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PFE.N - Q2 2022 Pfizer Inc Earnings Call

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OVERVIEW:

PFE reported 2Q22 revenues of \$27.7b and adjusted diluted EPS of \$2.04. 2Q22 reported diluted EPS was \$1.73. Expects 2022 revenue of \$98-102b and adjusted diluted EPS of \$6.30-6.45.

CORPORATE PARTICIPANTS

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Albert Bourla *Pfizer Inc. - Chairman of the Board & CEO*
Angela Hwang *Pfizer Inc. - Group President of Biopharmaceuticals Group*
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David M. Denton *Pfizer Inc. - CFO, Executive VP*
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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Second Quarter 2022 Earnings Conference Call. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chris Stevo, Senior Vice President and Chief Investor Relations Officer. Please go ahead, sir.

Christopher J. Stevo - Pfizer Inc. - Senior VP & Chief IR Officer

Thank you, Chelsea. Good morning, everyone. Welcome to Pfizer's Second Quarter Earnings Call. We anticipate that this call will last 90 minutes. I'm joined today by Dr. Albert Bourla, our Chairman and CEO; Dave Denton, our CFO; and Mikael Dolsten, President of Worldwide Research & Development and Medical. Joining for the Q&A session, we will also have Angela Hwang, Group President, Pfizer Biopharmaceuticals Group; Aamir Malik, our Chief Business Innovation Officer; William Pao, our Chief Development Officer; and Doug Lankler, our General Counsel.

The materials of this call and other earnings-related materials are on the Investor Relations section of pfizer.com. Please see our forward-looking statements disclaimer on Slide 3. And additional information regarding these statements and our non-GAAP financial measures is available in our earnings release and in our SEC Forms 10-K and 10-Q under Risk Factors and Forward-Looking Statements. Forward-looking statements on the call are subject to substantial risks and uncertainties, speak only as of the call's original date, and we undertake no obligation to update or revise any of the statements.

With that, I will turn the call over to Albert.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Chris. Hello, everyone. I'm proud to say that Pfizer continued to deliver strong operational performance in the second quarter and has increased its full year 2022 operational financial forecast for revenue and Adjusted diluted earnings per share, 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 including PAXLOVID, COMIRNATY, ELIQUIS and VYNDAREL/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 of this while also taking steps to help address broader issues impacting global health, including climate change, equitable access and the war in Ukraine.

So where do we go from here? After 2.5 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 health care 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' severity.

This is a scenario no one wants to imagine, but one for which we need to be prepared. And that's why we're doing all these investments. That's why also it is critical that Pfizer continues to invest in the research and development of COVID-19 vaccines and treatments. With this context as a backdrop, let me provide an update on our current COVID-19 offerings and then continue with other products.

I will start with COMIRNATY. Today, we have shipped more than 3.6 billion doses of our vaccine in 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 have increased from 52% in January of this year to 63% in July of this year. In developed markets, our share has increased from 59% to 68% over the same time period.

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 on the safety, tolerability and immunogenicity for the company's 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 and Drug Administration 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 this fall for rollout in the U.S., subject, of course, 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.

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 have 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 6 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.

As you can see on this slide, we have seen a nearly fivefold increase in PAXLOVID utilizations 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 are also continuing to work with states to educate consumers, health care 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 the 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.

For international developed markets, we are seeing significant increases in usage across many markets, reflecting the recent wave of BA.4/5 and the resulting increases in hospitalization, 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 people. 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 shares 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 performance 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 Pevnar 20 for adults. Second quarter U.S. revenues for our Pevnar family of vaccines for adults were up 337% operationally compared with the prior year quarter to \$431 million with Pevnar 20 representing more than 3/4 of the total adult revenue.

The great majority of U.S. health care networks, IDNs and retailers who have made formulary decisions have chosen Pevnar 20 alone as their higher valency pneumococcal vaccine of choice to help protect adults. This has resulted in Pevnar 20 having a 97% market share. This is also the first time there's been a routine recommendation for Pevnar for people in the 19 to 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 Pevnar 20 being the only vaccine that can help protect patients with one dose in one visit is 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, 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'm 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 with 100 Rwandan medical professionals to discuss efficacy, safety and dosing of this milestone. This is just the first step of accord's implementation, but an important one that will impact many lives.

We also recently announced our commitment to achieve the Net-Zero Standard across our value chain by year 2040. This is 10 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 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 8 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.

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 for 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.

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

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

I've appointed Annaliesa Anderson to lead Vaccine Research & Development, succeeding Kathrin Jansen, who previously announced her retirement. With more than 2 decades of biopharma R&D experience, Liesa most recently served as CSO for Bacterial Research and Hospital. Over the last 2 years, she has led a 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 CSO 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 antiviral strategies with additional efforts in antibacterial and antifungal 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 continuously 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.

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, 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.

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 to 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.

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 non-inferiority, and neutralization activity which increased substantially. The BA.1 vaccine neutralized wild-type and Delta similarly to the current version of the vaccine, suggesting that Omicron-modified version maintained response for the ancestral and other viral variants.

Based on these data and following guidance from regulators, we have completed regulatory submissions in Europe, U.K. and Canada for the 30-microgram bivalent vaccine individuals 12 and older and plan submissions in other markets soon. The data also showed this vaccine candidate neutralized Omicron BA.4 and 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.

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 vaccine. 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.

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've 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 FDA.

We aspire to continue leading with the science and are working to identify vaccines that would 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 1 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 pre-fusion spike proteins for the SARS-CoV-2 ancestral strain and an Omicron variant. The enhanced spike protein encoded from the mRNA 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 potential pan-SARS-CoV-2 vaccine 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 variants.

Now turning to PAXLOVID. Last month, we submitted a new drug application to 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 and 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're working with 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.

