Second-Quarter 2022 Earnings Conference Call Prepared Remarks
July 28, 2022

[Slide 4: Opening Remarks – Albert Bourla]

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

[Slide 5: Q2 2022 Key Highlights]

I am proud to say that Pfizer continued to deliver strong operational performance in the second quarter and has increased its full-year 2022 operational financial forecasts for revenue and adjusted diluted EPS, all while operating in a challenging foreign exchange environment.

Compared with the second quarter of 2021, global revenues were up 53% operationally to $27.7 billion and Adjusted Diluted EPS increased 100% operationally to $2.04. Both results exceeded consensus analyst expectations, and the quarterly revenue figure represented the largest in Pfizer’s history.

Key growth drivers for the quarter included Paxlovid, Comirnaty, Eliquis and Vyndaqel/Vyndamax globally, and our Prevnar family of products in the U.S.

Year to date, we have reached an estimated 845 million patients around the world with our innovative medicines and vaccines – which represents a 77% increase from the prior-year period.

And we did all this while also taking steps to help address broader issues impacting global health, including climate change, equitable access and the war in Ukraine.

[Slide 6: COVID-19: Where Do We Go From Here?]  

So, where do we go from here?

After two and a half long years, like everyone else, we would hope that this global health crisis would be over soon. But as much as hope is important, hope is not science. And science is telling us that COVID-19 likely will remain a major global healthcare concern for years to come. We believe that Pfizer is well positioned not only to maintain but to grow both our commercial and scientific leadership in the battle against COVID-19.
In terms of our commercial leadership, we believe Pfizer’s skills are even better suited for operating in open markets than they are for government-contracting markets – and will be even more competitive when this transition happens. Recently, Angela announced a new commercial structure that prepares us to provide even better support for the ongoing Comirnaty and Paxlovid revenue streams.

In terms of our scientific leadership, we expect to further enhance our position through the continued introduction of new innovations, including preparation for new variants of concern and potentially improving the durability of protection. So far, we have been fortunate that most of the variants have led to less severe illness, but there remains the possibility that a future variant could emerge that combines Omicron’s contagiousness with the original virus’s severity. This is a scenario no one wants to imagine, but one for which we need to be prepared.

That’s why it is critical that Pfizer continues to invest in the research and development of COVID-19 vaccines and treatments.

[Slide 7: Comirnaty: Continued Leadership In the Fight Against COVID-19]

With this context as a backdrop, let me provide an update on our current COVID-19 offerings. I will start with Comirnaty.

To date, we have shipped more than 3.6 billion doses of our vaccine to 180 countries and territories around the world. Comirnaty remains the most utilized COVID-19 vaccine in the markets in which we operate that report market share data. Pfizer’s cumulative share of doses administered in these markets has increased from 52% on January 1, 2022, to 63% on July 20, 2022. In developed markets, our share has increased from 59% to 68% over that same time period.

[Slide 8: Omicron-Adapted COVID-19 Vaccine Candidates for Fall 2022 Boosters]

Next, I would like to briefly touch on the topic of vaccine boosters for the fall.

Outside the U.S., global regulators have issued guidance to advance an Omicron-adapted bivalent vaccine candidate to help address the continued evolution of the virus. As such, Pfizer and BioNTech have submitted data to the European Medicines Agency (EMA) on the safety, tolerability and immunogenicity for the companies’ bivalent Omicron BA.1-adapted vaccine candidate. We also continue to work with health authorities around the globe on regulatory submissions.

The U.S. Food & Drug Administration (FDA) recently asked biopharmaceutical companies, including Pfizer, to develop a modified vaccine containing an Omicron BA.4/BA.5 component and begin clinical trials with these vaccine candidates. Pfizer is currently proceeding with development of a COVID-19 bivalent Omicron BA.4/BA.5 booster vaccine candidate and is targeting the fall for rollout in the U.S., subject to regulatory
authorization. Pfizer is well positioned to satisfy its current contractual obligations and potential demand within its production capacity through the end of the year.

Because of our robust manufacturing capabilities, we are planning to deliver both variant vaccines in the fall, pending regulatory approvals.

[Slide 9: Paxlovid: Expanding Access in U.S.]

Turning to Paxlovid, we continue to be very pleased with how things are progressing in the U.S. as we are seeing several initiatives supporting increased access for eligible patients. First, the number of facilities with Paxlovid supply has continued to increase with more than 41,000 sites live as of July 15, an increase of more than 7,000 sites since early May. We are pleased with the FDA’s July 6th revision of the Emergency Use Authorization for Paxlovid that authorized state-licensed pharmacists to prescribe the treatment under certain conditions, thereby expanding access for patients.

