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PFE.N - Q2 2020 Pfizer Inc Earnings Call

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OVERVIEW:

Co. reported 2Q20 total Co. revenue of $11.8b.

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Second Quarter 2020 Earnings Conference Call. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Thank you, operator. Good morning and thanks for joining us today to review Pfizer's second quarter 2020 financial results, our updated 2020 financial guidance, Pfizer's progress in helping find solutions for the COVID-19 pandemic as well as other relevant business topics. I'm joined today as usual by our Chairman and CEO, Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Angela Hwang, Group President, Pfizer Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler, General Counsel.

The slides that will be presented during this call were posted to our website earlier this morning and are available at Pfizer.com/investors. You'll see here that Slide 3 covers our legal disclosures. Albert and Frank will now make prepared remarks and then we'll move to a question-and-answer session.

With that, I'll now turn the call over to Albert Bourla. Albert?

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

Thank you, Chuck, and good morning, everyone. During my remarks, I will discuss our second quarter business performance, provide an update on our pipeline, and of course, speak to the progress we are making to combat the global public health challenge posed by the COVID-19 pandemic.

Our continued strong performance speaks to the resiliency of our business even during the most challenging times. The second quarter was the first full quarter impacted by COVID-19. Revenues in the quarter included an estimated net unfavorable impact of approximately $500 million or 4% due to COVID-19, primarily reflecting unfavorable disruption to wellness visits for pediatric and declines in adult patients in the U.S. and lower demand for certain products in China. These declines were partially offset by increased U.S. demand for certain sterile injectable products, increased adult demand for Prevnar 13 in certain international markets.

Let me start with an update on our Biopharmaceuticals Group. For the quarter, our Biopharma business grew 6% operationally driven by strong performances from many of our key growth drivers, including VYNDAQEL/VYNDAMAX, Eliquis, IBRANCE, Inlyta, XTANDI and our biosimilars portfolio. Our Oncology business was particularly strong, up 20% operationally compared with the year ago quarter. The global IBRANCE revenues increased 9% operationally to $1.3 billion during the quarter. In the U.S., IBRANCE revenues grew 11% and IBRANCE continues to retain a strong leadership position within the CDK class.

The international markets delivered strong 18% volume growth in the quarter. This volume growth was partially offset by price reductions in certain EU markets, which resulted in 3% operational revenue growth outside in the U.S. The price reductions occurred last year as a result of renegotiating long-term agreements, and we expect the impact will continue through to the fourth quarter of 2020 when the price changes annualize.

We were surprised and disappointed by the outcome of the PALLAS trial. However, we remain confident in IBRANCE's strong positioning and expected future performance within the currently labeled metastatic setting, given the different treatment paradigms and clinical endpoints used in the setting as opposed to the adjuvant setting.

For XTANDI, alliance revenues in the U.S. were up 32% for the quarter and when combined with our royalty income on ex U.S. sales, totaled $374 million for the quarter. The strong growth in the U.S. was driven by continued strong demand in both the metastatic and non-metastatic castration-resistant prostate cancer indication. We now have a leading share of new patient starts in both indications. And in the non-metastatic indication, we are also seeing the benefit of a longer duration of therapy.

Further strengthening XTANDI's performance during the quarter was the metastatic castration-sensitive indication driven by our ARCHES study. XTANDI's share on new patient starts increased by 24% this quarter, a strong early signal of the potential adoption by both oncologists and urologists. Global Inlyta revenues increased 89% operationally to $195 million during the quarter. In the U.S., Inlyta revenues more than doubled given by the strong uptake following last year's FDA approvals for 2 checkpoint inhibitors in combination with Inlyta for first-line treatment of patients with advanced renal cell carcinoma. The international markets also contributed to the performance of Inlyta with 48% operational growth.

Looking outside of Oncology, Eliquis has continued to deliver strong performance. Pfizer's share of the global alliance revenues, including direct sales markets, was up 19% operationally to $1.3 billion. I would also point out that the Bristol-Myers Squibb-Pfizer alliance has not yet received the decision from the U.S. district court related to the patent litigation for 2 patents covering Eliquis. The court has stated that it will issue its decision on or before August 7. We remain confident in the value of our innovative science and the strength of our patents.

VYNDAQEL and VYNDAMAX continued to show strong U.S. performance. Our disease awareness efforts helped drive the estimated diagnosis rate to 15% in the second quarter compared with only 1% to 2% prior to launch. At the end of the quarter, more than 15,000 patients have been diagnosed. More than 10,000 patients have received a prescription, and more than 6,200 patients have received the drug.

For the quarter, we estimate the average number of patients in the U.S. taking VYNDAQEL that was approximately 6,000 people. These numbers include patients who are receiving the drug at no cost through our patient assistance programs. That said, as a result of stay-at-home orders, as expected, we did see a slowdown in new diagnosis in Q2 as fewer patients were visiting doctors' offices for consultations or scintigraphy tests. However, as health systems have recently begun to resume effective procedures, we are seeing a gradual increase in diagnosis rates and we'll continue to monitor.

Global Xeljanz revenues were up 5% operationally in the quarter to $635 million. Revenues outside the U.S. were up 20% operationally while U.S. revenues were flat. The underlying prescription demand in the U.S. grew 14% compared with the second quarter of 2019 and 16% compared with the first 6 months of 2019.

However, higher rebating resulting in a lower net price has offset this volume growth. The higher rebating is a result of investments we have made in formulary access. The access is driving our volume growth, and we are pleased to have attained favorable access with most major payers in the U.S.

Our global Biosimilars portfolio grew by 36% operationally to $289 million. This was driven mainly by our oncology biosimilars, which increased 120% operationally to $139 million during the quarter. In the U.S., revenues from our oncology biosimilars portfolio grew up by 181%, driven by continued strong demand for our supportive care brands, especially RETACRIT, and from early results from our 3 monoclonal antibody biosimilars, which launched earlier this year. The international markets also contributed with 61% operational growth led by growth from TRAZIMERA and our supportive care brands.

Global Prevnar 13 revenues were down 2% operationally to $1.1 billion. Revenues outside the U.S. grew 18% operationally driven primarily by significantly increased adult uptake resulting from greater vaccine awareness due to the COVID-19 pandemic, although we should note that Prevnar 13 is indicated for another type of pneumonia as well as continued strong pediatric uptake in China. In the U.S., revenues were down 22%, primarily reflecting the expected impact that COVID-19 mobility restrictions had on wellness visits, particularly offset by the timing of CDC orders.

Looking at our Sterile Injectables portfolio. Our global revenue from the injectables portfolio grew 4% operationally in the second quarter and 10% operationally in the first half. More than 95% of our injectables portfolio is in stock today. In response to the increased demand during the early stages of the COVID crisis, we provided significant incremental shipments of sterile injectable medicines and largely maintained supply continuity. Demand for most of these medicines has since normalized, but we continue to monitor the situation.

Let me now briefly speak to some of the modifications we have made to our go-to-market approach that have allowed us to continue to effectively communicate with and serve health care providers and patients during the pandemic. We quickly adapted our promotional platform, amplifying our existing digital capabilities to reach health care providers and customers and provide critical education and information during this time. This included increasing the scale of our remote engagement.

All our U.S. sales representatives are digitally enabled, and we are currently conducting virtual detailing and remote sampling, which has proven to be an efficient way to interact with health care providers during this crisis. Overall, more than 75 markets have utilized virtual communication, with about 2/3 of our sales reps using the platform. This enabled us to reach 70% of our health care providers during this time.

Even after the pandemic is behind us, we anticipate digital will remain an important tool for our sales reps as they continue to tailor their approach to physicians and to help us communicate information on our medicines and vaccines when and how these health care providers want to receive it.