Turning now 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 public health and economic impact. In part, this is because the flu vaccine development cycle is inefficient. And even when the current seasonal vaccine strains match circulating strains well, they typically confer only 40% to 60% protection. Potential advantages of the mRNA platform include: shortened timeline to enable a quicker response each season; improved strain matching; faster and more reliable manufacturing; and broader immune response from both antibody and T cells, the latter needed particularly in older adults.

Based on our experience with COVID-19, T cell responses appear to be critical for the protection against severe disease and hospitalization in infectious viral disease. Here, we show Phase 2 T cell data for our quadrivalent modRNA flu vaccine candidates 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 7, the CD4 T cell response was more than twofold for all 4 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 twofold response. On the right, at day 7, the CD8 T cell response and responder rates were greater for all 4 strains for our vaccine candidate versus the comparator.

Our belief is that these encouraging T cell responses, combined with higher seroconversion rates for flu 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 the Phase 3 efficacy study this year.

We are 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 Conference in September. These investigational medicines were decided in-house by Pfizer's innovative chemistry and discovery teams.

In a Phase 1 study in adults with type 2 diabetes, after only 6 weeks of treatment, 1532 drug 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 nondiabetic obesity.

1532 is characterized by favorable once-daily pharmacokinetics, low risk for drug-drug interaction, 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 patients.

Over the 12 past 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 U.S. for adolescents 12 to 18 years. We are nearing a regulatory submission for etrasimod in ulcerative colitis. We have submitted regulatory application in U.S., Europe and U.K. for ritlicitinib for alopecia areata and are awaiting acceptances. We also plan to start a Phase 3 study of ritlicitinib 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 these candidates, a potential breakthrough therapy for hard-to-treat dermatomyositis which attacks 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 3 months of treatment.

Now both doses met the primary efficacy endpoint in skin-predominant disease. The disease also manifests with progressively debilitating muscle weakness and fatigue. Early data suggests 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 3 weeks. We plan to submit the data for presentation once the study completes.

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 the three major classes of medications approved for the disease. We saw a confirmed overall response rate of 64%. And 35% of patients achieved a stringent complete response or complete responses. More than half who received prior BCMA-directed therapy, such as antibody drug conjugate or chimeric antigen receptor T cell therapy, achieved a response. Responders' probability of being event-free at 9 months was 77%.

Elranatamab elicited a 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 60% -- 62% of those complete responders documented to have MRD negativity at more than 6 months, including 2 patients who were MRD-negative beyond the 18 months.

MagnetisMM-1 results and emerging data for MagnetisMM-3, which is studying triple-class refractory multiple myeloma, supports 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.

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 M. Denton - Pfizer Inc. - CFO, Executive VP

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 is clear to me the company is uniquely positioned for both growth and, at the same time, enhancing financial returns. And 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 3 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 that all three areas will contribute to our success.

More recently and year-to-date, we deployed more than \$12 billion into innovation, paid dividends of \$4.5 billion and repurchased \$2 billion worth of our shares. This demonstrates an ongoing commitment to our robust capital deployment framework. With that, 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, strong sales of the COVID-19 vaccine and underlying strength from a number of our key products. Excluding PAXLOVID and COMIRNATY, Biopharma product revenues grew operationally by 2% compared to the prior year.

In-line products, Xeljanz and Chantix were impacted by labeling changes and a global pause and shipments, respectively, while IBRANCE continued to transition into a new COVID normal market environment. PC1, our contract manufacturing business grew 89% operationally in the second quarter of 2021 and therefore faced a tough comparison versus last year with PC1 declining by 25% operationally. And now bringing that all together, Pfizer's non-COVID-related revenues grew by 1% operationally in the second quarter.

Adjusted cost of sales dollars grew more slowly than revenue, resulting in gross margin rate expansion of 570 basis points versus the second quarter of LY. This improvement in gross margin is largely due 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 is expected to expire. Given the unpredictable nature of the virus, we chose to manufacture and hold excess stock to ensure we can meet any 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 PAXLOVID and COMIRNATY and higher health care 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 both prevent and treat COVID-19 and cost to develop recently acquired programs.

The effective tax rate on Adjusted income in the quarter of 15.4% declined by 170 basis points versus last year driven by a favorable jurisdictional mix of earnings. And as a result, reported diluted earnings per share of \$1.73 grew by 77% while Adjusted diluted earnings per share of \$2.04 grew 92%. And on an operational basis, Adjusted diluted earnings per share grew 100% in the quarter. Foreign exchange movements continue to dampen our results negatively impacting revenues and adjusted earnings per share by 7% and \$0.08 per share.

So with that, let's move on to our 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 earnings per share. For the full year, we are increasing our operational revenue expectations by \$2 billion and operational Adjusted diluted earnings per share 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 approximately \$2 billion, leaving our reported revenue guidance range unchanged at \$98 billion to \$102 billion. This represents an operational growth rate of 29% at the midpoint compared to 2021, a 200 basis point improvement over prior expectations.

The improvement in our operational Adjusted diluted earnings per share 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 earnings per share outlook by \$0.05 to \$6.30 to \$6.45 a share. 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 the prior guidance provided on May 3, despite the impact of approximately \$1 billion of incremental negative foreign exchange. For PAXLOVID, we expect sales of approximately \$22 billion, keeping the guidance unchanged, again despite an incremental \$300 million headwind due to FX. Our non-COVID-related revenues are absorbing approximately \$700 million of impact from negative foreign exchange.

Now given the seasonality that we expect, I'd also like to give you some color on the expected cadence 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 billion 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 billion to \$12 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 that we completed in March of 2022.

So 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. And so with that, I'll now turn it over to Chris and start the Q&A session.

Christopher J. Stevo - Pfizer Inc. - Senior VP & Chief IR Officer

Thanks, Dave. At this time, let's start the Q&A session. (Operator Instructions) If you have remaining questions afterwards, the IR team will be available to answer those questions for you as well. Chelsea, if you could queue up the callers, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first questions come from the line of Carter Gould from Barclays.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Appreciate all the disclosures there at the end. But I wanted to follow up on the COMIRNATY guide again. Obviously, you had some incremental contracts that got signed since the last time you gave guidance. You highlighted sort of the FX headwind. So I guess, trying to tease out exactly kind of explicitly kind of what you're assuming around potentially, I guess, EU doses getting pushed into 2023 and just some additional color there, if you can, please.

