV-2 antiviral with the aim of achieving similar high clinical efficacy and pan-coronavirus design properties that maintain activity, with a favorable safety profile, and counter potential viral resistance—but without the need for ritonavir boosting.

A first in human study start is expected in the second half of 2022.

[Slide 26: COMIRNATY: Pediatric (6 months through 4 years) Update]

We also continue to advance vaccine development and have achieved emergency use authorizations for use in children as young as age five.

Effectiveness data for three doses of the vaccine for people 12 years and older, and early laboratory data observed with Delta and other variants of concern—including Omicron—suggest that people vaccinated with three doses of COMIRNATY may have a higher degree of protection against both symptomatic and severe outcomes compared to two primary doses.

Informed by these data, in addition to the immunobridging data, we are evaluating a third 3 µg dose in our study of children 6 months through 4 years of age, with the belief that a third dose may be optimal for this age group.

However, as pediatric cases and hospitalizations are at an all-time high, FDA urged us to start a rolling Emergency Use Authorization submission with the two-dose efficacy, immunogenicity and safety data we have accumulated thus far while we continue to collect data, including from third-dose administration.

We plan to submit third-dose data once they are available.

In the meantime, FDA has scheduled an Advisory Committee meeting for February 15 to consider the two-dose data collected to date.

If emergency use authorization of two doses is granted and the Centers for Disease Control and Prevention recommends usage, parents will have the opportunity to begin a COVID-19 vaccination series for their children between 6 months and 4 years of age while awaiting potential authorization of a third dose.

[Slide 27: COMIRNATY: Rise of Neutralizing Titers Against Omicron After 3rd Dose]

Turning to the adult population, in the wake of surging Omicron cases, in January we completed a laboratory analysis of the effect of a third dose boost of COMIRNATY on live virus neutralization.

Encouragingly, there was a more than 25-fold increase in Omicron live virus neutralizing titers observed between day of dose three and one month post-dose three.

We observed a moderate 4-month post-dose three antibody decay for Wild Type and the Omicron variant.
Between one month and four months post-dose three, neutralizing titers were 1.6- and 2-fold lower for Wild Type and the Omicron variant, respectively.

[Slide 28: COMIRNATY: Omicron-Related Emergency Visits & Hospital Admissions]

We’re now starting to see effects of a third dose boost in maintaining a high level of protection against Omicron in the real world.

These data from Kaiser Permanente Southern California show Omicron-related emergency department visits without hospitalization on top, and hospitalizations on the bottom.

Three doses of COMIRNATY provided better vaccine effectiveness against Omicron than two doses, and there was high vaccine effectiveness of three doses against Omicron-related hospitalization, similar to Delta-related hospitalization.

We did see some waning of effectiveness against emergency department admissions due to Omicron three months or more after a third dose, which suggests the potential need for another boost of the current vaccine or an Omicron-based vaccine.

[Slide 29: Omicron-Based Vaccine Candidate Study]

We have started an Omicron-based vaccine candidate trial in adults 18 to 55 years of age. The study will evaluate more than 1,400 participants across three cohorts:

   a. Those who have already received two doses of the current vaccine 90-180 days prior to enrollment will receive one or two doses of the Omicron-based vaccine;
   b. Those who have already received three doses of the current vaccine 90-180 days prior to enrollment will receive one dose of the current vaccine or the Omicron-based vaccine; and
   c. Those who are vaccine-naïve will receive three doses of the Omicron-based vaccine.

This study is part of our science-based approach to develop a variant-based vaccine that we hope achieves a similar level of protection against Omicron as the current vaccine has with both Wild Type and earlier variants, but with potentially longer duration of protection.

[Slide 30: CDK2/4/6 Inhibitor: Phase 1 Study Subset in HR+ Metastatic Breast Cancer]

Now, let’s turn to our next generation CDK inhibitors.

Most patients with advanced or metastatic breast cancer eventually develop resistance to both endocrine therapy and CDK4/6 inhibitors despite their transformative efficacy.
Inhibition of CDK2, delivered as a CDK2 selective active drug or a triple activity CDK 2/4/6 agent, may prevent, delay, or reverse resistance and prolong survival.