As expected, we understandably saw a significant decrease in in-person patient-physician engagements during the second quarter, and we continue to believe that Q2 and specifically April should be the low point in terms of physician engagement with their patients. We have begun to see a gradual recovery from the largest impact seen in April, and we anticipate health care activity to continue its gradual uptick, but we have not yet reached our pre-COVID trends. There are several factors playing out in real time, such as reopening and potentially reclosing efforts in certain states and countries as well as timing for resuming effective elective surgeries.

As we said last quarter, we see different business units and brands responding differently based on several factors, primarily including the medical necessity, reliance on new patients for growth, oral administration and patient affordability. Upjohn's second quarter revenue decline was, of course, driven by the impact of Lyrica generics in the U.S. This was our last full quarter of the Lyrica impact on the year-over-year comparisons. And excluding this impact, Upjohn revenue declined 6% on an operational basis to $2 billion as compared with a 31% operational decline with the Lyrica impact.

I know from an Upjohn perspective, there is a lot of focus on China, and I was very pleased to see that Upjohn's China business delivered 17% operational growth during this quarter compared with the second quarter of 2019. This growth was driven primarily by Lipitor and Norvasc.

Mylan shareholders have voted nearly unanimously to approve the combination of Upjohn and Mylan to create Viatris. Upjohn also completed a successful debt offering, raising approximately USD 7.5 billion dollar-denominated notes and EUR 3.6 billion in euro-denominated notes. The proceeds will almost entirely fund the $12 billion dividend to be paid to Pfizer once Upjohn is separated and the completion of the transaction. We are continuing to progress towards a successful close of the transaction, which is now expected in the fourth quarter of 2020.

Now I will turn to our R&D pipeline, beginning with an update on our COVID-19-related efforts. Yesterday, Pfizer and our collaboration partner, BioNTech, announced the start of a global, except for China, Phase 2/3 safety and efficacy clinical study to evaluate a single candidate from our BNT162 mRNA-based vaccine program against SARS-CoV-2. After extensive review of preclinical and clinical data from approximately nearly 120 patients in b2 from Phase 1/2 clinical trials in the U.S. and Germany and in consultation with the FDA and other global authorities, we have chosen to advance our b2 vaccine candidate into the Phase 2/3 study at the 30-microgram dose level in a 2-dose regimen. Dosing began in the U.S. yesterday.

Our b2, which recently received Fast Track designation from the FDA, encodes an optimized SARS-CoV-2 full-length spike glucoprotein, which is the target of virus-neutralizing antibodies. During preclinical and clinical studies of 4 RNA vaccine candidates, both b1 and b2 emerged as strong candidates based on assessments of safety and immune response. Pfizer and BioNTech selected b2 as the candidate to progress to a Phase 2/3 study based on the totality of available data from our preclinical and clinical studies, including select immune response and tolerability parameters.

In the preclinical studies, b1 and b2 candidates induced favorable viral antigen-specific CD4 and CD8 T cell responses, high cells -- high levels of neutralizing antibody in various animal species and beneficial protective effects in the primate SARS-CoV-2 challenge model. Preliminary clinical Phase 1 data from nearly 120 patients demonstrated a favorable overall tolerability profile for BNT162b2 from our b2 candidate as compared with our b1 candidate with generally mild to moderate and transient systemic events such as fever, fatigue and chills and no serious adverse events.

I also want to specifically mention that the effect we have observed in our preliminary data of the second boosting dose is important, and we believe it reflects a strength of the RNA platform. The ability to boost is important because it means that if immunity fades over time, it can potentially be restored by repeat immunizations. As we continue to evaluate the potential vaccine candidates, we look forward to gaining additional insights.

Yesterday's announcement is an important and encouraging milestone in our collective efforts to find potential medical solutions to help combat the current global health crisis. It's the culmination of an extensive, collaborative and unprecedented R&D program involving Pfizer, BioNTech, clinical investigators and study participants who all have a singular focus: developing a safe and effective COVID RNA vaccine.

We will continue to work closely with regulatory authorities, including the FDA, to advance our program while ensuring we maintain high standards of quality, safety and compliance in our development process. We know the FDA and other regulatory bodies will continue to uphold their high standards as well.

If the Phase 2/3 trial is successful, Pfizer and BioNTech expect to be ready to seek Emergency Use Authorization or some form of regulatory approval as early as October 2020. If authorization or approval is obtained, our companies currently aim to supply globally up to 100 million doses by the end of 2020 and approximately 1.3 billion doses by the end of 2021.

Last week, we announced 2 agreements that will help ensure people have access to this potentially breakthrough vaccine, assuming, of course, clinical success and regulatory approval. On July 20, we announced an agreement with the United Kingdom to supply 30 million doses of our vaccine candidate, which we expect to be delivering in 2020 and 2021, assuming clinical success and regulatory approval or authorization. Then on July 22, we announced an agreement with the U.S. government for up to 600 million doses. Under the agreement, the U.S. will pay Pfizer and BioNTech a total of $1.95 billion upon the receipt of the first 100 million doses. Following FDA authorization or approval, the U.S. also can acquire up to additional 500 million doses.

Pfizer's unique combination of experience, resources and manufacturing capabilities in vaccines is a competitive advantage for us and one of the reasons I'm confident in the potential of our collaboration with BioNTech to be successful. We are also moving forward with the development of a potential novel antiviral, which we hope to have in the clinic by September.

Now let's look at some highlights from the rest of the pipeline, which continues to be one of Pfizer's great strengths. In addition to our COVID-19 vaccine program, we recently started 4, I repeat, 4 Phase 3 studies for vaccines that we hope will make meaningful contributions to the lives of people everywhere.

These include: 2 studies of the 20-valent pneumococcal conjugate vaccine candidate, evaluating a 4-dose series in infants, starting at 2 months of age; a study -- a Phase 3 study of our respiratory syncytial virus vaccine candidate, RSVpreF, in pregnant women to evaluate the safety and efficacy of the candidate in infants born to immunized pregnant women as compared with placebo; and a Phase 3 study of the pentavalent meningococcal vaccine candidate, ABCWY, in adolescents and young adults to assess the safety, tolerability and immunogenicity of the vaccine candidate compared with licensed meningococcal vaccines. We also announced a collaboration with Valvena -- excuse me, with Valneva to co-develop and commercialize Valneva's Lyme disease vaccine candidate, VLA15, which is currently in Phase 2 clinical studies.

Our Vaccines teams accomplished all of this while also working with a deep sense of urgency in partnership with BioNTech to develop a potential COVID-19 vaccine. Despite the disruption that the pandemic has brought to our world, they stayed true to the ambitious timelines for our existing programs, and I couldn't be prouder of their commitment.

From our Rare Disease gene therapy portfolio, we had 2 important data readouts in the last quarter. We presented the data from our investigational mini-dystrophin gene therapy program for Duchenne muscular dystrophy at the American Society of Gene Cell Therapy Annual Meeting. The preliminary data from 9 ambulatory boys with DMD aged 6 to 12 indicate that the intravenous administration of our program was well tolerated during the infusion period with encouraging efficacy and manageable safety events.

Of interest, since those original 9 boys, for whom we shared data were dosed, we have dosed an additional 6 boys at the high dose in compliance with our modified protocols. To date, we have not seen any serious safety events in any of the 6 new boys, 5 of whom have reached at least 2 weeks post the treatment, which is the time period in which all previous adverse events were experienced. We look forward to starting the pivotal trial for this potential therapy later this year.

We also presented at the World Federation of Hemophilia 2020 World Congress hemophilia A data from giroctocogene fitelparvovec from our partnership with Sangamo Therapeutics. The data demonstrated that 5 subjects receiving the highest dose of the gene therapy have between 30 and 61 weeks of follow-up, sustained functional factor VIII activity levels without the need for additional factor replacement following an initial use of prophylactic factor. This shows the potential of our gene therapy to be differentiated from other hemophilia A gene therapies being evaluated in the clinic. Pfizer is currently enrolling subjects in a 6-month Phase 3 lead-in study for the hemophilia A gene therapy program, which will serve as the foundation of our Phase 3 registrational study expected to start again later this year.