[Slide 10: Paxlovid: Nearly Five-Fold Growth in U.S. Utilization Since Q1]

As you can see on this slide, we have seen a nearly five-fold increase in Paxlovid utilization since the first quarter. We also continue to retain greater than 90% market share of oral Covid-19 treatments in the U.S. and are taking a state-by-state approach to engaging key government officials to discuss their access strategies. We’re also continuing to work with states to educate consumers, healthcare providers and pharmacists about the importance of treating all appropriate high-risk patients rather than limiting treatment to the severely immunocompromised and unvaccinated. In spite of the strong growth we have seen in Paxlovid uptake in the U.S. due to our and the government’s efforts, we estimate that a significant amount of eligible patients outside the U.S. are not yet being treated with the drug and may not know they are at high risk of progressing to severe disease. So, we believe there remains substantial opportunity to grow Paxlovid utilization.

[Slide 11: Paxlovid: Expanding Access in International Developed Markets]

For international developed markets, we are seeing significant increases in usage across many markets reflecting the recent wave of BA.4/BA.5 and resulting increases in hospitalizations, ICU admissions and deaths. For example, over the month from June 24 to July 24, average daily deaths in Europe almost doubled from a low of 0.6 per 1 million people to 1.15 per 1 million; in Japan they almost tripled from 0.12 per 1 million people to 0.34 per 1 million; and in Australia they increased from 1.78 per 1 million people to 2.59 per 1 million. While we have less precise numbers on market share outside the U.S., our internal estimates indicate that we saw an estimated 116% increase in usage between June 24 and July 15 across international developed markets where we have supply agreements. So, we believe there is a significant opportunity to continue the growth outside the U.S. as physicians become more knowledgeable about Paxlovid and treat appropriate patients.
While COVID-19 remains top-of-mind for many people, we are seeing encouraging performances with some of our other innovative products, as well, and I wanted to take a moment to highlight two of them.

We are very pleased with the success of our U.S. launch of Prevnar 20 for adults. Second-quarter U.S. revenues for our Prevnar family of vaccines for adults were up 337% operationally, compared with the prior-year quarter, to $431 million – with Prevnar 20 representing more than three quarters of the total adult revenue. The great majority of U.S. healthcare networks, IDNs and retailers who have made formulary decisions have chosen Prevnar 20 alone as their higher valency pneumococcal vaccine of choice to help protect adults. This has resulted in Prevnar 20 having a 97% market share. This is also the first time there has been a routine recommendation for Prevnar for people in the 19-64 age group with underlying medical conditions. This group has an increased risk for contracting pneumococcal pneumonia and, unfortunately, has historically been the hardest to activate. Lastly, we believe the simplicity of Prevnar 20 being the only vaccine that can help protect patients with one dose in one visit makes it preferable to competitors’ offerings.

Quarterly revenues for Ibrance grew 1% in the U.S. compared with the same quarter last year, despite a continued increase in the proportion of patients accessing Ibrance through our Patient Assistance Program. This marked the first quarterly revenue uptick in the U.S. since the fourth quarter of 2020, which is an encouraging sign. Total volume in the U.S. increased 3% compared with the year-ago quarter.

Before I turn it over to Mikael, I want to touch on some actions we have taken recently to further demonstrate our commitment to Environmental, Social and Governance (or ESG) principles.

We recently announced an Accord for a Healthier World. Under this Accord, we are offering all of our patented, high-quality products that are available in the U.S. or the EU on a not-for-profit basis for 1.2 billion people living in 45 lower-income countries. This includes all future Pfizer products, as well.

I am thrilled to say that the first product under this Accord has arrived in Rwanda, with more on the way. Pfizer's experts also held a session for 100 Rwandan medical professionals to discuss efficacy, safety and dosing of this medicine. This is just the first step of Accord implementation, but an important one that will impact many lives.

We recently announced our commitment to achieve the Net-Zero Standard across our value chain by 2040. This is ten years ahead of a new voluntary external standard. This includes aiming to reduce our company emissions by 95% and value chain emissions by 90% within the next roughly 18 years.
In response to the war in Ukraine, we are donating the equivalent of all profits from our sales in Russia to causes that provide direct humanitarian support to the people of Ukraine. Our first down payment of $5 million is going to eight global and local NGOs to support humanitarian relief and response efforts, and we will continue to channel these profits to the Ukrainian people until peace is achieved.