David M. Denton - Pfizer Inc. - CFO, Executive VP

Carter, this is Dave. Thank you for the question. Let me walk you through the guidance for this year from a vaccine perspective. As you well know, we had a guidance of \$32 billion to begin with as we entered -- come out of Q1. There's really three moving parts as I think about our guidance for the year. One is we do have an incremental contract from the USG for 105 million doses this year, which is an uptick to that guidance. Secondly, we're experiencing headwinds from an FX perspective to the tune of \$1 billion since Q1, but for the year, really \$2 billion in that product alone.

And then third, as I just articulated, the cadence of deliveries in the back half is really skewed to Q4. And with that, some ex-U.S. deliveries could move from November into December of the calendar year. And if that were to occur, given our 1-month lag from a reporting perspective, that would fall -- those revenues would fall into Q1 of 2023. I do not know whether that's going to happen, but I'm planning that it might happen. So therefore, I'm probably being conservative in my approach in my outlook to the revenue guide for that specific medicine.

Operator

Your next questions come from the line of Robyn Karnauskas with Truist Securities.

Robyn Kay Shelton Karnauskas - Truist Securities, Inc., Research Division - Research Analyst

I guess, mine is on PAXLOVID. And maybe you could talk a little bit about -- I know there -- while you said there's low rates in line with clinical trials for rebounding, maybe that's under-reported and you outlined your plan for new trials. What are you doing in potentially decreasing that potential

for rebounding in the new studies? Are you extending and doubling the dose? And maybe some trends, help us -- give us more color on some trends that you're seeing on PAXLOVID. I know you mentioned globally. We're hearing in some states, it's more limited versus others. Maybe just give us some more color there on trends you're seeing on access.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. William, why don't you speak a little bit about the program that we have about rebounding. And then Angela, you speak a little bit about the trend of the revenues and the uptake.

William Pao - Pfizer Inc. - Chief Development Officer, Executive VP

Sure. Thanks, Albert, and thanks for the question. So as we reported earlier in the EPIC-HR study, we did see single-digit percent of potential rebound. But we also saw it in the placebo arm with a very similar rate. Since then, we have seen other studies coming out, including from the Mayo Clinic, Case Western, Kaiser Permanente and others showing data that's very consistent with ours in terms of single-digit percent of rebound. And it's also been seen not only with placebo but also with competitor antivirals. And internally, we also have data from real-world data as well as additional pharmacovigilance data showing again that it's a very similar low percentage rate of recurrence.

That said though, we are working with the FDA to finalize plans for a trial in which we would treat such patients. And we're still deciding on the final outline of that. And in addition, as Mikael outlined, we'll be looking at other cohorts of patients, for example, immunocompromised patients who have a large unmet medical need. And in that setting, we will be looking at, for example, 5, 10 and 15 days of dosing to determine the optimum dose regimen for those patients.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, William. And I need to say that we are very serious about PAXLOVID, and we are looking very diligently all the anecdotal reports that are coming. But all the data, I repeat all the data, our internal data that we are detecting rebounds by proactively checking viral loads or the external data that have been reported through pharmacovigilance to us or through studies that have been performed by third parties, very reputable third parties like Kaiser Permanente or Mayo Clinic, they are consistent that this is low single digit, actually less than 1% in the external studies. And it was, as we repeated, around 2% in the methodology we used in ours and very consistent with the numbers of the placebo. So although we try to see if there is a need to do something about it, seriously we can't find any data set other than anecdotal reports.

Also, I want to emphasize that even the anecdotal reports, they are all indicating that it is mild. So we don't have any rebound that it is more serious, right? And clearly, we haven't identified any single case that we have resistance to the PAXLOVID. So we are looking into it, and William said that we are going to run also some studies. We are discussing our protocols with FDA to see if retreatment of those cases could help. But so far, our conclusion, although we are looking a lot, it is very small percentage, similar to COVID placebo or COVID other antivirals and with very mild symptoms. Angela, what about the trends internationally and in the U.S., if you want?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

So globally, I think that we're doing really well and making excellent progress. We have made and manufactured 30 million doses. And we've delivered 23.5 million of those doses. So I think that the contracting is going well, the demand and expectations for the need for PAXLOVID is definitely up there. But maybe let me use some U.S. examples, where things are -- where we have a little bit more data and where things that I think are going particularly well.

The U.S. actually contracted 10.8 million doses with us so far and 7.4 million doses of all of those have already been allocated to all the states. So I think that gives you a sense of how much demand is coming in from all of the states. And then every single week, our utilization of PAXLOVID has

also increased. In fact, most recently, we hit an all-time high of 389,000 doses of PAXLOVID that were used just in 1 week. So that gives you a sense of sort of the increase and the momentum.

What's really driving this is obviously the education and the familiarity and the experience now of physicians as well as patients but also the excellent work that is being done at the federal as well as the state level -- at the state level in terms of education and utilization. And I want to call out, in particular, the Test to Treat program that I think has been particularly effective and very positive. To date, more than 41,000 pharmacies are now Test to Treat centers. And that means that, that just gives access to a tremendous amount of the population to be able to access PAXLOVID.

And also recently, pharmacists are now able to prescribe PAXLOVID within certain limitations. And over and above whatever states and the federal government are doing, Pfizer is also aggressively and assertively supporting education. So actually, we have leveraged the entire Pfizer field force to provide education. We're running webinars. And to-date, we've reached over 300,000 health care professionals as well as 80,000 pharmacists, just to give you a sense of the extent and the breadth of reach that we have accomplished.

