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EDITED TRANSCRIPT

PFE.N - Q3 2020 Pfizer Inc Earnings Call

EVENT DATE/TIME: OCTOBER 27, 2020 / 2:00PM GMT

OVERVIEW:

Co. reported 3Q20 results.

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Third 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 third quarter 2020 financial results, our updated 2020 financial guidance, Pfizer's role 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, Dr. Albert Bourla; Frank D'Amelio, our CFO; and Mikael Dolsten, our Chief Scientific Officer and President of Worldwide Research Development and Medical; Angela Hwang, Group President, Pfizer Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler, our General Counsel.

The slides that will be presented during the call were posted to our website earlier this morning and are available at pfizer.com/investors.

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You'll see here on Slide 3 our disclaimer regarding forward-looking statements we will make during the call regarding, among other topics, our anticipated future operating and financial performance, business plans and prospects and expectations for our product pipeline and in-line products, which, of course, are subject to risks and uncertainties as well as the use of non-GAAP financial information. Additional information regarding these forward-looking statements and our non-GAAP financial measures is available in our earnings release, including under the Disclosure Notice section and under Risk Factors in our SEC reports 10-K and 10-Q. Forward-looking statements on this call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements.

Albert and Frank will now make prepared remarks, and then we'll move to a Q&A 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. A great day here in New York. During my remarks, I will discuss our strong third quarter business performance, speak to the progress we are making in the battle against COVID-19, provide an update on our pipeline and how it is setting us up for an anticipated period of sustained growth and briefly touch on the topic of affordable access to innovative medicines and vaccines.

Let's start with an update on our Biopharmaceutical Group. For the quarter, revenues in our Biopharma business grew 4% operationally, driven primarily by the ongoing strong performance of Vyndaqel/Vyndamax; growth from our leading portfolio of biosimilars; and the continued strength of key brands, including Eliquis, IBRANCE, Xeljanz, Inlyta and XTANDI. These results include an estimated unfavorable impact of approximately $400 million or 4% due to COVID-19. Year-to-date, through 3 quarters, the Biopharma business grew revenues by 7% operationally, which includes an estimated unfavorable impact of approximately $600 million or 2% due to COVID-19.

Our global Oncology business was particularly strong, up 18% operationally compared to the year ago quarter. Global IBRANCE revenues increased 6% operationally to approximately $1.4 billion in the quarter. In the U.S., IBRANCE revenues grew 9% in the quarter, and IBRANCE continues to be a leader in the CDK4/6 inhibitor class for metastatic breast cancer. In fact, more than 8 out of 10 patients in the U.S. who were prescribed a CDK4/6 inhibitor received IBRANCE.

These should serve as a testament to the continued benefit it delivers to patients as well as its overall clinical profile.

The international markets delivered robust 26% volume growth in the quarter. The volume growth was offset by price reductions in certain EU markets, which resulted in 1% operational revenue growth outside the U.S. The price reductions occurred last year as a result of the renegotiation of long-term agreements, and we expect the impact will continue through to the fourth quarter of 2020 when the price changes annualize.

While we were disappointed by the outcomes of the PALLAS and PENELOPE-B trials for 2 new combination therapies, we remain confident in IBRANCE's strong positioning and expected future performance for the currently approved treatment of metastatic breast cancer. This confidence is driven by data. In HR+ HER2-negative metastatic breast cancer, IBRANCE is supported by an extensive body of evidence, including strong clinical data, evidence from real-world analysis, over 5 years of using everyday clinical practice as well as by continued positive patient and physician experience.

For XTANDI, alliance revenues in the U.S. were up 18% for the quarter and when combined with our royalty income on ex U.S. sales totaled $374 million. Growth in the U.S. was driven by a continued increase in utilization in the metastatic and nonmetastatic castration-resistance and metastatic castration-sensitive prostate cancer indications. XTANDI continues to lead in new patient starts across all approved indications, which tends to be a very good leading indicator of future performance.

Global Inlyta revenues increased 41% operationally to $195 million during the quarter. In the U.S., Inlyta performance was driven by the strong uptake following last year's FDA approvals for 2 immune 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 55% operational growth.