[Slide 15: MSCI ESG Rating Upgrade]

I am also very proud to share with you that in a recently published report from MSCI, Pfizer’s annual ESG rating increased three notches compared with June 2021, going from B to A. This is just the latest external recognition we have received for our commitment to sustainable and ethical business practices.

I couldn’t be prouder of our colleagues’ commitment to good governance practices, quality and integrity.

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

[Slide 16: Scientific Updates – Mikael Dolsten]

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

Thank you, Albert. I’d like to start by highlighting two recent leadership appointments.

[Slide 17: Leading the Way to Breakthroughs]

I’ve appointed Annaliesa Anderson to lead Vaccine Research & Development, succeeding Kathrin Jansen, who previously announced her retirement.

With more than two decades of biopharmaceutical R&D experience, Liesa most recently served as Chief Scientific Officer for Bacterial Research and Hospital. Over the last two years, she has led the team of infectious disease biologists that designed and delivered PAXLOVID to an emergency use authorization. Under her leadership, we also advanced several bacterial vaccine programs into clinical development and approval.

I’ve also named Charlotte Allerton Chief Scientific Officer for Anti-Infectives, a new research unit. Creating this new research unit allows us to expand our focus beyond medicines that typically are used in hospitals. Charlotte is an esteemed scientist who will broaden our anti-viral strategies with additional efforts in antibacterial and anti-fungal science and medicines. Charlotte has been our Head of Medicine Design—most notably co-leading the discovery and development of PAXLOVID—and will continue in that role, as well.
I have had the privilege to work closely with Liesa and Charlotte for more than 10 years and have been continually impressed by them as world class scientists in their respective fields of expertise. Both have demonstrated good product hunting skills and a sound business mindset. I’m looking forward to working with them in their new roles.

[Slide 18: The Pandemic Continues to Evolve]

Let’s begin with COVID-19. The pandemic continues to evolve into a disease which is causing significant disease burden, including high rates of acute disease, medical care utilization, hospitalization and deaths, during the entire year.

A growing number of patients affected by acute COVID infections are developing chronic disease and suffering from long COVID symptoms affecting multiple organs such as the lungs, heart, kidney and brain and the vascular system.

We have seen major waves of variants of concern emerge quickly, become dominant, then be superseded by the next variant.

Omicron and its sublineages are the most antigenically distant compared to prior variants of concern, more transmissible and show evidence of partial immune escape from existing vaccines.

[Slide 19: Advancing Omicron Variant-Modified Vaccine Candidates]

As the composition of SARs-CoV-2 changes, it is essential we advance new approaches to extend the level of protection that COMIRNATY originally conveyed.

In a clinical trial, we evaluated the safety, tolerability and immunogenicity of mono- and bivalent Omicron BA.1-modified vaccines administered as a fourth dose in more than 1,900 participants over age 55.

We are also evaluating different doses of mono- and bivalent BA.1 in participants 18-55 years of age.

While we saw promising responses to both mono- and bivalent versions in the over-55 population, we moved forward with bivalent following guidance from regulators.

[Slide 20: Advancing Omicron-Modified Vaccine Candidates]

The BA.1 vaccine candidate elicited a superior immune response for BA.1 compared to the current version of the vaccine, a seroresponse rate which exceeded noninferiority, and neutralization activity which increased substantially.

The BA.1 vaccine neutralized wild type and Delta similarly to the current version of the vaccine, suggesting the Omicron-modified version maintained responses for the ancestral strain and other variants.
Based on these data and following guidance from regulators, we have completed regulatory submissions in Europe, the UK and Canada for the 30-microgram bivalent vaccine in individuals 12 and older and plan submissions in other markets soon.

The data also showed this vaccine candidate neutralized Omicron BA.4 and BA.5, though to a lesser extent than BA.1.

This suggested a need to develop both a BA.1-modified vaccine and a BA.4/5-modified vaccine.

[Slide 21: Omicron BA.4/5 Monovalent and Bivalent Boosters in Mice]

We studied BA.4/5 monovalent and bivalent booster candidates in mice and found a substantial increase in neutralization responses to all Omicron variants of concern.

Neutralizing titers against BA.4/5 increased 11-fold for the monovalent and 4.8-fold for the bivalent compared to monovalent BA.1.

These data were shared at the recent FDA Advisory Committee meeting as a potential surrogate to help expedite development of a BA.4/5 vaccine.

[Slide 22: Bivalent Booster Strategy to Adapt to Pace of Virus]

We plan to submit the BA.4/5 bivalent vaccine candidate for Emergency Use Authorization in the U.S. in preparation for the fall booster campaign.