These are data from a subset in the CDK2/4/6 inhibitor Phase 1 dose escalation and antitumor activity study of heavily pre-treated patients with hormone receptor positive metastatic breast cancer.

The most improvement in terms of tumor size reduction was seen in patients treated with monotherapy or in combination with fulvestrant.

We observed three confirmed partial responses and three patients with stable disease for more than 12 months.

One patient has been receiving ongoing treatment for more than 28 months.

There has been an acceptable safety profile at the recommended Phase 2 dose, which is 25mg twice daily.

We plan to conduct a Phase 1 dose expansion and expect to complete it in the fourth quarter of 2022.

[Slide 31: CDK2 Inhibitor: Phase 1 Study in Breast Cancer]

Selective CDK2 inhibition may allow dose titration and has the potential to be used in combination with approved CDK inhibitors, such as palbociclib, or other next-generation CDK4 selective inhibitors.

There were two confirmed partial responses in the Phase 1 study of our selective CDK2 inhibitor in patients with advanced or metastatic HR+/HER2- breast cancer who had received/progressed on prior CDK4/6 inhibition and endocrine therapy.

One patient had a maximum tumor shrinkage of 54% following CDK2 inhibitor treatment for approximately 8 months, and the second had 100% shrinkage of all target lesions following treatment for approximately 9 months.

We are showing scans of the first patient at baseline and 8 weeks.

There was an acceptable safety profile as a monotherapy, and we are currently exploring combinations.

We expect the Phase 1/2 study to be completed in the second quarter of 2023.

[Slide 32: Lyme Vaccine (PF-07307405) Candidate: Lyme Disease]

Now, let’s turn to our six-valent Lyme disease vaccine candidate which we are developing in partnership with Valneva.
We have received further positive data from our Phase 2 proof of concept study and expect to start Phase 3 in the third quarter of 2022 with a dosing regimen of 0, 2, and 6 months to prime, followed by routine boosters before the start of a Lyme season.

Our Phase 2 study is continuing and includes a pediatric population aged 5 to 17 years.

[Slide 33: Lyme Vaccine: Phase 2 Data]

Since Lyme disease is seasonal, our goal is to establish a regimen that results in high antibodies at the beginning of each season. We therefore looked at a boost one year after the primary series.

We saw substantial boost antibody response in Phase 2 to all six serotypes present in North America and Europe following the three-dose primary series vaccination schedule, with a 14- to 31-fold rise in season one and a 51- to 69-fold rise in season two.

The vaccine candidate was generally well tolerated at all dose levels tested, and we are excited about further development and the potential to help prevent this debilitating disease.

[Slide 34: Fordadistrogene movaparvovec GTx*: Duchenne Muscular Dystrophy (DMD)]

Last quarter, we told you that we saw robust dystrophin expression out to one year in our Duchenne Muscular Dystrophy gene therapy Phase 1b study. I will show you encouraging functional motor data in a moment.

We recently shared some very sad news that a DMD patient with advanced disease in the non-ambulatory cohort of the Phase 1b trial passed away after presenting with hypovolemia and cardiogenic shock.

This patient was 16 years old and the first in the non-ambulatory cohort treated with Rapamune, along with steroids, as part of the immunosuppressive regimen. Rapamune is not used in the Phase 3 ambulatory study. Like most non-ambulatory DMD patients, he had more advanced disease with underlying cardiac dysfunction. There is evidence of an active viral infection and we are investigating how this may have contributed to the outcome.

Additional assessment will be required to define the steps needed to re-start the Phase 1b study in non-ambulatory patients who are more progressed in the disease.

I will now share the encouraging data we have seen from the ambulatory cohort of the Phase 1b study.

[Slide 35: Fordadistrogene movaparvovec: Phase 1b Ambulatory Population at 1 yr.]

Nineteen patients were enrolled, 16 of whom received the dose selected for our Phase 3 program and three of whom received a previously studied lower dose.
At one year post-treatment, there was a mean 5.6 point improvement in ambulatory function as measured by North Star Ambulatory Assessment compared to an external control, matched for age and baseline function.