In Internal Medicine, we recently presented at the American Diabetes Association conference Phase 1 data from our oral GLP-1, which saw reduction of glucose level and body weight. Our aspiration is to develop the most efficacious oral therapy for type 2 diabetes and develop the first small molecule oral GLP-RA for both obesity and type 2 diabetes mellitus. We are also aware of the increasing evidence indicating that the GLP-1 RA class may so promise for the treatment of NASH and are open to further exploration as we review the data.

In Inflammation and Immunology, we are excited that abrocitinib has consistently shown meaningful efficacy across all of our 4 studies from adolescents to adult patients with moderate to severe atopic dermatitis, results from our COMPARE study showing superiority in each at week 2 for the 200-milligram dose. And that indicates that abrocitinib can demonstrate a clinical benefit over Dupixent. Our program has advanced at a rapid pace and we intend to file with FDA this quarter.

In Oncology, building on our presence in genitourinary cancers. We are pleased by the FDA's recent approval of BAVENCIO as a first-line maintenance treatment for patients with locally advanced or metastatic urothelial carcinoma. BAVENCIO is the only FDA-approved immunotherapy with a

demonstrated overall survival benefit in the first-line setting in UC. And we believe it has the potential to become a new standard of care based on its demonstrated ability to extend the lives of patients and address a significant unmet medical need.

On July 16, the treatment was listed in the cancer treatment guidelines put out by the National Comprehensive Cancer Network. We look forward to providing further R&D pipeline updates during our upcoming Investor Day, which will be held over 2 days in a virtual format on September 14 and September 15.

Now before I turn it over to Frank, I want to speak to the Executive Orders the President signed on Friday. Overall, I'm disappointed by these Executive Orders. They pose enormous distraction at a time when the industry needs to be completely focused on developing a potential COVID-19 vaccine or treatment. The international price index is radical. Not only it is importing socialized medicine to America, it also will create uncertainty and could lead to job losses. We have plans to invest in both R&D and manufacturing in the United States. If finalized, these new Executive Orders could force us to rethink those plans, consider job reductions and add to the economic and health anxiety already widely felt in our country.

The one concept we agree with is the rebate rule because it will actually make the system work better by removing inefficiencies created by the middleman. It will ensure our discounts make it to patients. The patients are the ones that drive the volume of our medicines and in effect, earn the volume discounts we provide to middlemen. The problem has been that most of these discounts don't make it back to the patients.

In summary, our results continue to support our thesis of having multiple growth drivers across different therapeutic areas driving the business. As we have said in the past, by design, we are not overly dependent on any single growth driver, which gives us continued confidence in our ability to achieve our goal of at least 6% revenue CAGR through 2025 following the completion of the pending Upjohn/Mylan combination.

Following the expected separation of Upjohn in the fourth quarter of this year, Pfizer will be a more focused, science-driven company that is even better positioned to deliver our innovative medicines and vaccines to patients around the world. And when patients win, we all win.

Now I will turn it over to Frank.

Frank A. D'Amelio - *Pfizer Inc. - CFO & EVP of Global Supply & Business Operations*

Thanks, Albert. Good day, everyone. Starting with total company revenue, we generated $11.8 billion in the second quarter of 2020, down 9% operationally versus the year ago quarter. As in each of the last 3 quarters, the majority of this decline is due to the fact that we no longer report revenues for our Consumer Healthcare business. Adjusting for Consumer, total company revenues declined 3% operationally. As a reminder, the formation of the Consumer joint venture with GSK will annualize on July 31, so next quarter will be the last one impacted by this negative driver.

Albert did a really nice job of describing the revenue drivers for each of our businesses so I won't repeat them, but I do want to make one additional point on each business to punctuate what he said. For Biopharma, the growth that we are seeing is not reliant on net price increases. In fact, on a global basis, net price had a negative 2% impact on Biopharma growth this quarter and in the U.S., net price was flat. These dynamics are consistent with the pricing environment we have seen for several years now, and we continue to believe that pricing will not contribute to our expected growth for the foreseeable future.

For Upjohn, it is important to point out that despite a 31% operational decline in revenue this quarter, the business continues to perform in line with our expectations and the assumptions reflected in our initial Upjohn guidance. I should also point out that the 31% becomes minus 6%, excluding the impact of the Lyrica LOE.

Now moving down the income statement, we had another quarter with significant declines in adjusted SI&A expenses, which were down 17% operationally. Nearly half of that decline was due to the fact that we no longer report expenses for the Consumer Healthcare business. The remainder of the decrease was driven primarily by decreased sales and marketing activities compared to the prior year quarter due to restrictions on in-person meetings with health care professionals primarily in the U.S. and to a lesser extent, lower spending associated with corporate enabling functions.

Reported diluted EPS for the quarter was down significantly compared to the year-ago quarter, mainly driven by a onetime favorable tax settlement recorded in the prior year period. Adjusted diluted EPS was down 2% compared to the prior year second quarter. Excluding the $0.02 negative impact of foreign exchange rates in the period, adjusted diluted EPS was flat compared to the prior year. Foreign exchange also negatively impacted revenues in the quarter by $277 million or 2%.

On Slide 13, we are providing an update to the detailed assumptions reflected in our current financial guidance related to the impact of the COVID-19 pandemic on our business. Broadly speaking, we anticipate an ongoing gradual global recovery from the macroeconomic and health care impacts experienced during the second quarter of 2020 beginning in Q3 of 2020. The guidance also assumes we'll be able to continue to operate our manufacturing and supply chain without material disruption and that we will continue investing in potential treatments and vaccines against COVID-19 throughout 2020 but does not include any revenues for a COVID-19 vaccine candidate given that it has not yet been approved.

With that in mind, let's take a look at our guidance. Consistent with last quarter, we are providing 3 sets of financial guidance. Beginning with total company, we are raising our guidance range for revenues by $100 million and our guidance range for adjusted diluted EPS by $0.03 based on the strength and resiliency we see in our business and the dedication of our colleagues despite the challenges inherent in operating during this current global pandemic.

We are reaffirming all of the components of our 2020 financial guidance for total company. I want to point out that although changes in foreign exchange rates since mid-April have marginally benefited our full year outlook for revenue and adjusted diluted EPS, today's guidance increases are not primarily driven by changes in foreign exchange. And as a reminder, we maintained both of these guidance ranges last quarter despite absorbing much larger negative impacts from foreign exchange.

Moving on to financial guidance for new Pfizer and Upjohn. Both of the changes we made for total Pfizer guidance this quarter are reflected in the updates you see here to our new Pfizer financial guidance. On the Upjohn side, all financial guidance components are being reaffirmed, reflecting that the performance of that business continues to track in line with our expectations.

Moving on to key takeaways. In the second quarter, our company performed well, driven by the strong 6% operational revenue growth from our Biopharma business. We raised our 2020 total company and new Pfizer guidance ranges for revenues and adjusted diluted EPS, and we reaffirmed all of the components of our financial guidance, including all guidance ranges for our Upjohn business.

We raised sufficient funding through our Upjohn subsidiary to satisfy the $12 billion dividend to be paid to Pfizer upon the close of the combination of Upjohn with Mylan, which is expected to occur in the fourth quarter. We also achieved multiple product and pipeline milestones since our last quarterly update, some of which are listed here. A more complete listing can be found in this morning's press release.

Finally, we paid $4.2 billion in dividends to our shareholders in the first half of this year. As always, we remain committed to delivering attractive shareholder returns in 2020 and beyond.

Now I'll turn it back to Chuck.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Thank you, Frank. Operator, can we now please start to poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Steve Scala from Cowen.