To adapt more rapidly, we have agreed with FDA that this submission will be based on safety and immunogenicity data generated in adults with an Omicron-modified BA.1 vaccine and supported by BA.4/5 bivalent-specific preclinical data and BA.4/5 bivalent Chemistry, Manufacturing and Controls data.

This strategy is bolstered by previous experience showing that overall responses have been similar between human clinical and mouse data, our clinical experience with Beta- and Omicron-modified vaccine candidates, and by leveraging our mRNA platform and manufacturing experience for the current vaccine.

To support future potential U.S. licensure and global registrations, we plan to initiate a clinical study to evaluate the BA.4/5 bivalent vaccine. The clinical study design is under discussion with the FDA.

[Slide 23: Strategies Aiming to Provide Durable Disease Protection Against Emerging Variants]

We aspire to continue leading with science and working to identify vaccines that will help provide strong and durable protection as new SARS-CoV-2 variants emerge.

We aim to deliver a next-generation COVID-19 vaccine that can provide durable antibody and T cell immune protection against severe disease and hospitalization for at least one year.
We plan to take a stepwise approach by designing and testing different candidates that engage multiple arms of the immune system including antibodies and T cells.

First, yesterday we announced the start of a Phase 2 study evaluating a bivalent modRNA vaccine candidate which consists of RNAs encoding novel enhanced prefusion spike proteins for the SARS-CoV-2 ancestral strain and an Omicron variant.

The enhanced spike protein encoded from the mRNAs has been modified with the aim of increasing the magnitude and breadth of antibody neutralization response that could better protect against COVID-19. We project delivering key clinical data this fall.

Second, we plan to initiate a proof-of-concept study with a pan-SARS-CoV-2 candidate by the end of the year.

This combines the super-stabilized spike sequences with a T-cell enhancing construct, aiming to extend durability of protection against severe disease and new emerging SARs-CoV-2 viral variants.

[Slide 24: Continued Expansion of Paxlovid Clinical Studies]

Turning to PAXLOVID, last month, we submitted a New Drug Application to the U.S. FDA, seeking approval for the treatment of COVID-19 in both vaccinated and unvaccinated adults and pediatric patients 12 years and over weighing at least 40 kilograms at high risk for progression to severe illness. We anticipate a PDUFA date in the first quarter of 2023.

We plan to generate further data in those who are immunocompromised, hospitalized with severe COVID-19 and at increased risk for poor outcomes due to the disease, or who are pregnant.

We also are considering multiple collaborative studies to evaluate potential treatment for long COVID.

Finally, we are working with the FDA to finalize a protocol to study patients who may be in need of retreatment. According to CDC, a brief return of symptoms may be part of the natural history of SARS-CoV-2 infection in some people. We believe the occurrence of COVID-19 rebound is uncommon and not uniquely associated with any specific treatment. At this time, cases are being reported at a rate consistent with the EPIC-HR trial.

[Slide 25: Current Flu Vaccines are Suboptimal in Addressing Unmet Need]

Turning to flu, we know that currently available vaccines are not optimal in addressing the unmet need as each year many people are infected, hospitalized and die, resulting in tremendous economic and public health impact.
In part, this is because the flu vaccine development cycle is inefficient and even when current seasonal vaccine strains match circulating strains well, they typically confer only 40-to-60 percent protection.

Potential advantages of the mRNA platform include shortened timelines to enable a quicker response each season, improved strain matching, faster and more reliable manufacturing and broader immune responses from both antibodies and T cells, the latter needed particularly in older adults.

[Slide 26: Quadrivalent modRNA Flu Vaccine Candidate: Phase 2 Study]

Based on our experience with COVID-19, T cell responses appear to be critical for protection against severe disease and hospitalization in infectious disease.

Here we show Phase 2 T cell data for our quadrivalent modRNA flu vaccine candidate in subjects 65 and older. We believe this is the first evidence of a flu vaccine candidate inducing substantial responses for both CD4 and CD8 T cells.

On the left, at day seven the CD4 T cell response was more than two-fold for all four flu strains for our vaccine compared to a current high dose vaccine now recommended in the U.S. for adults 65 and older.

Over half of the cohort receiving our vaccine candidate had a more than two-fold response.

On the right, at day seven the CD8 T cell response and responder rates were greater for all four strains for our vaccine candidate versus the comparator.

Our belief is that these encouraging T cell responses, combined with higher seroconversion rates for A strains—which are the most predominant circulating strains and have pandemic potential—may translate into improved efficacy over current seasonal flu vaccines, particularly in those 65 and older.