This is particularly encouraging given that patients at this age and stage of disease typically experience a considerable decline in ambulatory function as illustrated by the external control.

On the right, we show time in study, with six participants nearing or more than three years since treatment. The ambulatory cohort in Phase 1b is similar, but slightly older on average, to the population in the Phase 3 CIFFREO trial.

Considering the favorable benefit to risk profile we have seen in the ambulatory patient population and in consultation with the Data Monitoring Committee, we believe the safety profile of our DMD gene therapy is manageable in this patient group.

Additional mitigations are being added to our study protocol in consultation with the eDMC and other medical experts.

Pending regulatory feedback, we anticipate Phase 3 study sites to begin to re-open in the next few months, with the potential to report topline results and, subject to clinical trial success, submit a BLA by the end of 2023.

[Slide 36: Anti-GDF-15 mAb (ponsegromab, PF-06946860): Cancer Cachexia]

Turning now to Internal Medicine, and ponsegromab, our candidate for cachexia due to cancer.

It targets GDF-15, which is frequently elevated in cancer patients, drives reduction of appetite and body weight loss, and is associated with poor outcomes. There may also be potential to treat cachexia associated with other chronic diseases such as heart failure and COPD.

We have encouraging Phase 1b data which I will show next.

[Slide 37: Anti-GDF-15 mAb: Phase 1b (Preliminary Data) in Cancer Cachexia]

Ponsegromab was evaluated in ten cancer patients who were undergoing anti-tumor treatment and had more than 5% body weight loss in the last 6 months, or more than 2% body weight loss with a body mass index of less than 20 kg per meters squared or diagnosed sarcopenia.

Ponsegromab administration was found to suppress circulating GDF-15 levels in cancer cachexia patients below the level observed in healthy subjects.
Preliminary data from the Phase 1b trial show ponsegromab treatment resulted in significant body weight gain compared to historical placebo. You can see that the nice trend in body weight increase remained even after the dosing was stopped at week 12. The gray dotted line indicates the historical cut-off associated with improved survival.

We are co-developing a companion diagnostic with Roche Diagnostics designed to enable precision medicine, and we expect to start a Phase 2 study in cancer cachexia in the fourth quarter of 2022.

[Slide 38: Oral GLP-1 Receptor Agonist (danuglipron, PF-06882961): T2DM & Obesity]

Injectable GLP-1 receptor agonists offer potent lowering of glucose and weight in diabetic and obese patients, with proven cardiovascular benefit, but this drug class is underutilized due to its injectable administration route.

Our small molecule GLP-1 receptor agonist danuglipron could potentially offer a convenient oral alternative to injectables and is being evaluated for the treatment of Type 2 diabetes, obesity and NASH.

It has been developed in our Internal Medicine research group with a vision to expand the use of this potent, easily administrated GLP-1 drug class to a primary care setting.

[Slide 39: Danuglipron (Oral GLP-1): Phase 2 Study in Type 2 Diabetes]

Here are data from the Phase 2 study in Type 2 Diabetes.

We recorded strong dose-dependent reductions in both HbA1c—a measure of long-term blood sugar levels—and body weight, compared to the marginal effects noted with placebo.

After 12 weeks of treatment with the 200 mg twice daily dose, HbA1c decreased by almost 1.6% and body weight decreased by 5.4 kilograms.

The safety and tolerability profile is consistent with the GLP-1 class and the most frequent adverse events were GI-related.

We expect to start a Phase 2b titration optimization study mid-2022 with doses up to 200 mg twice a day, and complete a Phase 2b study in non-diabetic subjects with obesity in the first quarter of 2023.

[Slide 40: Key 2H 2021 Achievements and 2022 Potential Milestones]

Here are select recent and potential upcoming milestones from across the pipeline.

The solid blue dots represent milestones achieved and the open blue dots represent anticipated milestones.

Programs in bold are major anticipated events.
Some of the programs on the right have already been designated as lightspeed, meaning they have accelerated development timelines, or are being considered for lightspeed designation.