I mean, all of that, also complemented by public service announcements about driving awareness of the treatment but also the individual risk that each patient could carry and making them aware that they could be a potential candidate for PAXLOVID. So I think with all of these efforts that have gone on and that we are continuing, we feel really good about the momentum of PAXLOVID, the utilization of PAXLOVID and the benefit that PAXLOVID can bring, particularly in a time when there's surges going on around the entire world.

Operator

Your next questions come from the line of Terence Flynn with Morgan Stanley.

Terence C. Flynn - Morgan Stanley, Research Division - Equity Analyst

I had a two-part one on your mRNA seasonal flu vaccine program. I was just wondering if you had any HAI titer data that you can share from the trial. We saw the T cell data. But again, I'm wondering if there's any titer data you can share. And then anything on the safety and tolerability there? Is it fair to assume that the profile is similar to COMIRNATY? Or are there any particular differences you'd like to call out?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you very much, Terence. So Mikael, why don't you take this question?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. We will share details in upcoming conference. But I can just give a little bit more color. As you know, the highest medical burden and hospitalization occurs in the 65-plus, where the A strains are the most dominant. We had very strong titers against the A strains and exceeding what you would see with the current recommended vaccines. So we are very bullish about our ability with mRNA to induce both strong antibody response and CD4/CD8 T cells, which are not in used by current standard of care.

And this is the reason why we are sharing today that we're announcing two Phase 3 studies. Tolerability -- sorry. Tolerability of this 30-microgram -- sorry, Terence, I didn't note that first. Tolerability is, of course, supported by our billions of doses of the platform in COVID. And on top of that, in older adults, the 30-microgram have a very good acceptance, the main patient group. And I believe it's going to be excellent and very similar to other available flu vaccines.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. And also, Mikael, you spoke about A. You didn't speak about the B strains in the immunogenicity results. They were similar to the current high dose of quadrivalent.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. I didn't mention the B strains. We noted in general, a lower response to B strains with both standard of care. And we hedged on the lower side with our vaccine. That's why I was so encouraged to see the unique T cell response against the B cell strain. And the totality of that data make us encouraged that we will have a strong product for both A and B.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

And then I think how confident we feel it is that although the regulatory pathway, it is just demonstrate non-inferiority in immunogenicity, we are going for an efficacy trial. So the trial that is -- we announced yesterday is going to measure real efficacy in flu, which we believe that we expect -- of course, science is unpredictable, but we expect to win with flying colors.

Operator

Your next question comes from the line of Umer Raffat with Evercore ISI.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

I had a question and a clarification. The question is on PAXLOVID. I know the Test to Treat program from the Biden administration has been a big driver of volumes. And my question is how would the demand dynamics change when we transition to a commercial purchasing model? And let's say the Test to Treat is still in place, would there be any change or not?

And my clarification is, Mikael, I think some comments you might have made at a recent non-transcripted meeting on the TL1A program and whether there's been a signal consistent across the Phase 2a and Phase 2b. Could you please clarify that? And I'm referring to the interim announcements that happened recently.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. Angela, what do you think? If we go to open commercial market, do you think that we will be better or worse off with PAXLOVID?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

So I think that there are elements that we will be able to implement in the commercial market that currently that we don't. So for sure, you've just heard me share comments about the efforts that we've put into PAXLOVID already here in the U.S. and ex U.S., right, the execution and the support of education, support of our entire field forces, support of retail, support of patients through education again and PSAs. All that will continue.

But I think what happens in a full commercial launch is that you will have multiple distributors and multiple points of distribution throughout the entire country. You will have stocking by every pharmacy and pharmacists and various points of use. And so I think that in a commercial setting, actually you'll be able to reach a much broader set of channels that we currently even do today. So I think that's one difference.

I think the second difference is that what you can do from a commercial perspective will also look different. Remember today, we're under an EUA. And while we can do a lot of education, key things like sampling cannot be done in an EUA. So that's going to be an example of another difference

that will happen post EUA. And then I think, finally, even if you think about consumer education, today, we've really limited ourselves to unbranded in sort of disease awareness education.

But again, in a commercial setting, you could support through branded education and talk a lot more about the product. And so all of these are things that actually Pfizer does and the commercial organization of Pfizer does really well. This is our sweet spot. So I think that we look forward to building on top of what the government has been doing, which has been really excellent, and building on top of that to do more and to support greater initiatives across the country.

Albert Bourla - *Pfizer Inc. - Chairman of the Board & CEO*

Thank you, Angela, well said. What about TL1A, Mikael?

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

Briefly, this is our internally discovered antibody against TL1A, remember the TNF super family that is associated with inflammatory diseases. Yes, we have consistent, robust efficacy for all-comer UC patients and very strong efficacy, consistent across the trial, for prospectively defined precision biomarker. Tolerability was very good. Now this is induction data. And later this year, we will have maintenance data. And as we get those dataset, we will decide about next step.

Operator

Your next questions come from the line of Mohit Bansal with Wells Fargo.

Mohit Bansal - *Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst*

And congrats on the early oral GLP-1 data, especially for once-daily. My question is how much incremental data we are going to see in September from the one you presented today? And also, how soon can you move this agent into bigger trials? And how do you see the biggest differentiation versus the oral semaglutide at this point?

Albert Bourla - *Pfizer Inc. - Chairman of the Board & CEO*

Sure. Mikael, maybe also you take that question.

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

Yes. We are very excited about this new dataset, 1532, that you will see at the EASD meeting in Stockholm in September. There will be additional data. And I think you will find Hba1c very encouraging, although this was a short study. I think compared to oral semaglutide, the differentiation is substantial. This is a true small molecule that can be given, it's a once-a-day, it's completely independent on fasting or meal concordance.