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

One for Frank. Pfizer delivered a much stronger quarter while some peers, including Novartis and Roche, were not as strong, yet the businesses are not that different. To what do you attribute the disparity that we're seeing in the industry? Is it product portfolio or cycle? Is it geography or is it execution? And then maybe for Mikael regarding the COVID-19 vaccine, can you elaborate on the immunogenicity and safety in older adults that was touched upon in the press release?

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

Thank you, Steve. Frank, why don't you take the first question? And maybe, Angela, also you can chime in and then if -- Mikael will answer the COVID question. Frank?

Frank A. D'Amelio - *Pfizer Inc. - CFO & EVP of Global Supply & Business Operations*

Sure. So Steve, obviously, I can't comment on what some of our competitors printed for the quarter. But obviously, we had a strong quarter, and I think I can attribute it to, quite frankly, the excellent execution that we continue to deliver.

If you look at the Biopharma business, really strong strength across the portfolio, 6% operational growth, about $600 million in revenue, VYNDAQEL -- I'm rounding the numbers. VYNDAQEL was up $200 million, Eliquis was up $200 million, IBRANCE was up $100 million, Inlyta was up $100 million, so really, really strong performance. And by the way, overall, that's despite $500 million hit to revenue from COVID, $400 million of which was in our Biopharma business.

Then if you look at our spending, I think we've done a nice job on managing our spending. Obviously, we're getting some help from COVID, but if you look at the rest of the business, we continue to be disciplined on how we spend money. So I think all in, I think we're continuing to execute in a very effective way.

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

Angela?

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

Sure. Just to build up what Frank said, I think in addition to the execution, which was a critical element of this, we also have a product portfolio, which, in combination, really worked well together. As you said, there are parts of our portfolio that are similar to others, but this particular collection of disease areas is quite unique.

You have oncology and our internal medicine, cardiology business that did not have -- didn't feel and didn't experience the kind of downturn in new Rxs unlike some other portfolios. You had the hospital BU that pulled through. You had portfolios that are very much about continuing patients, the large base of patients that are continuing with their medicine. So I think that it really speaks to the strength and the diversity of this portfolio and the unique attributes that make it very resilient in a time like this.

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

Mikael?

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

Yes. Thank you for the questions. We are very pleased with our -- both actually the b1 and the b2 vaccine candidate. And as we know, we have selected b2 and now started dosing of patients in a late stage trial. We have started b2 in near 120 patients in the Phase 1. And for the specific questions on the older adults, we were very pleased with the safety and tolerability seen in older adults after both the first injection and the boost. In general, mild to moderate reactions whether locally or systemic and overall, a very stable tolerability profile.

We also reported neutralizing antibodies after the boost, day 28, that exceeded a panel of convalescent plasma, which was very rewarding to see. Finally, I want to punctuate that in addition to neutralizing antibodies, our mRNA vaccine also elicits potent antiviral T cell activation, including CD8 T cells that have been implied as key cellular mediator to control viral infection, including coronaviruses.

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

Thank you, Mikael. And Steve, I can't resist also adding that as you are looking at new Pfizer, what we are trying to build, a much more science-focused Pfizer, you will see 3 themes: excellence in execution, speed and agility. And you will see that across commercial with the results that you see; across R&D with our ability to advance a program like COVID, very complicated, in such a speed; and across manufacturing, where in the middle of a pandemic, we maintain all our operational units up and running. And we experienced virtually very, very little stock disruptions in a period that demand for some injectables went 5, 4, 6x up.

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 couple of questions, please. Long-term revenue guidance in the past, you've said at least 6% on a 5-year CAGR basis, and that excluded anything from COVID-19 in terms of vaccine contribution. Does that guidance still stand?

And then second question on IBRANCE. When we see full PALLAS results, will there be an obvious reason why the trial failed? Was it mostly a compliance issue, for example? If so, then it seems like docs would likely stick with the brand. But you could argue it the other way, too, which is your product, while it was first to market and the class is the only one that doesn't have a survival benefit in metastatic and in adjuvant, it didn't work. So I guess can you just kind of give us a little bit of insight into PALLAS results? And are you confident that IBRANCE remains a growth brand over time?

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

Yes. Let me answer the first one and then Mikael will speak about the PALLAS. The answer is absolutely. It is not 6%, it is at least 6% and that we reiterate and we feel much stronger right now. And that excludes obviously any impact of COVID on the top line. And as I explained multiple times in investor events, the reason why our approximately 6% went to at least 6% while we lost PALLAS was because for PALLAS, we had $2 billion of revenues in our projections at 50% probability of success, so we lost $1 billion.

But at the same time, since we had given the 6%, we advanced -- we had successful Phase 3 study in adults, pneumococcal. We have successful POCs in multiple vaccines, which we advanced already right now to Phase 3. 3 vaccines, as I spoke, we advanced in Phase 3. We have Duchenne muscle dystrophy, positive POC. We have a lot of positive news that when we update the probability of success in our model, more than offset the PALLAS. And with that, I want to ask Mikael to comment on why he thinks PALLAS failed.

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

Yes. Thank you for the question. We are now analyzing data and details, looking at various sub-analysis and sensitivities. So it's still too early to have a view on what made this study not successful. And as Albert alluded to, IBRANCE has been and is a very strong brand in the metastatic setting. It has a favorable tolerability profile and is supported by a number of randomized controlled clinical studies.

And I wanted to just add that real-world data studies have also replicated a progression-free survival and added overall survival data using real-world evidence for IBRANCE in the metastatic setting. Now we'll continue to share with you the learnings we have. And of course, we have the PENELOPE-B study to read out, which we can't comment on. It includes a different patient type than in PALLAS.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Maybe Angela could add on the commercial front for IBRANCE?

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

Sure. Thanks, Chuck. Actually, we continue to see great opportunities in the metastatic indication for IBRANCE. As you can tell, we are firmly entrenched as a leader in metastatic. And even recent research that we conducted with our prescribers, our physician prescribers indicate that they see early treatment, so the early indication as well as metastatic indication quite differently, and that what is being used within each of these indications will have their own role.

So when you look at our market share, both in terms of in-line as well as across all the lines, after 5 years in the market, IBRANCE has consistently had dominant market share. So we come into this with a -- with confidence in owning metastatic.

But I think it's also important to remember the experience and the confidence that both prescribers and patients have in this -- the metastatic disease that has been established through time. And to build off of what Mikael said, we do have overall survival benefit. And we saw that in our real-world studies, and we're the only CDK inhibitor that has these real-world studies. And certainly, these studies will further strengthen our leadership in metastatic.

So I think on all accounts, when we look at where we are, the real-world data that we've generated, the experience as well as new data and new studies that are ongoing that demonstrate that patients can be retreated. So therefore, if you have already treated a patient early, you can -- with a different CDK, you can certainly retreat them again when they become metastatic with something like an IBRANCE. And so on all accounts, we continue to be very bullish about our position with IBRANCE in metastatic cancer, metastatic breast cancer.

Operator

Your next question comes from Vamil Divan from Mizuho Securities.

Vamil Kishore Divan - *Mizuho Securities USA LLC, Research Division - MD*

Just a couple, if I could, one on the vaccine. I'm just curious, I guess, for Mikael, based on what we know now, do you expect this COVID vaccine would be a recurring vaccine that people would take annually or to be just sort of 2 shots initially? And I guess the reason I'm asking is, when you think about sort of the longer-term outlook, I think a lot of people wanted a Pfizer outlook beyond 2026 when you start losing patent protection for some of your key products. Do you see this as potentially a meaningful contributor at that point in time? Or is it maybe more of an opportunity for the next 2 to 3 years?

And then my other question is just back on the Executive Orders. I appreciate the comments you made, Albert, in your prepared remarks. Just any -- I know there's supposed to be a meeting today potentially with the Trump administration to discuss the orders that was canceled. I'm wondering

if you have any insights you can share on that. Or are there any other plans to discuss the orders with the administration over the next month or so?