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Now turning to certain key products from our other therapeutic categories. Eliquis has continued to deliver strong performance. Pfizer's 50% share of the global alliance revenues, including direct sales markets, was up 9% operationally to $1.1 billion in the third quarter. In the U.S., strong volume growth was partially offset by a lower net price due to an increased number of lives in the Medicare coverage gap and the expansion of that gap as well as unfavorable channel mix. VYNDAQEL and VYNDAMAX continued their very strong U.S. performance. Our disease awareness efforts helped drive the estimated diagnosis rate to more than 17% in the quarter and compared with only 1% to 2% prior to launch. At the end of the quarter, more than 17,500 patients have been diagnosed, more than 12,000 patients have been received a prescription and more than 7,300 patients have received the drug. For the quarter, we estimate the average number of patients in the U.S. taking VYNDAQEL was approximately 7,000. These numbers include patients who are receiving the drug at no cost through our patient assistance programs.

I will also point out that in Q3, we began to see a rebound from the slowdown in new diagnosis that we had expected and saw in Q2 due to stay-at-home orders, and we will continue to monitor.

Global Xeljanz revenues were up 10% operationally in the quarter to $654 million, primarily driven by 6% growth in the U.S. and 18% operational growth in international developed markets. The underlying prescription demand in the U.S. grew 13% compared with the third quarter of 2019. We have invested in formulary access in the U.S., which has played a vital role in enabling this volume growth.

Revenues from our global biosimilars portfolio grew 80% operationally to $424 million. This was driven primarily by our oncology biosimilars, which generated revenue of $261 million.

Global Prevnar 13 revenues were down 3% operationally to $1.5 billion. Revenues outside the U.S. grew 14% operationally, driven primarily by increased adult uptake in certain international markets, resulting from greater vaccine awareness arising from the COVID-19 pandemic, although we should note that Prevnar 13 is indicated for the prevention of pneumonia resulting from pneumococcal bacteria, not SARS-CoV-2, as well as continued strong pediatric uptake in China.

In the U.S., revenues were down 14%, primarily reflecting timing of government ordering patterns compared with last year and the impact of a shared clinical decision-making, adult recommendation, meaning the decision to vaccinate should be made at the individual level between health care providers and their patients. All of this was partially offset by the recovery of a portion of missed doses from second quarter.

Now a few words about Upjohn. Upjohn revenues totaled $1.9 billion in the quarter, down 18% operationally. The decline that was expected was driven primarily by 3 factors that we had anticipated: the significant volume declines for Lyrica in the U.S. due to multisource generic competition that began in July of 2019; lower revenues for Lipitor and Norvasc in China due to the impact of the volume-based procurement program, which was initially implemented in March 2019 and expanded nationwide in December 2019; and lower volume for Celebrex in Japan, resulting from generic competition, which began in June 2020. We continue to expect the closing of the Upjohn transaction with Mylan to occur this quarter.

Now I will turn to our R&D pipeline, beginning with an update on our COVID-19-related efforts. The global Phase 3 study for our mRNA vaccine candidate that we are developing with our partner, BioNTech, is ongoing at approximately 150 clinical sites around the world, including the United States, Germany, Turkey, Brazil, South Africa and Argentina. To date, the trial has enrolled more than 42,000 participants with nearly 36,000 of them having received their second dose. We expanded our initial planned enrollment in the study from 30,000 people to approximately 44,000 people. This has allowed us to include additional populations in our study, including people as young as 12 years old and people with chronic, stable HIV, hepatitis C and hepatitis B.

As we reiterated in an open letter, we may know whether or not the vaccine demonstrates efficacy soon. In case of a conclusive readout, positive or negative, we will inform the public as soon as we complete the necessary administrative work, which we estimate to be completed within 1 week from the time we know. I can say today that the Data Monitoring Committee has not been unblinded to efficacy data nor has it conducted any interim efficacy analyses to date. But I want to be clear that after today's earnings call, we do not intend to speak publicly about interim analyses until we have a conclusive readout from the Data Monitoring Committee.