Finally, I would like to take a moment to thank Morrie Birnbaum, our outgoing Chief Scientific Officer of the Internal Medicine Research Unit, for his immense contributions over the last seven years, and welcome Bill Sessa, who joins us from Yale School of Medicine following a decades-long career in academia—including serving as Vice Chair of Pharmacology, Professor of Medicine, and Director of the Vascular Biology & Therapeutics Program at Yale.

Bill is an eminent leader in this field, a groundbreaking scientist and a celebrated innovator, and I know he will bring his tremendous vision and insights to our investigation of cardiovascular and metabolic diseases.

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

[Slide 41: Financial Review – Frank D’Amelio]

Frank D’Amelio – Pfizer Inc. – Executive Vice President, Chief Financial Officer

[Slide 42: 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 and Mikael have already addressed the key points on the COVID-19 landscape.

Turning to the income statement. Revenue increased 106% operationally in the fourth 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 excluding the COVID-19 vaccine direct sales and alliance revenues and Paxlovid contribution, the fourth quarter was slower than the first nine months of the year, declining by 2% operationally. As we discussed during our third quarter call, there was a 4% negative impact, or approximately $500 million, from fewer selling days in the US and International. Excluding that impact, operational growth would have been 2%, which is still lower than the mid-to-high single digit growth we had experienced during the rest of the year.

This was factored into our forecasts for the year but let me briefly walk you through this. In our Biopharma business, you will remember that the fourth quarter of 2021 faced a tough comp from the fourth quarter of 2020 for Prevnar, as pneumococcal vaccinations were strong ahead of COVID-19 vaccine availability. Excluding vaccines from the current and comparable period would add 5 percentage points to the growth.
Adjusting for the unusual comparative period differences related to Vaccines and selling days, our revenue growth would have been approximately 7 percent, which is similar to what we've been delivering lately.

For the year, operational revenue growth was 92%. Excluding Comirnaty direct sales and alliance revenues and Paxlovid, 2021 operational revenue growth was 6%. This is consistent with our projected revenue CAGR of at least 6% from 2020 through the end of 2025. Of course, there will be some variability in quarterly and annual growth rates due to a variety of factors, but we continue to expect at least a 6% CAGR through 2025.

The Adjusted cost of sales increase shown here reduced this quarter's gross margin by approximately 16 percentage points compared to the fourth quarter of 2020, which is almost entirely driven by the impact of the COVID-19 vaccine.

Adjusted SI&A expenses in the fourth quarter increased primarily due to increased product-level spending, including Comirnaty, including higher healthcare reform sales-based fees.

The increase in Adjusted R&D expense this quarter was primarily driven by increased investments in late-stage pipeline projects, including additional spending related to our oral COVID-19 treatment.

The growth rate for reported diluted EPS was +293%, while Adjusted diluted EPS grew +152% for the quarter.

Foreign exchange movements resulted in a negative 1% impact to revenue as well as a 4% benefit, or $0.02, to Adjusted diluted EPS.

[Slide 43: 2021 Financial Guidance vs. Results]

As you can see, we achieved or exceeded each of the components of our 2021 financial guidance.

[Slide 44: 2022 Financial Guidance]

Let's move to our first time 2022 guidance.

We've again provided total-company guidance, which includes the business with the COVID-19 vaccine. We will continue to provide insight into our expected revenues for Comirnaty, and, now for the first time, we will also provide some color on our expected revenues for Paxlovid. However, note that we will no longer be providing EPS guidance for the business excluding Comirnaty. Similarly, we won't provide EPS guidance for Paxlovid.

Our revenue guidance represents a record for Pfizer, and we expect total company revenue to be in a range of $98.0 to $102.0 billion, representing an operational growth rate of 24% at the mid-point. Please consider that this revenue range reflects approximately $1.1 billion of anticipated negative impact from
changes in foreign currencies and also the impact of the loss of Meridian's sales of approximately $300 million, both of which your models may not take into account.