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

Yes. On the first question, Mikael can speak, but also, I think Angela can add how we see this evolution. So -- and then I will answer the second one. Mikael?

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

Yes. Thank you for the question. Of course, there is a lot of unknown here with a disease that has just been known to the medical community for maybe 6 months. But we have seen a dramatic expansion of the coronavirus SARS-CoV-2 across the globe, including appearance of new variants. So we look upon it as in 2 phases. The first one is the pandemic phase where, of course, coming with a safe, high-quality efficacious vaccine soon is important. And that's why we are so pleased to be able to announce, as we did yesterday, dosing of patients in our pivotal trial. And for that, a 2-shot vaccine is likely to give a protection if successful in the clinical study based on both antibody-mediated and cell-mediated, the CD8 T cells that seems to be important in protection against viruses.

Considering the -- beyond the pandemic phase, which may likely, at the global level, last a few years, it is hard to be certain about the future. But I do think there are scenarios which are very reasonable and we need to be prepared for, that COVID-19 has established itself as a prominent virus, as much circulating in society as flu. And as we will understand the -- how long-lasting the various vaccines are, it will allow us to better predict how often one should consider to reimmunize. A platform such as mRNA has the advantage that there is no anti-vector immunity and if needed, you could immunize annually every 2 years, every 4 years.

And I just wanted to add that beyond being a very important pillar in the future defense against COVID-19 and probably reasonable to assume that there will be other coronaviruses, as we have seen how they have accumulated in a recombined form in many different species, but this platform will be possible to also disrupt the flu market, novel vaccines against CMV and even to go into a novel age group of RSV. So we see a very large opportunity based on the leadership we have with this mRNA platform, particularly by being able to engage both neutralizing antibodies and antiviral CD8 cells. Angela?

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

Thanks, Mikael. So picking up on your -- the points about the 2 phases. Some additional comments on these 2 phases. I think when it comes to the pandemic phase, we're thinking about it from the perspective of the fact that it could last until the end of 2021 or into 2022 where high volumes of doses will need to be provided for mass vaccinations to take place, right? And so I think in this pandemic period, the way that we're thinking about it, and as you've seen, is that we're pricing the vaccine for broad access. Broad access is our main goal and making sure that we can supply it to multiple governments around the world.

After that, the next phase is a phase where we think it will become more standard, more seasonal, as you've described it, I think, where we anticipate that we will have to have continued vaccination for a number of years. And this is going to be important to create and maintain the herd immunity globally.

So in this time period, we anticipate to return to more regular supply channels and a more value-based pricing approach. So a combination of both of these 2 is how we see the next many years playing out.

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

Thank you, Angela, and thank you, Mikael. That was very comprehensive, I think. Now as regards to the Executive Orders, as I said, obviously, I was very disappointed to see those orders coming because I feel that they are coming at a period of time that this is not what is needed. This is a period of time that our scientists are working to develop a vaccine or a treatment, and our manufacturing workers are working day and night to maintain, under COVID conditions, supply of medicines and also provide additional supplies for this vaccine.

They should worry only about how to defeat this virus and how to maintain the supply and should not start worrying about their jobs. I think the timing was wrong. And I believe that there is a need for a dialogue so that we can move forward, like look backwards.

But clearly, there is a need for -- on the technical level first, to be an agreement. I don't think there is a need for, right now, for White House meetings. There is a need for people that they understand the topics from both sides, work to find solutions how we can decrease the contribution -- how can we decrease the out-of-pocket expense of the Americans that has gone to levels that they are unacceptable right now. This is the real problem and this is what we see that we need to reform.

Operator

Your next question comes from Randall Stanicky from RBC Capital Markets.

Randall S. Stanicky - *RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst*

Albert, I wanted to follow up on the last question. The vaccine opportunity could be a very big one but perhaps may not sell for the 2026 LOE and arguably could add to it. So as you think about business development priorities near term, has anything changed on that front? And when can we expect to see Pfizer get more active there?

And then the second question, just on the vaccine, how should we think about U.S. versus OUS pricing given that you disclosed the U.S. contract with the U.S. government, but we may not get color OUS?

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

Yes. Thank you. Very good questions, both of them. In our M&A strategy, nothing has changed. It is exactly what we have defined. We are in the street to be aggressive and deploy capital to license in or acquire early to mid-stage clinical projects that could become medicines in the years '23, '24, '25, '26, and then they can start picking their sales so that we can maintain post-'26 the 6% growth.

And that has not changed. We never say never to anything, particularly if people are asking if we want to do a big acquisition. We never say never to anything. And by the way, our firepower allows us to do vertically -- virtually anything that we could decide. But our strategic direction is clear, laser-focused on this area so that we can maintain the growth.

And we did have significant achievements in that front. I will mention to you the last 2 vaccines that we licensed in, which is the Lyme vaccine a few months ago and the COVID vaccine in our agreement with BioNTech. What was the second question?

Frank A. D'Amelio - *Pfizer Inc. - CFO & EVP of Global Supply & Business Operations*

It was U.S. pricing versus outside pricing for the vaccine.

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

Yes, yes. Why don't I let Angela answer the question on the U.S. pricing of the vaccine?

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

The pricing strategy for our vaccines is universal across the board. And it is based on volumes, advanced commitments, equity and affordability principles. So this agreement in the U.S. that you referred to relates to the first 100 million doses for which Pfizer will receive $1.95 billion, and this is assuming the regulatory approval or authorization. And if the government would like to purchase an additional 500 million doses, it would be at that same price and it's also subject to future mutual agreements.

Switching over to the EU or ex U.S., I think, was your other question, how we're thinking about that. Again, we're using the same pricing principles across the globe. And specifically, I won't be able to disclose to you the content of those confidential discussions. But again, the principles are the same. And because of that, no country in the developed world will receive doses at a lower price than the U.S. for similar volume commitments.

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

Yes. And I want to emphasize what Angela said in her statement that no country in the developed world, which means Europe, Japan, all the countries that are developed right now, will not receive a lower price for the same volume commitment than the U.S. But that, of course, excludes African countries or other countries that they don't have the means to pay over there. We may do exceptions and offer it to lower price. Thank you very much, Angela.

Operator

Your next question comes from Terence Flynn with Goldman Sachs.

Terence C. Flynn - *Goldman Sachs Group, Inc., Research Division - MD*

Congrats on all the progress of the vaccine. I guess this might be a question for Frank. Just wondering, based on the commentary in the press release versus what you guys outlined in the first quarter, it seems to suggest that maybe you're now assuming a somewhat more gradual recovery in the second half. Just wondering if I'm interpreting that correctly. And is that driven by global data points you guys are seeing? Or is that really a result of what's been going on in some states in the U.S.?

And then the second question relates to the Phase 3 COVID-19 vaccine program. Was just wondering if you can give any more details on the powering assumptions of the primary end point. And then also, you talk about the interim analyses. Any more details on that front?

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

Frank, go ahead, please.

Frank A. D'Amelio - *Pfizer Inc. - CFO & EVP of Global Supply & Business Operations*

Yes. So Terence, you're absolutely right. We talked about a gradual recovery in the quarter. And we're saying that in terms of patient visits to doctors, vaccination rates, elective surgeries, where we're expecting a gradual increase, a gradual improvement over Q2 levels beginning in Q3. Same thing with new-to-brand prescriptions, where we're expecting a gradual improvement over 2Q levels beginning in Q3. And then in the U.S., just a gradual improvement in terms of our reps visiting and getting to meet face-to-face with health care professionals.

So it's definitely a gradual improvement. That's an update from the language we put into Q1, and most importantly, all of which we have factored into the latest guidance that we provided to you all today for 2020. And that includes total company, new Pfizer and the Upjohn guidance that we provided.