Based on these data, we plan to initiate a Phase 3 efficacy study this year.

[Slide 27: PF-07081532: Potential Best-In-Class Once-Daily Oral GLP-1 Profile]

We’re excited to share that new data on our oral GLP-1 receptor agonists—two abstracts on twice-daily danuglipron and one on our once-daily candidate known as 1532—have been accepted for the European Association for the Study of Diabetes meeting in September.

These investigational medicines were designed in-house by Pfizer’s innovative chemistry and discovery teams.

In a Phase 1 study in adults with Type 2 diabetes, after only six weeks of treatment, 1532 robustly reduced Mean Daily Glucose to almost near-normal levels.

Participants also experienced weight loss of up to 5 kilograms, compared with 2 kilograms for placebo.
We believe this to be a potentially best-in-class profile across both injectables and orals.

Similar changes in body weight were observed in participants with non-diabetic obesity.

1532 is characterized by favorable once-daily pharmacokinetics, a low risk for drug-drug interactions, robust efficacy across multiple metabolic endpoints, and GLP-1 receptor agonist class-like tolerability which overall encouraged us to plan for a phase 2 study to pick the winning candidate prior to a potential phase 3 study start.

These development programs may lead to potential indications in Type 2 diabetes, obesity, NASH and cardiovascular risk reduction in Type 2 diabetes and obesity.

[Slide 28: Anti-IFN-β: Potential to Address Key Driver of Autoimmunity]

Over the past 12 months, we have built a strong Inflammation & Immunology portfolio with diverse products to help address multiple drivers of disease and unmet need.

CIBINQO was approved for atopic dermatitis in adults and last week received priority review designation in the U.S. for adolescents 12 to 18 years. We are nearing a regulatory submission for etrasimod in ulcerative colitis. We have submitted regulatory applications in the U.S., Europe and UK for ritlecinitib for alopecia areata and are awaiting acceptances. We also plan to start a Phase 3 study of ritlecinitib in vitiligo this year.

We are pleased to now share promising new updated data from our anti-Interferon beta monoclonal antibody in specialized rheumatology.

Patients with dermatomyositis show elevated Type I Interferon gene signature in blood, skin and muscle, correlating with disease activity in skin.

As we continue our development of this candidate—a potential breakthrough therapy for hard-to-treat dermatomyositis which attacks the skin and muscles—we believe it may have the ability to address a broader set of inflammatory autoimmune diseases, possibly including polymyositis and lupus.

On our third quarter 2021 call, I shared data from our ongoing Phase 2 dermatomyositis study, focused on skin inflammation and showing significant reduction in disease activity when compared with placebo in just three months of treatment.

[Slide 29: Anti-IFN-β: Updated Phase 2 Dermatomyositis Positive Data]

Both doses met the primary efficacy endpoint in skin predominant disease.

The disease also manifests with progressively debilitating muscle weakness and fatigue.
Early data suggest that in a small cohort of patients with muscle predominant disease, our candidate resulted in numerically better efficacy scores across all key muscle endpoints—including patient-reported outcomes—after three weeks.

We plan to submit the data for presentation once the study completes.

[Slide 30: Follow-up Phase 1 MagnetisMM Trial of elranatamab for MM]

Now, a promising update on elranatamab, our investigational B-cell maturation antigen CD3-targeted bispecific antibody.

At ASCO, we presented data from a Phase 1 trial in people with relapsed/refractory multiple myeloma whose disease is refractory to at least one agent in each of three major classes of medications approved for the disease.

We saw a confirmed overall response rate of 64 percent and 35 percent of patients achieved stringent Complete Response or Complete Response.

More than half who received prior BCMA-directed therapy, such as an antibody-drug conjugate or chimeric antigen receptor T-cell therapy, achieved a response.

Responders’ probability of being event free at nine months was 77 percent.

[Slide 31: Follow-up Phase 1 MagnetisMM Trial of elranatamab for MM]

Elranatamab elicited durable Minimal Residual Disease or MRD negativity—meaning no disease was detected after treatment—in all evaluable patients who experienced a Complete Response or stringent Complete Response.

Molecular responses were durable as well, with 62 percent of those complete responders documented to have MRD negativity at more than six months, including two patients who were MRD negative beyond 18 months.

MagnetisMM-1 results, and emerging data from MagnetisMM-3—which is studying triple-class refractory multiple myeloma—support further development across a broader program with potential registration-enabling studies MagnetisMM-5 in patients with double-class exposed multiple myeloma and MagnetisMM-7 in newly diagnosed post-transplant patients with multiple myeloma.