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For Emergency Use Authorization in the U.S. for a potential COVID-19 vaccine, FDA is requiring that companies provide 2 months of safety data on half of the trial participants following the final dose of the vaccine. Based on our current trial enrollment and dosing pace, we estimate we will reach this milestone in the third week of November.

And finally, Pfizer has been investing at risk since the early days of the pandemic in an effort to perfect our manufacturing processes and rapidly build up capacity. We expect to have our manufacturing data ready for submission before the safety milestone is reached.

So assuming positive data, Pfizer will apply for Emergency Use Authorization in the U.S. soon after the safety milestone is achieved, which we expect to be in the third week of November.

Regarding our antiviral candidate, we believe this potential first-in-class protease inhibitor may give us the opportunity to demonstrate meaningful antiviral activity to help treat COVID-19 patients. We initiated a Phase 1b study in September, and we are planning a pivotal Phase 2/3 study start in late 2020, early 2021, with the hopes of submitting for approval in the second half of 2021.

Now let's look at some highlights from the rest of the pipeline, which continues to be one of Pfizer's great strengths. During our virtual Investor Day event in September, we presented data from our Phase 1b Duchenne muscular dystrophin gene therapy product. Since our update at Investor Day, we have dosed an additional boy at the high dose, bringing us to a total of 16 treated with a high dose and 19 boys treated overall. Importantly, no serious adverse events were observed among the 10 additional boys who were treated using a modified immunomodularity regimen and monitoring regimen. Additionally, on October 1, we received fast track designation from the FDA for this program. We plan to begin dosing participants in our Phase 3 clinical study before the end of the year.

On October 7, we, along with our partner, Sangamo, issued a joint press release to announce that we have dosed the first participant in the Phase 3 AFFINE study of SB-525, which is an investigational gene therapy for hemophilia A patients. The primary endpoint is impact on annual bleed rate through 12 months following treatment compared with factor VIII replenishment therapy collected in the Phase 3 lead-in study period.

On October 8, we issued a press release with our partner, OPKO, announcing that our Phase 3 randomized, multi-center, open-label, crossover study, evaluating somatrogon dosed once weekly in children 3 to less than 18 years of age with growth hormone deficiency met its primary endpoint of improved treatment burden compared to GENOTROPIN for injection administered once daily. No serious adverse events were reported. We plan to file our Biologics License Application with the FDA this quarter.

Our next-generation CDK inhibitor programs build on our IBRANCE leadership and our deep knowledge of metastatic breast cancer. Our CDK4 selective inhibitor has been shown preclinically to target CDK4 with more than 10x the potency of IBRANCE and without the neutropenia sometimes seen with CDK6 inhibition. This improved therapeutic index may provide more opportunity for potential safe combination treatments in breast and other cancer types. Our CDK2 selective inhibitor has been shown in preclinical models to combine with IBRANCE to prevent or overcome resistance in HR+ breast cancer and has the potential to drive efficacy in a variety of tumors, including CDK2 activation, especially in combination with standard of care therapies. Because of these strong preclinical results, we have started dosing patients in Phase 1 studies for these 2 programs, for both.

Our BCMA/CD3 bispecific monoclonal antibody generated Phase 1 data supporting a strong clinical signal of efficacy, with very high response rate in heavily pretreated multiple myeloma patients. We plan to soon expand the program into a pivotal study and multiple clinical drug combination projects.

Our new drug application for abrocitinib for the treatment of moderate to severe atopic dermatitis in patients age 12 years old and up has been accepted by the FDA, with a priority review PDUFA day in April of 2021. Additionally, the European Medicines Agency has validated for review the marketing authorization application. Our Phase 3 clinical trial program has shown that abrocitinib demonstrated statistically superior improvements in skin clearance, disease extent and severity as well as improvements in itch versus placebo.