And I think you will be able to reach higher effects on both glucose as well as on weight reduction. As I reported now, we were almost at 100 mg per deciliter reduction over 4 to 6 weeks and 5 kilogram. And we haven't yet optimized the titration to even higher doses. So we are very encouraged of what we see. We're going to share with regulators soon our next trial set and move swiftly to allow us to pick the winner and the regimen for a potential Phase 3 study to come after the Phase 2b.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Mikael. And also to add to that, this is, for us, clearly a high-priority project. We have a designation within the company what we call the Lightspeed Project, project of significant value to patients and, as a result, also significant economic value, where we give this designation. And so we move them with the speed of light. And we overinvest to make sure that we de-risk and we move fast. And I review personally on a biweekly -- on a bimonthly basis the progress of this program. So that is going to be one of them.

Operator

Your next questions come from the line of Evan Seigerman with BMO Capital Markets.

Evan David Seigerman - BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

Congrats on the progress. I would love for your perspective on the provision for Medicare to negotiate directly with manufacturers as a part of the now-coined Inflation Reduction Act that we have press reports reporting a deal between Manchin and Schumer. Well, kind of what's the potential long-term impact on your R&D and innovation?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. I'm disappointed with what I'm reading in the newspapers. Of course, we can't know exactly what will happen because we have seen that this situation is very volatile. But everything that they are reporting, they are going to implement a price setting. In reality, it's not a price negotiation because they are forcing their will by implementing a 95% tax according to previous guidance. That will cause the industry significant. We estimate \$270 billion over 10 years. There is a positive provision there that they are reducing the out-of-pocket cost for the patient. That's a significant one, but it's too little and too late.

They could do way more because that will cost 10% of the \$270 billion that they're going to collect. They are basically not doing that to alleviate patients' cost because they could give all the money and then make significant, significant difference to the patient. They're just giving a part of that. And they want even to start it, if I understood well, from year 2025. So although the out-of-pocket is a very positive provision, but the [rest one] is a provision that I think will force the industry to reduce R&D if it goes the way that they are they are suggesting. So other than that, I don't have anything to add. We will wait to see how the -- what exactly in reality that means and we'll go from there.

And also I want to say it is very disappointing that they are choosing to single out one industry. Everything in this bill, from what I understand, tax, all of that, that is affecting everyone. But then there are specific measures to affect only the pharma industry, particularly when we are out of a pandemic, where this industry has proven the value that brings to public health and to the global economy. We would be in a very different point in this global economy if we didn't have the investments in the thriving life sciences sector. And they are choosing to single out this industry. I think it's wrong. And I hope that reason will prevail when these discussions go to Congress.

Operator

Your next questions come from the line of Louise Chen with Cantor Fitzgerald.

Louise Alesandra Chen - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

Just curious if some of the setbacks that we have seen in the CD47 space changed your view on the market opportunity for your Trillium assets.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. Why don't we go to William?

William Pao - Pfizer Inc. - Chief Development Officer, Executive VP

Yes, sure. So thanks for the question, Louise. So we saw the news the other day. Internally, we remain confident in our program with Trillium. And we proceed with the programs that we are planning. And we'll let the data speak for itself when they come out.

Operator

Your next question comes from the line of David Risinger with SVB Securities.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Congratulations on the performance. I wanted to ask a little bit about VYNDAQEL and VYNDAMAX. The performance was below our and consensus expectations. If you could speak to that and also talk about the sequential prospects going forward, i.e., has the product peaked out in the U.S.? And how should we think about future prospects relative to the sales that you booked?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Well, thank you, David. Angela, what do you think?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Well, we continue to be really pleased with how VYNDAQEL is doing. If you look at just from a diagnosis perspective, quarter-over-quarter, year-over-year, we continue to do a really great job of effectively finding and identifying who the ATTR-CM patients are, diagnosing them and then bringing them on to therapies. So in this quarter, we have reached an all-time high of 40% diagnosis rate. And I think that this is well beyond what we thought we would be able to do in the time frame that we have had. So we continue to believe in the growth that this product has.

The real-world data that has been generated now and the overall survival benefits are really compelling. And the fact that we are the only product being able to demonstrate these benefits, I think, speaks well to how we'll continue to be able to build in this market despite competition that will arise. I think what you're referring to in terms of the impact and the expectations really is a one-time effect, and it was in Japan. And this was a very specific price decrease that was planned and driven by regulation.

When VYNDAQEL was launched in Japan, again based on pricing regulation in the country that was specific to the country, it was a much higher price than any other country we had. And so by regulation again, it's the 75% price decrease that we're seeing is a function of that. But the underlying growth of VYNDAQEL in Japan is really strong. We had, just in the first half of 2022, 69% volume growth. We had 32% year-over-year of new patient starts. So hopefully, this gives you a sense that the net revenue impacts you see are, in fact, not a reflection of the demand and the true underlying demand, whether it's in the U.S. or ex U.S.

Operator

Your next question comes from the line of Tim Anderson with Wolfe Research.

Timothy Minton Anderson - Wolfe Research, LLC - MD of Equity Research

A question on your RSV vaccine. There doesn't seem to be anything but a brief mention of the program in the press release or the slides and really nothing in prepared remarks, but we have Phase 3 data results coming out very soon. I'm wondering why.

But really, my main question is why you recently changed the primary endpoint in the Phase 3 trial, including downsizing of the trial? And that comes on top of a delay in readouts as announced earlier this year. And if I can slip one in on your quadrivalent mRNAs flu, when would we likely see results from your Phase 3 that you're starting up?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. Mikael, both questions go to you. I think the first question, I think, was for RSV, right?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. We have made great progress in the RSV adult trial. As you know, we ran it through two different seasons in the Northern and Southern Hemisphere to make sure we had good patient experience and cases, seems looking good for a readout that will come soon. I remain very positive about RSV adult based on our Phase 2 challenge data that was stellar and the role that this particular antigen that we're targeting play. And as you know, we're the only one that are targeting the two forms of this pre-fusion.