There is potential for deep and durable results that can be broadly accessible to patients due to off-the-shelf, subcutaneous, and convenient dosing.
The efficacy and safety profile we have seen to date in a challenging patient population supports advancement into earlier lines of treatment.

[Slide 32: Select 2022 Milestones]

Finally, here is a snapshot of select milestones for this year, showing healthy progress in the pipeline.

It was an important quarter for COVID execution, and we look forward to sharing complete readouts from anti-Interferon Beta and the modFlu candidate before the end of the year.

Thank you for your attention. Let me turn it over to Dave.


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

[Slide 34: Generating Significant Free Cash Flow]

Thank you, Mikael and good morning, everyone.

As this is my first call as CFO, I thought I would set the stage for the next chapter of Pfizer, and our relentless focus on creating long term shareholder value. Over the past few years, Pfizer’s cash generation capabilities have expanded significantly, and the efficient deployment of this capital is more critical than ever. It’s clear to me the company is uniquely positioned for growth, and at the same time, enhancing financial returns.

[Slide 35: Efficient Capital Deployment Focused on Three Pillars: 2019-2021]

As we look to the future of the company, we are focused on three primary areas to drive significant shareholder value.

First and foremost is our continued emphasis and investment in science and innovation. We are investing internally and externally to create breakthrough medicines, deploying more than $50 billion in this area in the past three years alone.

Our second priority is maintaining and growing Pfizer’s dividend, paying out more than $25 billion to shareholders over this period. We recognize that our dividend represents an important component of returns for our investors.

And finally, from time to time, we will return capital to shareholders through value-enhancing share repurchases. Over the past 3 years, the company has allocated nearly $9 billion in this area.
Clearly, maximizing shareholder value will be a major focus and I believe all three areas will contribute to our success.

[Slide 36: Efficient Capital Deployment Focused on Three Pillars: YTD 2022]

More recently, in year to date, we deployed more than $12 billion into innovation, paid dividends of $4.5 billion, and repurchased $2 billion of our shares. This demonstrates an on-going commitment to our robust capital deployment framework.

[Slide 37: Quarterly Income Statement Highlights]

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

Turning to the income statement. Revenues increased 53% operationally in the second quarter of 2022. These results were driven by momentum in Paxlovid sales and strong sales of the COVID-19 vaccine; and underlying strength from a number of our key products.

Excluding Comirnaty and Paxlovid, Biopharma product revenues grew operationally by 2% compared to the prior year. In-line products, Xeljanz and Chantix, were impacted by labelling changes and a global pause in shipments, respectively. Ibrance continued to transition into a new COVID normal market environment. PC1, our contract manufacturing business, grew 89% operationally in the second quarter 2021, and therefore faced a tough comparison versus last year, with PC1 declining by 25% operationally. Bringing that together, Pfizer's non-COVID-related revenues grew by 1% operationally in the quarter.

Adjusted cost of sales dollars grew more slowly than revenues, resulting in gross margin rate expansion of 570 basis points vs. the second quarter of last year. This improvement in gross margin is largely attributable to the impact of higher-margin Paxlovid sales; partially offset by higher COVID-19 vaccine sales; and the impact of a $450 million write-off of COVID-related inventory that had expired or are expected to expire. Given the unpredictable nature of the virus, we chose to manufacture and hold excess stock to ensure we could meet global health demand for products if an extreme need were to arise.

Adjusted SI&A expenses in the second quarter grew by 7% operationally. The increase was primarily driven by spending for Comirnaty and Paxlovid, and higher healthcare reform fees.

The 27% operational increase in Adjusted R&D expense in Q2 was primarily driven by investments in multiple late-stage clinical programs, including programs to prevent and treat COVID-19, and costs to develop recently-acquired programs.

The effective tax rate on adjusted income in the quarter of 15.4% declined by 170 bps vs last year, as driven by a favorable jurisdictional mix of earnings.
As a result, reported diluted EPS of $1.73 grew by +77%, while Adjusted diluted EPS of $2.04 grew 92%; on operational basis Adjusted diluted EPS grew +100% in the quarter.

Foreign exchange movements continue to dampen our results; negatively impacting revenues and Adjusted EPS by 7% or $0.08 a share.

[Slide 38: 2022 Financial Guidance: Revenues and Adjusted Diluted EPS]

Let’s move to our updated 2022 guidance.