Lastly, our partner, Valneva, announced positive initial results for its second Phase 2 study of Lyme disease vaccine candidate, VLA15. Compared with the first study, which had a dose schedule of months 0, 1 and 2, this study investigated the vaccination schedule of the months 0, 2 and 6

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based on matching doses. The VLA15 vaccine candidate displayed an encouraging immune response profile, with seroconversion rates of greater than 90%, including in older adults and the serum bactericidal assay demonstrated antibodies were induced against all studied serotypes. VLA15 was found to be generally well tolerated across all doses and age groups tested. And the tolerability profile, including fever rates, were comparable to other lipidated recombinant vaccines or lipid-containing formulations combinations. Most important, no related serious adverse events were observed in any treatment group.

Given these 2 positive Phase 2 studies, we feel increasingly confident about this Lyme vaccine candidate and are eagerly awaiting the final Phase 2 study to define Phase 3 dosing regimen, followed by an expected pivotal event study.

As you know, following the expected closing of the Upjohn-Mylan transaction, Pfizer will be a smaller but focused and innovative biopharma company. Following the Upjohn separation, we expect a 5-year revenue CAGR of at least 6% on a risk-adjusted basis and continued growth beyond that time frame from the next wave of our patent-protected portfolio.

Our adjusted EPS during that same 5-year period is expected to grow approximately 10%. I would remind you that these projections exclude any potential impact from our COVID vaccine and antiviral programs. We believe that during our Investor Day, we provided a clear path to this growth projection. In fact, we indicated that by 2025, we need only about 40% of our non-risk-adjusted projected pipeline revenue to achieve the expected 6% 5-year CAGR, so we believe we have a very good safe margin of error.

Abrocitinib is the one potential near-term compound where we see the biggest difference compared with consensus. We see abrocitinib, and JAKs in general, serving to increase the number of patients treated, and that this is not a zero-sum game with the biologics in the treatment of moderate to severe atopic dermatitis.

Lastly, we are finalizing our enabling functions review and related actions, and we expect the anticipated financial benefits from these actions to begin being realized in 2021.

Before I close, I want to say a few words about affordability. As we have said in the past, our breakthrough medicines and vaccines won't do anyone any good if people can't affordably access them. We are committed to working with both parties in Washington to put patients first. That means prioritizing policies that take aim at better aligning insurance design with patient needs, like reforming Medicare Part D to create an out-of-pocket cap and ensuring that rebates are passed on to patients instead of being kept by the middlemen. Regardless of what happens in November, we will be ready to take a seat at the table and play a constructive role in shaping the debate for the benefit of the patients.

Now I will turn it over to Frank.

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

Thanks, Albert. Good day, everyone. I know you've seen our release, so let me provide a few highlights regarding the quarterly financials.

Our Biopharma business, which will become new Pfizer following the close of the Upjohn transaction, generated $10.2 billion in revenue for the quarter, which represented 84% of total company revenue. On an operational basis, biopharma revenue grew 4% in the quarter and 7% for the first 9 months of the year. The 7% year-to-date operational revenue growth for Biopharma was driven by continued solid volume growth, and our price-to-volume mix was a 9% increase in volume and a 2% negative impact from price.

For Upjohn, although the year-over-year comparison is skewed again by the impact of generic Lyrica and changes in the China market, the business continues to perform in line with our expectations and assumptions already reflected in our Upjohn guidance for the year.

Now moving down the income statement. I'll touch quickly on gross margin, which saw a slight negative impact during the quarter, mainly driven by lower sales from Lyrica, Celebrex, Lipitor and Norvasc, which are all part of our Upjohn business, as well as some incremental costs due to COVID 19. There was some offset to this impact due to lower inventory write-offs compared to the year ago quarter.

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We had another quarter where we saw a significant year-over-year decline in adjusted SI&A expenses, which were down 10% operationally. There are 2 obvious factors at work here: the exclusion of Consumer Health expenses and lower selling expenses due to COVID; but also a third factor, which is a planned reduction in spending associated with our corporate-enabling functions. We're in the midst of aligning those functions to the new Pfizer structure, which will be a smaller and less complex organization. We are finalizing this initiative, and we'll be able to better quantify the expected financial benefit when we provide our 2021 financial guidance for new Pfizer.