You also asked about modRNA flu. Yes, as Albert mentioned, we are going big here with an efficacy study. We are encouraged about the data we're seeing. We think it's a unique dataset. And we plan to soon embark on a Phase 3 after proper dialogue with regulators. Of course, this is an event trial. But if the season is robust, which you can never know, we would expect the Phase 3 to read out next year.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Exactly. And also, I'm sorry if we gave the impression that RSV is not important to us, it's extremely important. If there is no better good news, this is why we didn't mention it much but still remains the very good news. But the previous studies were extremely strong and the current studies are progressing very well. So we have very high confidence, absent a surprise, that we will launch next year a very robust product both in adults and in maternal, the maternal, both studies are progressing very well.

Operator

Your next questions come from the line of Geoff Meacham from Bank of America.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Just had a couple on PAXLOVID real quick. Can you give us an update on the number of countries you're in contract discussions with? I'm just thinking relative to the start of the year. And then related, what's been the biggest contributor of supply expansion in 2Q? And when do you think you guys will be fully, fully normalized?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Let's go to Angela for the number of countries and where we are with that.

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Yes. So we are in contract with a significant number of countries at this point. Maybe I can talk about it from a dose perspective. So more than 35 million treatment courses have already been contracted with a number of countries. And this is what we publicly disclosed. There are additional doses that I can't talk about because either the country didn't want us to disclose them publicly or we're in the middle of negotiations with them. So I think to answer your question, since we last left off, we have made progress with our contracting.

I think what's -- maybe what's more important to clarify is just that the approach that countries are taking to contract with us is just really different to where we were in COMIRNATY. In COMIRNATY, they were interested in securing large amounts of doses upfront. But that's, in fact, not the case here in PAXLOVID. And the reason being that, number one, they're being prudent with how they are ordering. And they are able to do that because they know that we have the manufacturing capacity and that we can pivot as we need. The countries are also trying to manage inventory and not to have too much aged product lying around. And so I think that this is what's driving the more smaller, more frequent contracting rather than big, big contracts that -- like you saw in COMIRNATY.

The other thing I will also say is -- and the reason why I'm talking in doses rather than specific countries is because we're also working with super national organizations, who are acting on behalf of multiple countries. So think Global Fund, think UNICEF, these are, in addition to the bilaterals, are also important organizations who are helping us to supply and bring doses into the countries. So I think all in all, great progress. And I think you should expect to see that this is one of these things that will just keep inching away because of how countries want to manage the inventory and the supply.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Angela. And also to -- because you had also a question on supplier ramp-up. We have done tremendous progress on that field. Actually, we have been able to reduce dramatically the lead time, so to how much time it's needed for manufacturing, and we have improved dramatically our yields. So supply is not an issue. Actually, we moved almost everything in-house now in terms of API and finished products.

Operator

Your next questions come from the line of Chris Schott with JPMorgan.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Just one follow-up on the PAXLOVID comments. As we move, I guess, from some of these large government orders that we saw with the U.S., et cetera, earlier this year to maybe these more kind of on-demand smaller contracts, how do we think about what the impact that has on pricing? Because I think you were giving some volume-based discounts before. And just help us -- I guess, think about kind of 2023 and beyond what pricing does for that business?

And then kind of the bigger question I had was just on IBRANCE dynamics. I think you mentioned in the prepared remarks, you're seeing signs of a recovery for your business there. I'm just interested in how you kind of see the balance of just overall market dynamics relative to the competitive landscape with obviously one of your competitors with an adjuvant indication.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you very much. Chris, we do not provide, let's say, forward-looking projections on pricing. And particularly, every time I speak about pricing, it's becoming big news. So I want to make sure that we respect that. I know what you are asking. And I can give a very high-level answer. Clearly, we are providing special pricing when we are contracting very, very big quantities with governments. That's also the incentive for the government to buy big quantities because the price is really, really very attractive.

But if we move to a normal market, the prices would reflect both in vaccines and in antivirals, the prices of similar value, similar technology products that they are out there. And clearly, also when you move to private commercial markets, the complexities are getting way, way higher. We will need to go to single doses in the vaccines. So manufacturing complexities are very higher. We need to have distribution to small distribution centers, including physician offices. So all of that creates a very big complexity but also could be taken into consideration as we price our products at that time.

And I want to emphasize that also those present significant opportunities for us. Because the open market, it is way more complex, way more diverse to have millions of customers rather than one or two. And this plays to our strengths in terms of having global presence or within the U.S., dramatic presence in every single territory of the country with thousands of people that they are calling physicians, hospitals, accounts, in payers' accounts, et cetera, et cetera. So it's something that if we see a turn into this market, also we will see us being able to compete more of a position of strength than now. As regards to IBRANCE, Angela?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Sure. Well, as you say, the metastatic breast cancer CDK4/6 market is incredibly competitive yet. I will emphasize that IBRANCE continues to be the leading CDK4/6 inhibitor. In fact, we have a 74% market share across all patients in first-line therapy. And I think that this number has been pretty consistent because we talk about it every quarter. And I think it demonstrates just the tremendous experience that physicians and patients have and the confidence they have in IBRANCE despite new competition.

The patient experience, the fact that we have real-world clinical evidence, all of this really adds to the confidence that we have in this brand. And even though IBRANCE is a mature brand, we do continue to see growth. And where the growth will come from are from the following places. You're going to see growth from the CDK class. You're going to see growth from the recovery of new patient starts, which, as you know, has not recovered to the levels prior to the pandemic as well as stabilization of the PAP through time when economic conditions improve.

And I actually want to make a special point of this class growth. Because therein lies, I think, a tremendous opportunity for all of us. Today -- well, last year this time, the CDK class was 48% in first-line metastatic breast cancer use. This quarter, it was 54%. So even though it's grown, it still means that the majority of the time, CDKs are not being used. And I think we, all of us in this class, really need to focus on this as the leading priority in helping to grow each of our brands but also to grow the class to impact patient outcome.

Operator

Your next questions come from the line of Chris Shibutani with Goldman Sachs.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

First, a quick word of welcome and appreciation to David for your proactive commentary on the phasing of revenues. It really mirrors what your predecessor had often fondly referred to as the rhythm of the numbers, very helpful to get insights on near-term factors that are generating push-pulls on those numbers. My question is on business development, however. And I'm not sure that Aamir has joined us.