Regarding our COVID-related revenues, we now expect the COVID-19 vaccine revenue for the year to be approximately $32 billion, an increase of approximately $1 billion compared to our prior guidance provided on December 17. For Paxlovid, we expect sales of approximately $22 billion.

This means that excluding the COVID-related revenues, we expect sales to be $46 billion at the midpoint, representing operational growth of 5%. While this is slightly below the 6% CAGR that we continue to expect between 2020 and 2025, I would remind you that there will be volatility along the way.

Let me give you some detail on our cost and expense guidance.

For Adjusted cost of sales, we are expecting a range of 32.2% to 34.2%. Given that we are now more than 12 months past the launch of Comirnaty, we expect its negative impact on cost of sales margins to be less than it was in 2021, assuming a similar level of revenues. Further, Paxlovid is expected to have a very positive impact on cost of sales as a percent of revenues in 2022.

On Adjusted SI&A, we expect $12.5 to $13.5 billion, an increase of $900 million at the midpoint, as compared to 2021.

In addition, we expect our Adjusted R&D guidance range to be $10.5 to $11.5 billion; at the midpoint, that is about $500 million higher than last year.

We expect an adjusted effective tax rate for the year somewhat higher than 2021 at Approximately 16.0%.

These assumptions yield an Adjusted diluted EPS range of $6.35 to $6.55 or 47% operational growth at the midpoint compared to 2021, excluding an expected $0.06 negative impact from foreign exchange.

I would like to point out some additional information which may be helpful for your models. You will note that our guidance assumes a weighted average share count of approximately 5.8 billion, which represents an increase of approximately 100 million shares over 2021. This accounts for the number of shares that we normally issue for employee compensation annually. The increase of 100 million shares over 2021 decreases our EPS by about 10 cents at the mid-point. I notice that most of your models instead assume a flat share count for 2022 as compared to 2021.

From the first quarter of 2022 and going forward, we've made a decision to modify our adjusted financials' treatment of amortization of intangibles. Previously, we only excluded amortization related to large mergers and acquisitions, but we will now exclude all intangible asset amortization expense. This is anticipated to contribute 6 cents to our 2022 adjusted diluted earnings per share, and helps improve comparability with our peers.
2022 guidance once again assumes no share repurchases. You will note that Pfizer did not repurchase shares in either 2020 or 2021. While we continue to have outstanding unused authorization to repurchase another $5.3 billion of stock and can be opportunistic, given the potentially value-enhancing business development opportunities which are available to us, we do not expect to repurchase shares in 2022.

Now a word on our 32% stake in the Consumer JV with GSK. As you know, GSK has announced its intention to engage in a demerger transaction for at least 80% of its 68% stake in the JV in summer 2022. We talked about our stake as a non-core asset whose value we will seek to realize over time. While we have determined neither the manner nor timing of how we will do so, there are a number of possible alternatives and we will attempt to monetize this asset in the manner which will create the most value for our shareholders. We receive approximately $600 million in pre-tax income from the JV annually, and this will not change as a result of the demerger transaction, and our guidance assumes that this will continue throughout 2022 with no change to our 32% stake.

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

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 4 billion doses in total by the end of 2022.

The $1 billion increase in expected COVID vaccine revenues to approximately $32 billion in 2022 primarily represents the impact of contracts signed since mid-December, which was the cutoff for our prior guidance. While we can't predict what may be needed due to omicron or other variants, I would also caution you that there is less potential upside to this guidance through the year, compared to the situation we faced in 2021 when the vaccine was newly available and few people had received any doses of the vaccine.

As you will remember, 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 expect that the Adjusted income before tax margin for the COVID-19 vaccine contribution to be slightly higher than the high 20’s as a percentage of revenue that we had in 2021.

Unlike the situation for Comirnaty, demand for Paxlovid should have upside from these levels, depending on the outcomes of discussions with certain governments and potential purchases for stockpiling against future coronavirus pandemics.
If we remove the projected COVID-19 vaccine and Paxlovid contribution from both periods, you will see that we expect the 2022 revenue range to be $45 to $47 billion, representing approximately 5 percent operational revenue growth at the midpoint.