Reported diluted EPS for the quarter was down significantly compared to the year ago quarter, mainly driven by the nonrecurrence of a onetime gain from the Consumer joint venture formation in the year ago quarter, and adjusted diluted EPS was down 3% compared to the prior year quarter. Excluding the $0.02 negative impact of foreign exchange rates in the period, adjusted diluted EPS was $0.01 lower compared to the prior year. Foreign exchange also negatively impacted revenues in the quarter by about $100 million or 1%.

Consistent with last quarter, we are providing 3 sets of financial guidance, a few points here regarding our assumptions. The guidance continues to only include the at-risk spending on our COVID vaccine candidate but does not include any potential revenue we may receive this year if the vaccine is authorized and we deliver doses to various governments where we have agreements.

In terms of our broader COVID-related assumptions, we expect the gradual recovery in health care activity for the remainder of the year. I'd also note that upon the closing of the Upjohn transaction, we will treat the Upjohn business as a discontinued operation. So assuming the completion of the Upjohn transaction before December 31, the financial guidance we are providing will not be aligned with the ultimate numbers we print for the year. I'll start by saying there were no changes made to either the new Pfizer or Upjohn 2020 guidance factors and only slight refinements to Total Company guidance.

For Total Company, we are tightening our guidance range for revenues, which results in a small decrease in our midpoint, and this is mainly a factor of reducing the top end of the range as opposed to a change in our forecast. COGS as a percentage of revenue is slightly increased, mainly due to COVID-related costs, while the SI&A range is lowered a bit at the midpoint, mainly COVID and enabling function-driven and R&D increases slightly, mainly due to additional COVID program spending. This nets out to a slight increase in the midpoint of our adjusted diluted EPS range.

Moving on to financial guidance for new Pfizer and Upjohn, which is shown here. As I referenced, we are not making any changes to either new Pfizer or to Upjohn.

Moving on to key takeaways. In the third quarter, our company performed well, driven by strong revenue growth from our Biopharma business. We narrowed ranges for our 2020 Total Company guidance for revenues, cost of sales, SI&A, R&D and adjusted diluted EPS. And we reaffirmed our existing guidance components for both new Pfizer and Upjohn. 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 $6.3 billion to our shareholders in the first 9 months of this year. As always, we remain committed to delivering attractive shareholder returns in 2020 and beyond.

Now I'll turn it back over to Chuck.

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

Great. Thank you, Frank and Albert, for the prepared remarks. So time now to start our Q&A session. And operator, can I ask you to please poll for the questions?

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QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Umer Raffat from Evercore.

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

I know there's a ton of questions that everyone has, but let me just ask one, Albert, for all the generalist investors listening in, which I think all the specialists understand, but can you just remind everyone that -- how a blinded trial works and whether -- and how you guys don't have, I think, visibility on where the trial is tracking for the generalists?

But let me get to my question now. In your trial, the definition of a positive COVID revolves around 1 general symptom and 1 positive PCR. However, the general symptoms could be very broad. So I guess my question is the fact that there wasn't any sterilizing immunity in the nonhuman primates, isn't it reasonable to assume that we could see some positive PCRs on vaccine, even though there's a good amount of neutralizing titers? And if you could remind us, what's the cycle threshold for PCR you're using.

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

Thank you, Umer, and I will ask Mikael to comment on that, just a couple of words before. A study usually -- a pivotal study needs to be blinded, so nobody knows who has received the vaccine or the placebo. That includes the doctor or the nurse that administer the vaccine or the patient who is receiving it. And of course, all are going to the database and that is locked with a code, so no one can have access from the Pfizer, except a very small team that it is protected with Chinese walls.

And of course, the DMC is going to -- is receiving periodically information unblinded, but not -- they didn't start yet. So the Data Monitor Committee is -- it's composed by independent experts, but they haven't seen any unblinded data yet, and they haven't performed any analysis -- interim analysis yet.

And with that, I will ask Mikael to speak a little bit about the specific technical question.