But perhaps if you could update us on your latest thoughts of the team in terms of how you're feeling about areas of focus, particularly in view of recent broader commentary, for instance, from the FTC, taking a look at competitive dynamics there. And then secondly, as you reflect upon the overall ecosystem and the receptivity, given things like lowered, relatively speaking, biotech valuations, are you sensing any shifts or trends or changes in the mindset of potential targets, partners, acquirers?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you very much. Aamir is here, and he will be happy to speak about it. Aamir?

Aamir Malik - Pfizer Inc. - Executive VP & Chief Business Innovation Officer

Chris, thank you for the question. Let me just start with your specific FTC point. I think we've demonstrated a very strong track record of shepherding our transactions to date through the regulatory process. And that's been largely built on having just a close, successful, constructive and collaborative relationships with regulatory bodies globally. In addition, our business development focus, and I'll recap our priorities in a second, is focused on how do we use our unique abilities to translate emerging science into breakthrough medicines.

So most of the deals that we do are pro-patient and they're pro-innovation. So we're confident that we can continue to advance our BD strategies in a successful way. We've been very clear that our goal is to add \$25 billion of risk-adjusted revenue by 2030. And I think we are making very good progress against that. This year, you saw our transaction with ReViral and subsequently with Biohaven, which, respectively, we believe have the potential to add \$1.5 billion and \$6 billion in peak sales to our business. And this was on the back of a very active 2021.

And going forward, we're leaving very few stones unturned when we look at opportunities. And our focus is going to be consistent. It's on scientific substrate that has a potential breakthrough for patients, deals that accelerate our top line growth in the back half of the decade and then opportunities where we can add substantial value, whether that's through our scientific chops and/or our commercial capabilities. And we're going to be very open to deal structures. And we've said before, we're also going to be agnostic to size.

We've been clear about the fact that cost synergy-driven deals are not where our focus is going to be. And we're going to be extremely disciplined. I think we're very excited about the opportunities that are ahead of us and the flexibility that our balance sheet gives us to pursue those. And on your question on valuation fluctuations, those market valuation fluctuations are not going to drive our BD strategy. We're going to remain focused on fundamentals in the way that I described.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. And it is very important when we are aiming very high to also be able, at the same time, to be disciplined. Disciplined in valuing the science and paying the right price for the right science so that the capital that we will dispose will be maximized in producing value for patients and the shareholders. So we go very big, \$25 billion. But as we have proven, we are very, very disciplined in how we're allocating our capital. And we will continue doing that.

Operator

Your next questions come from the line of Andrew Baum with Citi.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

A two-part question, please. Your former Head of Vaccines is now ensconced at your competitor, GSK. When he top lined the recent positive Phase 3 data for their RSV vaccine candidate, which is adjuvanted, an observation he made was he stressed the same level of efficacy in the older patient cohort than in the younger patient cohorts. It's possible to imagine that this may be uniquely related to the adjuvant that they have, given the immunosenescence of the aging population of T cells. Given your vaccine does not have an adjuvant background, is that a concern, particularly over follow -- longer years follow-up?

And then second, just following up on a question on IBRANCE. Could you talk to your Arvinas compound, ARV-471? We come up with market shares which are materially lower than yours. But whatever the number is, it's clearly reducing quite significantly as competition builds momentum in the market. How are you thinking about, as you transition this drug into Phase 3, both what combinations you're going to run and what are you going to use as the control arm for the combination of a SERD plus a CDK4/6?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Andrew. Just to make a correction, it was not the Head of our Vaccines that joined, it was another member of the Vaccines team but by no means was the head. Let's move to Mikael.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. I am very optimistic about our RSV vaccine construct. We have seen high immune titer that are critical for the vaccine across all ages. In fact, we are the only one that have showed cross-strain A and B for RSV, the very high titers, which differ between all the vaccines, including the one that you mentioned because they mainly measure crosser activity from A to B strain. So that was supported also by our challenge data that looked formidable.

So while nobody can predict exactly the outcome of studies and comparing one study to another, we remain very bullish that our bivalent vaccine should stand out in performance and in tolerability. Please note some of the adjuvants, including the one that you referred to, often associated with somewhat unpleasant side effects. And that was one part of our differentiation to achieve with a bivalent, very high data and with best-in-class tolerability.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

And what about IBRANCE?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

The ARV-471, I can only speak about the science here that we see that drug being active in several lines as by itself, best-in-class estrogen receptor, PROTAC. And we are going to set up our studies in a patient population which contains many estrogen receptor mutants, which often are poorly managed by the current available fulvestrant or other SERDs. And we think this is a unique opportunity.

And number two, the drug seemed to combine very well with our own CDK4/6 drugs. And we think it could advance into early metastatic lines. And possible over time, even to early breast cancer, maybe they are combined with our CDK4. So we have very high hopes for that class of drugs, ARV-471 combined with our pipeline.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. Anything to add, William?

William Pao - Pfizer Inc. - Chief Development Officer, Executive VP

Yes, I would just add, as you mentioned, Mikael, the preclinical data shows that the ER degradation could be superior to selective estrogen receptor degraders. And so we're very excited about this potential to be superior to SERDs that are being developed.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, from your lips to God's ears. Also, I want to add on the RSV because it's the second question that came and maybe gave the impression that we are not very hot on it. We are extremely hot on it. Clearly, a very important product for us, clearly a very important project for GSK. So there will be a lot of speculation. Maybe the other one will do that or maybe the other thing will do this.

I think data will speak on themselves. With the totality of data available, so far that I have seen, we have high reasons to believe we are better. But you never know before the end of the trials. But right now, with all, looks like we have a very, very strong profile with all the data that I have seen so far. We are waiting a lot with a lot of excitement to unblind the data and see the realities. And then of course, the best will win. Let's move now to Steve.