Given our strong second quarter performance and our improving outlook for the year, we are increasing our operational expectations for both revenues and Adjusted EPS. For the full year, we are increasing our operational revenue expectations by ~$2 billion, and operational adjusted diluted EPS expectations by $0.24.

Unfortunately, given additional U.S. dollar strengthening since we last updated guidance in early May, foreign exchange negatively impacts revenues by (~$2 billion), leaving our reported revenue guidance range unchanged at $98.0 to $102.0 billion. This represents an operational growth rate of 29% at the mid-point compared to 2021, a 200 basis point improvement over prior expectations.

The improvement in our operational adjusted diluted EPS outlook of $0.24 is also negatively impacted by foreign exchange movements, compressing EPS by ($0.19). The net impact of these cross currents allows the company to raise the low-end of its adjusted EPS outlook by 5 cents to $6.30 - $6.45. This represents 65% operational growth at the midpoint compared to 2021.

Regarding our COVID-19-related revenues, we continue to expect the vaccine revenue for the year to be approximately $32 billion, unchanged compared to our prior guidance provided on May 3, despite the impact of ~$1 billion of incremental negative foreign exchange. For Paxlovid, we expect sales of approximately $22 billion, keeping the guidance unchanged, despite an incremental ~$300 million headwind due to foreign exchange. Our non-COVID-related revenues are absorbing approximately $700 million of impact from negative foreign exchange.


Given the seasonality that we expect, I would also like to give you some color on the expected phasing of these COVID-related revenues across the second half. Based on current guidance for Comirnaty, we expect approximately 25% of second half sales in Q3 and 75% of sales in Q4, driven by expected deliveries of Omicron-adapted vaccines in Q4, again subject to regulatory approval. Conversely for Paxlovid, we expect approximately 60% of sales in Q3 and 40% in Q4.
So, with that, let me give you some detail on changes in our cost and expense guidance.

We are decreasing our expected adjusted SI&A spend by $300 million across the range to $12.2 to $13.2 Billion.

Additionally, we are also increasing our guidance for adjusted R&D expense by $500 million at the low-end only, with the new range of $11.5 to $12.0 Billion, reflecting incremental investments in multiple programs, including mRNA vaccine programs outside of COVID-19 and other programs.

We are also slightly reducing our expected effective tax rate on adjusted income by 50 basis points to Approximately 15.5%.

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

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

With that, let me turn it over to Chris to start the Q&A session.
risks and uncertainties. You can identify these statements by the fact that they use future dates or use words such as “will,” “may,” “could,” “likely,” “ongoing,” “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “assume,” “target,” “forecast,” “guidance,” “goal,” “objective,” “aim,” “seek,” “potential,” “hope” and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially from past results and future plans and projected future results are the following:

Risks Related to Our Business, Industry and Operations, and Business Development:

- the outcome of research and development (R&D) activities, including, the ability to meet anticipated pre-clinical or clinical endpoints, commencement and/or completion dates for our pre-clinical or clinical trials, regulatory submission dates, and/or regulatory approval and/or launch dates; the possibility of unfavorable pre-clinical and clinical trial results, including the possibility of unfavorable new pre-clinical or clinical data and further analyses of existing pre-clinical or clinical data; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; and whether and when additional data from our pipeline programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations;
- our ability to successfully address comments received from regulatory authorities such as the U.S. Food and Drug Administration or the European Medicines Agency, or obtain approval for new products and indications from regulators on a timely basis or at all; regulatory decisions impacting labeling, including the scope of indicated patient populations, product dosage, manufacturing processes, safety and/or other matters, including decisions relating to emerging developments regarding potential product impurities; the impact of recommendations by technical or advisory committees; and the timing of pricing approvals and product launches;
- claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates, including claims and concerns that may arise from the outcome of post-approval clinical trials, which could impact marketing approval, product labeling, and/or availability or commercial potential, including uncertainties regarding the commercial or other impact of the results of the Xeljanz ORAL Surveillance (A3921133) study or actions by regulatory authorities based on analysis of ORAL Surveillance or other data, including on other Janus kinase (JAK) inhibitors in our portfolio;
- the success and impact of external business-development activities, including the ability to identify and execute on potential business development opportunities; the ability to satisfy the conditions to closing of announced transactions in the anticipated time frame or at all; the ability to realize the anticipated benefits of any such transactions in the anticipated time frame or at all; the potential need for and impact of additional equity or debt financing to pursue these opportunities, which could result in increased leverage and/or a downgrade of our credit ratings; challenges integrating the
businesses and operations; disruption to business and operations relationships; risks related to growing revenues for certain acquired products; significant transaction costs; and unknown liabilities;