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

Yes. Thank you for the question. So Umer, we have, as you know, 2 primary endpoints. The first relates to impact of naive patients to the first infection, and the second one relates to the same but also adding reinfection in those that were previously infected with SARS-CoV-2. We use PCR machines on a commercial platform that we have thoroughly validated and feel very comfortable with and use established criteria for positive cases.

The central read in our large laboratory is the crucial one here. We are also able, at the end of the study, to look at patients that did not develop symptoms since, as you said, we are particularly focused on illness cases. So we use a serology test for the nucleocapsid protein that allow us also to look at impact at the end of the trial for patients that were asymptomatic.

The symptom in the scale that we use was established in consultation with many KOL and FDA, but we also have secondary endpoint that uses CDC's symptom scale. So I think, hopefully, that covered many aspects of your questions.

Operator

The next question comes from the line of Vamil Divan from Mizuho.

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

Great. So maybe one in Eliquis and then one back on the COVID-19 vaccine. So on Eliquis, I saw the commentary around the net price being lower due to coverage gap and also the channel mix. I'm wondering if you can maybe just sort of quantify that a little bit more for us and maybe any sort of sense of how we should think about the pricing dynamics of that product going forward just since it's obviously an important product for you guys.

And then on the COVID-19 vaccine, Albert, appreciate your comments today around communicating when you have specific information. I think one thing that's just sort of been a little bit confusing a bit more and maybe you're trying to address that now is the sort view of when you'll have conclusive results on an interim analysis. And so maybe can you just sort of talk to that or maybe Mikael can comment on some of the confidence you have that an interim analysis in this trial should be sufficient to show conclusive efficacy as opposed to waiting for the final results.

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

Yes. Thank you. I will ask Angela to speak about the Eliquis. Let me take first a little bit this COVID-19. Look, we are cautiously optimistic that we will have results and possibly an interim analysis. We never -- you never know before you have the final analysis. This cautious optimism is coming from the very strong immunogenicity data that we have, very strong neutralizing titers and a very strong T-cell response, including CD8, which is one of the important. But as I said, you never know until you have a study readout. And we have reached the last mile here, right, so we expect that these things will start coming soon. So let's all have the patience that's required for something so important for public health and global economy.

And with that, I will ask Angela to comment on Eliquis.

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

So thanks for the question. So this gross-to-net adjustment is clearly a key feature of Eliquis because of the large number of Medicare patients that we have. And every year, not only are there a different number or an increasing number of Medicare patients, but also there are changes in the coverage gap. And as we mentioned, the key change this time is the length of time that patients are in this catastrophic coverage gap, which is longer in Q3 of 2020 compared to Q3 of 2019 by about 25%, and this is sort of the level of impact that we saw this year.

And so obviously, this increases our expense and is the reason for the unfavorable impact. But hopefully that gives you some sense of what happened between Q3 of this year and Q3 of last year.

Operator

The next question is from Gregg Gilbert from Truist.

Gregory B. Gilbert - *Truist Securities, Inc., Research Division - Analyst*

First, Albert, you noted that there's still that gap on abrocitinib versus Street estimates and what the company sees. I was hoping you could provide a little more detail behind your bullish view beyond what you offered on the call about it not being a zero-sum game. And the second part of my question is, Albert, you've expressed a lot of confidence in Pfizer's ability to hit that revenue CAGR, and you did so again today without COVID and without deals. But how focused are you and the team on bringing in assets to buttress that growth and/or add growth drivers that come later in the decade?

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

Thank you very much. I will answer the second part, and then I will ask Angela, actually, to walk us through the abrocitinib projections that we are having.

We are very confident on the 6% CAGR. And I think we have broken it down to what we believe will take to reach there. Right now, if you take the middle point of our guidance with $41.6 billion, we will need additional $14 billion by 2025 to achieve 6% growth. We believe $8 billion are projected to come from our in-line portfolio, and we put that during our earnings release. So that means that we are having a $6 billion that need to come from our current pipeline. Based on our projections on the revenue, this requires only 40% adjustment. So $6 billion of the $15 billion that we are expecting to have non-risk adjusted in that year is a very good safety margin.