Please remember our guidance excludes the former revenue contribution of approximately $300 million for Meridian, and all 2021 quarters have been recast to exclude Meridian as discontinued operations, accounting for its divestiture.

Going forward, we will not give earnings guidance excluding the estimated income from our Comirnaty direct sales and alliance revenues and Paxlovid. [However, to help you with your forecasting, a couple of minutes ago, I gave you my view on 2022 Comirnaty pre-tax margins. For Paxlovid, I would think about its margins as being typical for a small molecule drug, and unlike Comirnaty, it is expected to not be dilutive to pre-tax margins. To help you further, several years ago before COVID-19 existed, I spoke about our business being on a path back to a 40% plus pre-tax margin and we expect to achieve this level in 2022 for the business excluding Comirnaty direct sales and alliance revenues and Paxlovid.]

[Slide 45: 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 46: Key Takeaways]

In summary, an exceptionally strong quarter and year, based on continued strong performance for our growth drivers. During the year, we raised guidance, and for the year, we met or exceeded our guidance in all key metrics. Our pipeline continues to advance, and we have invested [record amounts] to support that advance. Last week, Arena's shareholders voted to approve Pfizer's acquisition of the company. We look forward to a targeted closing of the Arena acquisition as soon as the first half of 2022, subject to the satisfaction of the closing conditions, including antitrust approvals. We continue to expect to be active in regards to business development throughout 2022, as we continue to get access to the best external science and bring breakthroughs to patients in 2025 and beyond.

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 February 8, 2022. We assume no obligation to update any forward-looking statements contained in these prepared remarks as a result of new information or future events or developments.

These prepared remarks contain forward-looking statements about, among other topics, our anticipated operating and financial performance; reorganizations; business plans 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 oral COVID-19 treatment (Paxlovid); and our expectations regarding the impact of COVID-19 on our business, operations and financial results that involve substantial risks and uncertainties. You can identify these statements by the fact that they use future dates or use words such as “will,” “may,” “could,” “likely,” “ongoing,” “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “assume,” “target,” “forecast,” “guidance,” “goal,” “objective,” “aim,” “seek,” “potential” 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, including the scope of indicated patient populations, product dosage, manufacturing processes, safety and/or other matters, including decisions relating to emerging developments regarding potential product impurities; the impact of recommendations by technical or advisory committees; and the timing of pricing approvals and product launches;

- claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates, including claims and concerns that may arise from the outcome of post-approval clinical trials, which could impact marketing approval, product labeling, and/or availability or commercial potential, including uncertainties regarding the commercial or other impact of the results of the
Xeljanz ORAL Surveillance (A3921133) study or actions by regulatory authorities based on analysis of ORAL Surveillance or other data, including on other Janus kinase (JAK) inhibitors in our portfolio; the success and impact of external business-development activities, including the ability to identify and execute on potential business development opportunities; the ability to satisfy the conditions to closing of announced transactions in the anticipated time frame or at all; the ability to realize the anticipated benefits of any such transactions in the anticipated time frame or at all; the potential need for and impact of additional equity or debt financing to pursue these opportunities, which could result in increased leverage and/or a downgrade of our credit ratings; challenges integrating the businesses and operations; disruption to business and operations relationships; risks related to growing revenues for certain acquired products; significant transaction costs; and unknown liabilities;

competition, including from new product entrants, in-line branded products, generic products, private label products, biosimilars and product candidates that treat or prevent diseases and conditions similar to those treated or intended to be prevented by our in-line products and product candidates;

the ability to successfully market both new and existing products, including biosimilars;

difficulties or delays in manufacturing, sales or marketing; supply disruptions, shortages or stock-outs at our facilities or third-party facilities that we rely on; and legal or regulatory actions;

the impact of public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic), including the impact of vaccine mandates where applicable, on our business, operations and financial condition and results, including impacts on our employees, manufacturing, supply chain, sales and marketing, research and development and clinical trials;