Operator

Your next question comes from Steve Scala with Cowen.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

I would just like to understand more deeply Pfizer's thinking on factor XI. I could think of three possibilities. First, Pfizer believes there is simply no room to improve upon ELIQUIS. Second, Pfizer believes factor XI could be very useful, but you haven't found the ideal candidate. Or third, Pfizer is not sure the jury is still out. Any thoughts?

Albert Bourla - *Pfizer Inc. - Chairman of the Board & CEO*

I think we have answered it before. And maybe Mikael also can give some color because it's a very, very good question. But bottom line is we are looking for science that it could provide hope that we can have something better than ELIQUIS. And we haven't found it yet. So that's the reality. According to our opinion, there is not much maturity right now to overcome the brilliant -- the very good profile of ELIQUIS. Mikael, anything to add? It's as simple that.

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

I think you said it very well. In the atrial field, the platelet inhibitor and [ASA] are or are going to be genericized. ELIQUIS and rivaroxaban, great drugs, ELIQUIS being a market leader, factor X inhibitor, or by the time factor XI comes to market, close to or already genericized. So the room for an expensive drug in an area with these many great treatments, that requires tremendously high R&D expense coming off the patients that have gone through multiple other grade drugs. For us, it doesn't look like the best area to deploy capital. We always wish others would like for the benefit of patients.

Operator

Your final question will come from the line of Elliott Bosco with UBS.

Elliott Andrew Bosco - *UBS Investment Bank, Research Division - Associate Analyst*

This is Elliott Bosco from UBS on for Colin Bristow. Just a few on PAXLOVID, you mentioned countries needing to manage older supply. Do you think that current PAXLOVID use trends will result in excess inventory versus what has been contractually purchased? And additionally, could you comment on the recent Codexis retainer arrangement and how we should think about that with regard to a 2023 PAXLOVID demand?

Albert Bourla - *Pfizer Inc. - Chairman of the Board & CEO*

Angela?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Sure. No, I think that the way we are manufacturing PAXLOVID with, of course, great knowledge from our prior experiences with COMIRNATY but also in terms of our negotiations and discussions with countries is actually allowing us to do supply planning very well. So we are manufacturing as we need and according to the contracts and according to the demand that the countries are providing us. So I think we're doing that on a -- in a very prudent and in a very -- in a prudent and an effective way. So I didn't -- we didn't -- your second question?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes, what was the second question? I'm not sure.

Christopher J. Stevo - Pfizer Inc. - Senior VP & Chief IR Officer

Codexis, the enzyme supplier for...

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes, it was the -- do you want to -- I did refer to it, but maybe also you can reiterate it, David.

David M. Denton - Pfizer Inc. - CFO, Executive VP

Yes, I think Albert indicated this earlier in his remarks is that, in fact, over the last several quarters, we've improved our manufacturing process, reduced the cycle time and importantly improved the yield from an output perspective. So therefore, we don't need as much raw materials and API to produce the same amount of finished goods. And then finally, we've actually invested in our network to make sure that we can actually produce some API as well. So we're in good shape.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

What I said before, we are moving most of it now because we could weigh faster than what we anticipated, move it inside. So that creates some cancellations of raw materials to some external suppliers. I'm sorry about that. I think that was the last question.

Let me close with a few takeaways. The first one, as you see, we continue to deliver strong operational performance. We increased our full year '22 operational financial forecast while maintaining a challenging foreign exchange environment. So I think few companies likely will be able to do that. We believe we are well positioned not only to maintain but also to grow both our commercial and scientific leadership in the battle against COVID-19. It will be, for us, a very important focus. And we believe that the medical need will be there for the years to come. That's why we're investing so heavily.

We continue focus on driving long-term shareholder returns by remaining very disciplined both on our operations and our incremental capital deployment. You saw even in this quarter. But even more, we are squeezing our administrative expenses, our SI&A is going down and then we reinvest in R&D because we have programs that we are starting that we feel is a very good return on our investment. And we continue to advance our internal scientific pipeline while executing against our previously announced plans to potentially add at least \$25 billion of risk-adjusted revenues through business development opportunities from 2030 top line.

Thus, I want very quickly to see that these results in R&D are yielding results. Just to mention a few of the potential approvals and launches that we are going to have in the next few months. CIBINQO, we expect to launch the adolescence next year. And of course, next year will be the real first year where we expect to have full access for this drug. We expect to launch next year, RSV maternal. We expect to launch next year, RSV adults.

We expect to launch next year, Prevnar 20 for pediatrics. We expect to launch next year elranatamab for triple-class refractory myeloma. We expect to launch next year ritlecitinib for atopic -- for alopecia areata.

We expect to launch next year, pentavalent meningococcal vaccine. We expect next year, TALAPRO for prostate cancer metastatic castration patients. We expect to launch -- or we did already MYFEMBREE for endometriosis. And then a little bit later, we expect maybe this in '23 or beginning of '24, DMD and flu mRNA. So it is -- this is the organic. I'm not referring to the Biohaven NURTEC that is coming and to other molecules, I'm referring mainly to the organically developed pipeline assets.

I don't think that much of that has been a factor into what some of the analysts are projecting. That's why I'm emphasizing them so that they can pay a little bit more attention. Those are very high probability of success, the ones that I mentioned. They are not in the pocket clearly, all of them. And some clearly might not make it to the first line. But we believe they are seriously de-risked, all of that.

So with that in mind, I'm really looking forward to have a 6% CAGR by '25 in our business as we promised in 2019. In fact, year-to-date, we are at 6%, excluding BD and excluding COVID. And I think we will do that by 2025. We will maintain this 6% CAGR. And we'll do more by BD that we are right now implementing. So I think we have a very good growth prospect. And we will maintain our leadership in COVID. Thank you very, very much for your interest. And for those that didn't have summer vacations yet, enjoy your summer vacations.

Operator

Ladies and gentlemen, this concludes Pfizer's Second Quarter 2022 Earnings Conference Call. You may now disconnect.

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