That being said, also, we generate a lot of cash, and we want to invest this cash. And right now, our business development strategy, it is to invest in something that we believe can generate significant value for the shareholders, and this is to our R&D machine, an R&D machine that has completely turned around its productivity and right now is having industry-leading metrics in the multiple fronts.

So our business development will be invested in Phase 2-, Phase 3-ready programs that could become medicines in the period of '23, '24, '25, '26. And those, from one hand, can enhance the 6% growth, but even more importantly, will allow us to maintain and sustain this growth beyond 2026.

So with that clarification, and thank you very much, Gregg, for the question, I would like to ask Angela to speak a little bit about abrocitinib.

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

Thank you, Albert, and thanks for the question and giving us the opportunity to follow up since our discussion during R&D Day. We are really excited about this opportunity, and we're enthusiastic about it because it is a condition that has a large number of patients, a significant unmet need. And both of these things is what we believe drives the size of opportunity for abro.

So let me unpack that a little bit. First of all, there are significant number of AD sufferers. Globally, there are 60 million AD sufferers age 12 and up, and 27 million of those are in the U.S. And just for a bit of context, that is 10x the number of RA sufferers today. Of those 60 million, only 7% of them today are being treated with a systemic agent. And so the systemic market opportunity has the real potential to more than double with the introduction of better systemic treatment because the patient need is just so high.

And let me just also put that in context with a market that we know very well today, which is psoriasis. The market for systemic in psoriasis doubled over the last 10 years, with the introduction of advanced systemic biologics and also, more recently, the IL inhibitors. So if we step back and take a look at those numbers, even at a modest 1% share of the 60 million patient population or if you think about the future systemic market, all I need is 8% of that systemic market for abro to reach a $3 billion revenue at peak.

And so when you think about all of that and think about the advanced systemic markets that are also in place today, of which there is just one, and 60% of those patients who are on this product are not reaching clear or almost clear skin at 16 weeks, it demonstrates that there really is a lot of room for additional systemic options. So to Albert's point earlier about the fact that this is not a zero-sum game, we don't see the opportunity for abro as only being about gaining market share from competitors. Actually, the way we see it is that it is an opportunity to grow the advanced systemic market through the introduction of excellent treatment options. And we believe that the differentiated profile that abro has will allow us to be a leader in this growing market.

And also, don't forget market development and creating new markets is a real sweet spot for Pfizer. So we are very excited about the launch and look forward to bringing this important medicine to the market.

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

Thanks, Angela. And Gregg, yes, just one comment on your second question about the deals. A reminder that Valneva in the Lyme disease vaccine area is going well. Arixa, a deal we just announced in the antibiotic segment. So clearly, Pfizer is still going to remain active in bringing in assets that can help bolster the long-term revenue growth of the company there.

Operator

Your next question comes from the line of Terence Flynn from Goldman Sachs.

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

Thanks again for all the work on the COVID treatment and vaccine front. I guess I know you can't provide a lot of commentary, but I think what people are trying to understand is just if there have been any changes to the mandate of the DMC with respect to some of the new FDA guidance, so regarding the timing of the interim efficacy analysis. So essentially, is the DMC mandated now to wait for either a certain number of severe cases that have to happen or 2 months of safety follow-up data to kind of, at that point, take a look at the efficacy basis because I think you guys have been pretty confident about reporting data in October -- by the end of October. And so just trying to understand kind of the timing of the analysis and maybe any new inputs there.

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

Thank you, Terence, and I understand how the whole world is looking for any possible information. And we try to make sure that we maintain a very responsible way of, from one hand, being transparent and, from the other hand, not feeding speculations.

So what I can tell you to your very specific question is, until now, as we are speaking of today, no, DMC has not been changed, their mandates. There have not been any changes like that. And I can still repeat that we haven't performed any interim analysis yet, and that we believe that the analysis will start soon on efficacy. And if the efficacy is positive or if the efficacy is negative, we will announce it. And that will happen a few days after the DMC announce that to us, which usually takes 5, 6, 7 days. And that, if it happens before the third week of November, which is very likely because, as I said, we are expecting it soon, a few days before the end of October -- a few days after the end of October, but if it happens before the 15th of November, we will announce it before the 15th of November. As I said, right now, no analysis has been performed. DMC is completely blinded in any data. Of course, we are completely blinded in any data. And once we have the conditions met, they will unblind their data, and they will start informing us.