risks and uncertainties related to our efforts to develop and commercialize a vaccine to help prevent COVID-19 and an oral COVID-19 treatment, as well as challenges related to their manufacturing, supply and distribution, including, among others, uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with pre-clinical and clinical data (including the Phase 1/2/3 or Phase 4 data for Comirnaty, any other vaccine candidate in the BNT162 program, Paxlovid or any other future COVID-19 treatment) in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection; the ability to produce comparable clinical or other results for Comirnaty or Paxlovid, including the rate of effectiveness and/or efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial for Comirnaty or Paxlovid and additional studies, in real-world data studies or in
larger, more diverse populations following commercialization; the ability of Comirnaty or any future vaccine to prevent, or Paxlovid or any other future COVID-19 treatment to be effective against, COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine or Paxlovid will lead to new information about efficacy, safety or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program, Paxlovid or other programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future pre-clinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for Comirnaty or any potential future vaccines in additional populations, for a booster dose for Comirnaty or any potential future vaccines (including potential future annual boosters or re-vaccinations), and/or biologics license and/or EUA applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty or any other potential vaccines, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when submissions to request emergency use or conditional marketing authorizations for Paxlovid or any other future COVID-19 treatment and/or any drug applications for any indication for Paxlovid or any other future COVID-19 treatment may be filed in any jurisdiction, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when any application that may be pending or filed for Comirnaty, other vaccines that may result from the BNT162 program, Paxlovid or any other future COVID-19 treatment or any other COVID-19 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine’s or drug’s benefits outweigh its known risks and determination of the vaccine’s or drug’s efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine or drug, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that other companies may produce superior or competitive products; the risk that demand for any products may be reduced or no longer exist; the possibility that COVID-19 will diminish in severity or prevalence, or disappear entirely; risks related to the availability of raw materials to manufacture or test any such products; challenges related to our vaccine’s formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to
successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-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, Paxlovid or any other COVID-19 program; challenges and risks associated with the pace of our development programs; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine or any treatment for COVID-19, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine or treatment courses of Paxlovid within the projected time periods; whether and when additional supply or purchase agreements will be reached; the risk that demand for any products may be reduced or no longer exist; uncertainties regarding the ability to obtain recommendations from vaccine or treatment advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; pricing and access challenges for such products; challenges related to public confidence or awareness of our COVID-19 vaccine or Paxlovid, including challenges driven by misinformation, access, concerns about clinical data integrity and prescriber and pharmacy education; trade restrictions; potential third-party royalties related to our COVID-19 vaccine or Paxlovid; and competitive developments;

- trends toward managed care and healthcare cost containment, and our ability to obtain or maintain timely or adequate pricing or favorable formulary placement for our products;
- interest rate and foreign currency exchange rate fluctuations, including the impact of possible currency devaluations in countries experiencing high inflation rates;
- any significant issues involving our largest wholesale distributors or government customers, which account for a substantial portion of our revenues;
- the impact of the increased presence of counterfeit medicines or vaccines in the pharmaceutical supply chain;
- any significant issues related to the outsourcing of certain operational and staff functions to third parties; and any significant issues related to our 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 internationally and in the U.S., including, among others, potential adoption of global
minimum taxation requirements and potential changes to existing tax law by the current U.S. Presidential administration and Congress;

Risks Related to Intellectual Property, Technology and Security:

- any significant breakdown or interruption of our information technology systems and infrastructure (including cloud services);
- any business disruption, theft of confidential or proprietary information, extortion or integrity compromise resulting from a cyber-attack;
- 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 our oral COVID-19 treatment.

We cannot guarantee that any forward-looking statement will be realized. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 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 February 8, 2022.

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

Emergency uses of the Pfizer-BioNTech COVID-19 Vaccine and Paxlovid have not been approved or licensed by the FDA. Emergency uses of Comirnaty 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 the 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 5 years of age and older, and a booster dose for individuals 12 years of age and older. Paxlovid has been authorized for emergency use by the FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg [88 lbs]) with positive results of direct SARS CoV-2 viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization or death. 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 the EUA Fact Sheets at www.cvdvaccine-us.com and www.covid19oralrx.com.

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