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

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

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

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

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

• trends toward managed care and healthcare cost containment, and our ability to obtain or maintain timely or adequate pricing or favorable formulary placement for our products;
• interest rate and foreign currency exchange rate fluctuations, including the impact of possible currency devaluations in countries experiencing high inflation rates;
• any significant issues involving our largest wholesale distributors or government customers, which account for a substantial portion of our revenues;
• the impact of the increased presence of counterfeit medicines or vaccines in the pharmaceutical supply chain;
• any significant issues related to the outsourcing of certain operational and staff functions to third parties; and any significant issues related to our joint ventures and other third-party business arrangements;
• uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, uncertainties related to the impact on us, our customers, suppliers and lenders and counterparties to our foreign-exchange and interest-rate agreements of challenging global economic conditions, such as inflation, and recent and possible future changes in global financial markets;
• any changes in business, political and economic conditions due to actual or threatened terrorist activity, civil unrest or military action;
• the impact of product recalls, withdrawals and other unusual items, including uncertainties related to regulator-directed risk evaluations and assessments, including our ongoing evaluation of our product portfolio for the potential presence or formation of nitrosamines;
• trade buying patterns;
• the risk of an impairment charge related to our intangible assets, goodwill or equity-method investments;
• the impact of, and risks and uncertainties related to, restructurings and internal reorganizations, as well as any other corporate strategic initiatives, and cost-reduction and productivity initiatives, each of which requires upfront costs but may fail to yield anticipated benefits and may result in unexpected costs or organizational disruption;

Risks Related to Government Regulation and Legal Proceedings:

• the impact of any U.S. healthcare reform or legislation or any significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health programs or changes in the tax treatment of employer-sponsored health insurance that may be implemented;
• U.S. federal or state legislation or regulatory action and/or policy efforts affecting, among other things, pharmaceutical product pricing, intellectual property, reimbursement or access or restrictions on U.S. direct-to-consumer advertising; limitations on interactions with healthcare professionals and other industry stakeholders; as well as pricing pressures for our products as a result of highly competitive insurance markets;
• legislation or regulatory action in markets outside of the U.S., including China, affecting pharmaceutical product pricing, intellectual property, reimbursement or access, including, in particular, continued government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs in those markets;
• the exposure of our operations globally to possible capital and exchange controls, economic conditions, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, as well as the impact of political unrest or civil unrest or military action, including the ongoing conflict between Russia and Ukraine and the continued economic consequences, unstable governments and legal systems and inter-governmental disputes;
• legal defense costs, insurance expenses, settlement costs and contingencies, including those related to actual or alleged environmental contamination;
• the risk and impact of an adverse decision or settlement and the adequacy of reserves related to legal proceedings;
• the risk and impact of tax related litigation;
• governmental laws and regulations affecting our operations, including, without limitation, 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 or other malfeasance by third parties, including, but not
  limited to, nation states, employees, business partners or others;
- the risk that our currently pending or future patent applications may not be granted on a timely basis
  or at all, or any patent-term extensions that we seek may not be granted on a timely basis, if at all; and
- our ability to protect our patents and other intellectual property, such as against claims of invalidity
  that could result in loss of exclusivity, including challenges faced by our collaboration or licensing
  partners to the validity of their patent rights, 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

We cannot guarantee that any forward-looking statement will be realized. Should known or unknown risks
or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary
materially from past results and those anticipated, estimated or projected. Investors are cautioned not to
put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and
other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31,
2021 and in our subsequent reports on Form 10-Q, in each case including in the sections thereof captioned
“Forward-Looking Information and Factors That May Affect Future Results” and “Item 1A. Risk Factors,”
and in our subsequent reports on Form 8-K.

These prepared remarks include discussion of certain financial measures that were not prepared in
accordance with generally accepted accounting principles (GAAP). Reconciliations of those non-GAAP
financial measures to the most directly comparable GAAP financial measures can be found in the
Company’s Current Report on Form 8-K dated July 28, 2022 and the Company’s earnings presentation for

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

Paxlovid and emergency uses of the Pfizer-BioNTech COVID-19 Vaccine 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 6 months of age and older. Comirnaty is licensed by the FDA for individuals 12 years of age and older. In addition, Comirnaty is under EUA for individuals 6 months of age and older, a third dose for certain immunocompromised individuals 5 years of age and older, a booster dose for individuals 5 years of age and older, and a second booster dose for individuals 50 years of age and older and for certain immunocompromised 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.

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