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

Thank you very, very much, Frank. And Mikael, can you speak a little bit about our study design, the powering assumptions, interim analysis, et cetera?

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

Yes. Thank you for the question. So we started dosing yesterday in which will be 30,000 healthy adults aged 18 to 85. We have more than 30 states in U.S. picked in areas that will contribute to both enrollment as well as event rate, and that is supplemented by South America and Europe sites.

When it comes to how the study will be executed, it is currently assumed that we will have sufficient number of individuals enrolled by early September to allow several interim analysis to support potential filing that could start in September or in October, depending on event rates as well as vaccine efficacy. And at this time point, I think I don't want to give more details.

The primary endpoint is efficacy against confirmed COVID-19 in participants without evidence of infection before vaccination as well as efficacy against confirmed COVID-19 participants with and without evidence of infection before vaccination. And we use PCR technology to confirm infection of SARS-CoV-2 as well as using antibody tests to confirm previous exposure.

So all in all, it's well-powered study to detect a meaningful vaccine efficacy, and interim analysis would lead to an opportunity to start planning for filing from September running into October. And this is, of course, pending our assumptions on event rate.

I want to say that our assumptions were made a few weeks ago, looking at incidence of disease in U.S. and elsewhere. And over the last few weeks, unfortunately, the incidence rate has made the disease even more prevalent. So if anything, we would expect on that planning to be able to hit event rates sooner rather than later, which is, of course, favorable for a potential filing of this vaccine September to October time frame.

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

Thank you very much, Mikael. And again, we said it very clearly in our press release. The study design has been discussed extensively with FDA, and we are following all the guidelines that FDA has put out there. And that should be the golden standard for anyone who is doing studies for COVID-19.

Operator

Your next question comes from Louise Chen from Cantor.

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

So my first question is basically, there have been some concerns that Pfizer could have a hard time meeting this 6% CAGR projection or at least 6% CAGR projection through 2025. What do you think the street is missing here?

And then at your upcoming Investor Day, on the R&D Day, what kind of new data and pipeline can we expect to see? And what do you hope to address, the key things that you want to address at this meeting?

And then last question I have for you is as you move towards being a biopharma pure play, what kind of margin expansion can we expect to see over the next several years?

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

Yes. I will answer the 6%, and then I will ask John Young to speak a little bit what you should expect during the R&D Day. And then obviously, Frank can speak about the margin expansions.

Now, as I said, the 6% CAGR, we feel very, very strongly about it. And I don't think that the time horizon on this call will allow me to speak about the entry that we have in our models that I don't see, frankly, in most of the analyst expectations, but let me try.

Let's start with the vaccines because it's so much into the -- right now, it's so much data and it's so much into the news. I think that the analysts are having, as appropriately, expectations for pneumococcal 20 as we do. But I haven't seen anyone having anything about Clostridium difficile, which is running a Phase 3 study and is expected to read out, I think, late this year or beginning -- I think later in the year.

I don't think anyone has anything about RSV that has started a pivotal study. I don't think that anybody has anything about pentavalent meningococcal that has started a pivotal study. I don't think anyone has anything about the Lyme vaccine, but it is in Phase 2 study and is progressing, and it is -- all of that are vaccines that are -- there is no basically a similar vaccine in development. You can say pneumococcal 20 has a competing pneumococcal 15. But the rest, I don't think anything like that.

We have right now, together with COVID, 7 vaccines in the clinic, 7, right? Let's go now through rare diseases. I think everybody is putting some revenues on the VYNDAQEL and rightly so. But I don't think anyone is having anything about our gene therapy platform, almost nothing.

And there is that one, which is the one that we're discussing recently because we had data releases like the Duchenne muscle dystrophy. There are others that are coming sooner to the market like hemophilia A or hemophilia B. And these are very, very big markets, and we're having very, very strong data, so significant probability that we will be successful. I don't think anyone is factoring anything there. And also, some smaller products, but altogether, they have a contribution like the hemophilia, the pan-hemophilia product, TFPI and also about the growth hormone. I don't think anyone is factoring anything there.

When you go to internal medicines, I don't think anyone is factoring anything. And we have been able to present recently very good data from our NASH portfolio that's progressing very nicely, but also the GLP, which could be a tremendous opportunity to move, and I can go on and on.

So there is a lot of standard -- I think right now, people are not modeling. And that could explain why people -- some of the people are maybe factoring that the 6%, I don't know, it's 4% or 5%. But I don't think anything -- anywhere, when I see the analyst expectations, there's a very big discrepancy between the 6%.

But I think that as we have proven to all of you and to the market our ability to execute on these studies and as we start having readouts, I think people will see it and will assign the right value. With that being said, a good way to do that, it is to have a good discussion with you during the Investor Day. And I will ask John to discuss with us what shall we expect to see that day.

John D. Young - *Pfizer Inc. - Group President & Chief Business Officer*

Thanks, Albert, and thanks for the question, Louise. So I think Albert's just given you some great highlights of some of the programs that -- in our pipeline that we believe are potentially underappreciated and maybe haven't been as visible to the analyst community. So our goal for the Investor Day is that we really want to highlight what we are very excited about in terms of the strong capability and the productivity of our R&D organization. We're going to provide an update on each of our 5 core R&D-driven business units in our pipeline.

And I think we feel this is exactly the right time to do that with the announcement of the Upjohn transaction and our pipeline, as Albert has just commented, really being stronger than it's been in years. We really do feel this is a perfect time to share the excitement about Pfizer's profile as a leading pure-play, innovative biopharmaceutical company.

So I won't repeat the detail that Albert has gone through, but I would just say that we'll focus the day on programs that we expect to launch by 2025, 2026, programs that the analyst community are generally not currently modeling in their valuations and some programs where there's new data. So I expect that we'll be able to shed some light on several pipeline opportunities that we see as promising and certainly including some of the specific programs that Albert has mentioned.

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

Thank you very, very much, John. And of course, also, the unique thing with this day is that we will try to also present the people behind this success. So we will give you visibility to our scientists and the commercial people that are driving each one of these units. Frank, can you please answer the question on the margin?

Frank A. D'Amelio - *Pfizer Inc. - CFO & EVP of Global Supply & Business Operations*

Sure. So Louise, let me just start with what's in the release, which is if you look at our guidance for new Pfizer, one of the things we say is 37%, we call it IBT adjusted margin. Now just to refresh everyone's memory, IBT is income before taxes. But in Pfizer, that's basically operating income, and then it includes other income because we have significant equity income coming into that line item from the Consumer joint venture.

So now with that as framing, the way I think about this is we grow the top line, to Albert's point, at least 6% on a CAGR basis through 2025. We will leverage that to the bottom line. So we're growing -- when we're growing the top line of at least 6%, we're going to clearly have operating income that's growing at a rate that's greater than that.

We also believe -- I also believe there's opportunities to be more efficient in our SI&A spend so that, that 37%, what we'd like to do, what we expect to do is to see that go from 37% into the higher 30s, so 38%, 39%. And then ultimately, I'd like to see that begin with a 4. That's how we think about it.

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

Thank you, Frank. And I realized as I was trying to save some time that I didn't speak about oncology and immune inflammation in things that the analysts are not modeling and -- because I may get into trouble with the people of this unit.

About immune inflammation, I think a lot of analysts are modeling the abrocitinib. But I don't think that anybody is modeling all the rest of the JAK portfolio. Right now, we have 5 new molecular entities that we are trying in 10 different indications and that was by design. Our strategy was very different than the strategy of other companies that usually, they try for efficiency to select the best target and develop it for everything.

What we did, we selected the best target for a specific disease because different drugs or different molecules, they respond very differently if the disease is on the skin or on the gut or on the -- or if it is an arthritis. So this strategy now is about to start giving significant readouts for all the other molecules that are coming.

And of course, in oncology, in addition to the work that is happening in new model CDKs and resistance to cancer from our La Jolla group -- don't forget the acquisition of Array, that is the Boulder, Pfizer Boulder, we call it right now, that they are an extremely productive group, that they are -- keep providing with new leads, and we're expecting to have, in the clinic from this group, 1 to likely 2 new molecules every month. So -- sorry, it was a long answer, but it's a long list.

Operator

Your next question comes from Chris Schott from JPMorgan.

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

My first one was just coming back to COVID vaccine pricing. I guess my question is, do you see this initial $19.50 per dose pricing that we saw last week as a decent proxy for pricing over time? Or should we expect price to decline here as we think about a range of potential vaccines being developed and some of your competitors have maybe different pricing strategies coming to market?

And then my second question was kind of a bigger picture one here. It seems like you're running kind of an unprecedented development program with the COVID vaccines. To the extent this is successful, do you see an opportunity to apply some of these approaches to broader product development in an effort to maybe speed development timelines in areas of unmet need? I'm just trying to think here is like, is there some read across the rest of the portfolio to the extent that this study is successful?

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

Chris, in the interest of time, instead of asking Angela to answer the first question -- that it is -- the person that is managing. Look, it's -- the price that we have said in the U.S. is the price that basically is a good benchmark for this level of volumes that people will order. If they order less, the price would be higher. If they order more, it could be a little bit lower.

But this is a very good benchmark. And I don't think that this will change during the pandemic because irrelevant how many products will be -- it's not irrelevant, but I assume that -- and I hope that many vaccines will be registered and will make the cut. But still, the demand for 7.5 billion people will be very, very high. And so this, I think, will be maintained.

As Angela said in her answer, after the pandemic, which is, after we have this significant surge of volumes, demand for volumes now, which will take us all the way to '21, beginning maybe of '22, obviously, we could go to a much more normal type of situation where volumes will be much more normal and the price also will be based on the competition of the time and also will be based on the value that the product brings, which is not the case right now. Obviously, it is priced well, well, well below the value that it brings to society this product.

And as regard to your second question, instead of also moving to Mikael about -- can we use this platform? We can use this platform. Don't forget that we are working already 2 years for a flu vaccine by using the RNA platform. And already, Mikael spoke in his question that he sees, in an answer to a similar question before, that he sees multiple opportunities to use the platform in different type of diseases.

Operator

Your next question comes from Umer Raffat from Evercore.

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

I have 2, if I may. And perhaps first, Albert, I know Moderna's CEO said that he expects, based on his data, a 75% to 80% odds of clearing the Phase 3 bar set by FDA for the COVID vaccine. I'm curious...

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

Say it again. I'm not sure I -- can you say it again, what he said?

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

Sure, Albert. So Moderna's CEO believes the odds of clearing Phase 3 is 75% to 80% based on the data they've produced. Are you in the same ballpark based on the data you're seeing?

And one for Mikael, if I may. Mikael, in the press release last night where you decided to take the b2 vaccine construct to Phase 3 and not the previously published b1, what I noticed was the pivotal factor was perhaps that there were more spike-specific T cell epitopes being seen with this second construct.

Can you give us a little more specifics on that? And can you also speak to the fact that several studies are suggesting about half of T cell response could actually be on epitopes, which are beyond the spike in the first place?

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

Yes. Thank you very much, Umer. Look, I don't want myself to speculate now what is the probability that I see if the product will be successful. The study started and the only one that will tell us is the data readout. But I will share the optimism here because the data that we have seen so far are very, very, very strong. But again, there have been cases that you have very, very strong clinical data in the Phase 2, and the Phase 3, for some reason, doesn't work. But I think it's very high. I'm optimistic based on the data that I have seen so far, but we need to wait to see what the readout will be. And then Mikael can explain all the excellent questions that you asked.

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

Yes. Thank you, Albert. So I just want to say it was a great question. And as we said, we had 2 great vaccine candidates. And in the end, the data of totality favor the b2.

And the specific question around spike, yes, we detected a number of epitopes. In the spike, there's one fragment that contains RBD but also in the S2 fragment that's outside RBD. And we think there is a richness of T cell epitope for CD4 T cells and for CD8. I would like particularly to punctuate that the majority or the overwhelming use in the field of immunology is that to fight against viruses with immune system, you need neutralizing antibodies when the virus is outside the cell, but you need CD8 T cells to kill viral containing cells when the virus is hiding in the cell. And that was really part of our full platform.

And it's not just related to spike. It's related to how you construct the envelope, the lipid nanoparticles and how you modify the RNA. And we spent several years to get into that goal that's been associated, over a long time, a successful way of preventing viral infection by vaccination.

And I think we're on to something really unique in our platform here with that dual way of combating the infection. And of course, it also was related to really good tolerability, low dose, nice immune response in older and younger. So all of that, of course, gives us a lot of encouragement for moving forward here.

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Congrats on all of the positive update. So I have 2 questions on the COVID vaccine. First, should we expect to see primate data in coming weeks, which provide information on the durability of your vaccine after the second dose? The reason why I ask is, obviously, there's a need for a booster just 30 days after the first dose. So it would be helpful to better understand how durable the efficacy is post the second dose.

And second, with respect to your arrangements that you're -- that you booked with the U.S. government and that you plan to arrange with ex U.S. governments and entities, could you just discuss Pfizer's COVID vaccine liability shield expectations, specifically what the U.S. government can protect you against in the event that there are surprising adverse events down the line and then what you can arrange with ex U.S. entities?

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

Thank you, Dave. Very good questions, both of them. Mikael, can you please answer the question about when we can expect primate data, the durability? And by the way, our -- Dave, our booster is coming 21 days after the first dose. And then I will ask Doug Lankler to comment on the liabilities.

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

Yes. Thank you, Albert. Yes, the primate data, I think, have 2 key components. One is that we were able to show that there is no signs of any augmentation of a negative effect on disease outcome. On the contrary, we were able to show that our b1 and b2 were able to prevent disease in airways, including lung and also nose and that b2 was very effective in this, suggesting that we can protect the individuals that will be exposed to the virus and possibly, as it needs to be confirmed in humans, also reduce the risk of spreading the virus.

It still will be a bit too early to have a lot of data on durability. We are following it in animals and in humans. And we have seen so far that the neutralizing antibodies actually tend to rise even though the total number of antibodies tend to stabilize at some level. And that suggests that we actually continue to evolve a new response with more potent binding antibodies.

I want to just also add that when it comes to durability, Dave, if you look in the literature, in general, antibody durability after vaccination can last quite some time. But the really long-lasting durability is in the T cell compartment. And for viral disease, particularly CD8-positive cytotoxic cells, they have been detected 10 years or more after SARS-CoV-1.

And then finally, while we will monitor durability, of course, in the human study for several years, our platform has the advantage that we can easily boost at an appropriate time point with no anti-vector immunity, and we are likely to boost those antibodies and T cells. And that's, of course, different from a lot of adenovirus platforms that have difficulty to boost even one time. And we tried all of the platforms, whether viral platforms, protein-based and mRNA and for a pandemic of this, we selected a construct based on a large number of knowledge and experience cross platform and cross constant. Thank you.

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

Thank you, Mikael. Doug?

Douglas M. Lankler - *Pfizer Inc. - Executive VP & General Counsel*

Yes, thanks. In the U.S., we expect the PREP Act and the Vaccine Act are going to provide Pfizer broad protections against any personal injury claims that might come out of any type of problems from the vaccine or side effects or otherwise. We're pursuing similar liability protections outside the United States through contractual and/or legislative efforts, and we believe this is going to be manageable.

Operator

Your final question comes from the line of Geoffrey Porges from SVB Leerink.

Geoffrey Craig Porges - *SVB Leerink LLC, Research Division - Director of Therapeutics Research & Diversified Biopharma and Senior Research Analyst*

Just to follow up on the COVID pivotal trial over the next few months, could you clarify what you'll be telling us and when and then how that will affect the blinding and ultimately getting the full safety data for a full approval? It sounds as though, as we all know, you're going to get the number of events pretty quickly.

So will you communicate when the study is enrolled? Will you communicate the efficacy results at the interim to the extent that you hit the statistical endpoint? And then again, what effect will that have on the full safety data that presumably you still need to get to achieve full approval?

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

Yes. Just for the interest of time, Geoff, obviously, if we hit, in an interim approval, an effective -- the effectiveness endpoint, we will certainly communicate that. And then I'm not sure right now if we will provide regular updates as to how many have enrolled and when the enrollment is completed. As Mikael said, it's going to be a very rapid enrollment anyway.

So we plan by the end of August to have enrolled the majority of our 30,000 patients. And then the results could come, depends on the efficacy of the vaccine and depends also on the burden of the disease. From September to October, this is the current assumptions. And with that, we will make it known.

Obviously, we have done in the past ways that we can unblind data for FDA, and we can still maintain the blindness when the studies are continued because the studies anyway are planned to continue for 3 years that we are going to be monitoring our patients. So that's what I can give you right now.

Let me then thank you all for joining us today and for your continued engagement with Pfizer. I really enjoyed this earnings call, very strong operational performance. So very, very few questions on products and a lot of questions that dominated the call on our pipeline, of course, with, number one, COVID-19 because this is a tremendous opportunity for the world to be able to bring an effective and safe vaccine.

As you have heard, our key in-market medicines remain strong, our pipeline remain robust and we remain fully confident in the potential of the long-term growth strategy to yield at least 6% CAGR through 2025 following the completion of the pending Upjohn/Mylan combination.

We discussed a lot about our hard work to combat COVID-19, and we have been very encouraged by the early data of our mRNA-based vaccine program with BioNTech. My heartfelt thanks go out to all the colleagues at both companies who are working tirelessly to find medical solutions to this global pandemic. And because of their efforts, I'm confident to say that science will win. Have a rest of the day -- a great rest of your day.

Operator

Ladies and gentlemen, this does conclude Pfizer's Second Quarter 2020 Earnings Conference Call. You may now disconnect.

Forward-Looking Statements

This communication contains “forward-looking statements”. Such forward-looking statements may include, without limitation, statements about the proposed combination of Upjohn Inc. (“Newco”) and Mylan, which will immediately follow the proposed separation of the Upjohn business (the “Upjohn Business”) from Pfizer Inc. (“Pfizer”) (the “proposed transaction”), the expected timetable for completing the proposed transaction, the benefits and synergies of the proposed transaction, future opportunities for the combined company and products and any other statements regarding Pfizer’s, Mylan’s, the Upjohn Business’s or the combined company’s future operations, financial or operating results, capital allocation, dividend policy, debt ratio, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competitions, and other expectations and targets for future periods. Forward looking statements may often be identified by the use of words such as “will”, “may”, “could”, “should”, “would”, “project”, “believe”, “anticipate”, “expect”, “plan”, “estimate”, “forecast”, “potential”, “pipeline”, “intend”, “continue”, “target”, “seek” and variations of these words or comparable words. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: ongoing challenges and uncertainties posed by the COVID-19 pandemic for businesses and governments around the world; the parties’ ability to meet expectations regarding the timing, completion and accounting and tax treatments of the proposed transaction; changes in relevant tax and other laws; the parties’ ability to consummate the proposed transaction; the conditions to the completion of the proposed transaction not being satisfied or waived on the anticipated timeframe or at all; the regulatory approvals required for the proposed transaction not being obtained on the terms expected or on the anticipated schedule or at all; inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements and the providing of estimates of financial measures, in accordance with U.S. GAAP and related standards or on an adjusted basis; the integration of Mylan and the Upjohn Business being more difficult, time consuming or costly than expected; Mylan’s, the Upjohn Business’s and the combined company’s failure to achieve expected or targeted future financial and operating performance and results; the possibility that the combined company may be unable to achieve expected benefits, synergies and operating efficiencies in connection with the proposed transaction within the expected time frames or at all or to successfully integrate Mylan and the Upjohn Business; customer loss and business disruption being greater than expected following the proposed transaction; the retention of key employees being more difficult following the proposed transaction; Mylan’s, the Upjohn Business’s or the combined company’s liquidity, capital resources and ability to obtain financing; any regulatory, legal or other impediments to Mylan’s, the Upjohn Business’s or the combined company’s ability to bring new products to market, including but not limited to where Mylan, the Upjohn Business or the combined company uses its business judgment and decides to manufacture, market and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an “at-risk launch”); success of clinical trials and Mylan’s,

the Upjohn Business's or the combined company's ability to execute on new product opportunities; any changes in or difficulties with Mylan's, the Upjohn Business's or the combined company's manufacturing facilities, including with respect to remediation and restructuring activities, supply chain or inventory or the ability to meet anticipated demand; the scope, timing and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on Mylan's, the Upjohn Business's or the combined company's consolidated financial condition, results of operations and/or cash flows; Mylan's, the Upjohn Business's and the combined company's ability to protect their respective intellectual property and preserve their respective intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; actions and decisions of healthcare and pharmaceutical regulators; the impacts of competition; changes in the economic and financial conditions of the Upjohn Business or the business of Mylan or the combined company; the impact of outbreaks, epidemics or pandemics, such as the COVID-19 pandemic; uncertainties regarding future demand, pricing and reimbursement for Mylan's, the Upjohn Business's or the combined company's products; and uncertainties and matters beyond the control of management and other factors described under "Risk Factors" in each of Pfizer's, Newco's and Mylan's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission ("SEC"). These risks, as well as other risks associated with Mylan, the Upjohn Business, the combined company and the proposed transaction are also more fully discussed in the Registration Statement on Form S-4, as amended, which includes a proxy statement/prospectus (as amended, the "Form S-4"), which was filed by Newco with the SEC on October 25, 2019 and declared effective by the SEC on February 13, 2020, the Registration Statement on Form 10, which includes an information statement (the "Form 10"), which was filed by Newco with the SEC on June 12, 2020 and declared effective by the SEC on June 30, 2020, a definitive proxy statement, which was filed by Mylan with the SEC on February 13, 2020 (the "Proxy Statement"), and a prospectus, which was filed by Newco with the SEC on February 13, 2020 (the "Prospectus"). You can access Pfizer's, Mylan's and Newco's filings with the SEC through the SEC website at www.sec.gov or through Pfizer's or Mylan's website, as applicable, and Pfizer and Mylan strongly encourage you to do so. Except as required by applicable law, Pfizer, Mylan and Newco undertake no obligation to update any statements herein for revisions or changes after this communication is made.

Additional Information and Where to Find It

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended. In connection with the proposed transaction, Newco and Mylan have filed certain materials with the SEC, including, among other materials, the Form S-4, Form 10 and Prospectus filed by Newco

and the Proxy Statement filed by Mylan. The Form S-4 was declared effective on February 13, 2020 and the Proxy Statement and the Prospectus were first mailed to shareholders of Mylan on or about February 14, 2020 to seek approval of the proposed transaction. The Form 10 was declared effective on June 30, 2020. Newco and Mylan intend to file additional relevant materials with the SEC in connection with the proposed transaction. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYLAN, NEWCO AND THE PROPOSED TRANSACTION. The documents relating to the proposed transaction (when they are available) can be obtained free of charge from the SEC's website at www.sec.gov. These documents (when they are available) can also be obtained free of charge from Mylan, upon written request to Mylan or by contacting Mylan at (724) 514-1813 or investor.relations@mylan.com or from Pfizer on Pfizer's internet website at https://investors.Pfizer.com/financials/sec-filings/default.aspx or by contacting Pfizer's Investor Relations Department at (212) 733-2323, as applicable.