So let's all be very patient. I know how much the stress levels are growing. I know how much a vaccine is needed for the world. We are seeing right now the worst fears that we've had before during -- before are becoming true. The COVID is coming back in Europe and the U.S. and globally, and we are working very diligently, very carefully to make sure that we will bring this project through the finish line.

Operator

Your next 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*

Albert, I'm sorry to keep pushing on this COVID readout, but you seem very bullish that you will have a positive efficacy readout, I think you've said by the end of October, and that you will disclose it. Now it's clear it will be within 5 to 7 days after that. So that suggests that you believe that you'll -- I think the hurdle for the first interim is something in the range of 75% to 80% efficacy. So is that your expectation?

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And then secondly, could you comment on the realistic timing for the first dosing given that the FDA has said, they need to convene an AdCom, presumably you also need to have an ACIP recommendation, then you need to distribute the vaccine. Can you comment on whether it's realistic in your planning right now that anyone will be vaccinated outside the clinical trial by year-end?

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

Thank you, Geoff. And no apologies are needed to be asked. I understand that this is very important for the whole world issue.

Let me clarify, I'm not bullish that the vaccine will work. I'm cautiously optimistic that the vaccine will work. What I said very clearly, it is that we may know by the end of October if it works or not. And I think -- I reiterate this statement today. It could be -- as I said, the October is not for us -- I know it's compared with the elections time. But for us, the elections is an artificial milestone. This is going to be not a Republican vaccine or a Democratic vaccine. That will be the vaccine for the citizens of the world, and this is how we see it. So I hope that it is going to be effective. I hope that it is going to be effective with very high protection ability, but we have to wait to see the results of the study.

Now when it comes to distribution, assuming we have positive data, assuming that means that we will be ready to apply in the U.S. for Emergency Use Authorization soon after we received the safety data, so the safety data are expected to mature in the third week of November. So let's say, we apply around that time, third, fourth week of November, then it is up to FDA to take as much time as they need to make the approval. It's not up to us, so I cannot comment on that. What I know it is -- but we will be ready with product available. Again, if all goes well, but we are very well undergoing through our plans. We will be ready to distribute an initial number of those. And I believe that in the U.S. that you are asking, we have a contract with the U.S. government that we should provide them 100 million doses by March, and we are feeling very good about our ability to do it. But also, there's a provision that we should provide 40 of this million doses in this year. So I think we should be able -- 30 million to 40 million to be able to provide if we receive approval and if the U.S. government distributes their vaccines.

Just to put things into perspective, let's say, 30 million doses, it's 15 million people. So if we make available in the U.S., the vaccine, that will be for 15 million people by the end of the year, which is a very small part of the population. So it's not going to be massively available. It's going to be targeted in its availability. As we move into the first months of 2021, then we are going to have much more massive distribution of the vaccine around the world. So I hope that helps put things into perspective. Again, thank you for the interest. We all keep our fingers crossed that science will win.

Operator

Your next question is from Louise Chen from Cantor.

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

First question I had was, is there any way to help us think through if you've reached these 32 events yet? I know there's a lot of investor interest here, so just trying to get as much color as we can. And then can you provide an update on how many actual doses of vaccine you've already manufactured? It sounds like you're obviously very positive on your goals here. And the last question is, will you continue to look at potential adjuvant opportunities for IBRANCE? Or are you really just going to focus on next-generation CDKs?

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

Again, let me take this question. So far, we have produced hundreds of thousands of those, and we are moving very rapidly with both sites to start initiating a much larger production. When it comes to thinking through, I don't think I can help you think more than what we have said so far. We are blinded, events will accumulate. We will unblind the data. DMC will tell us negative, positive or continue. If it is negative or positive, we will let you know. If it is -- and then if it is continue, we will continue until the next milestone is reached. There's nothing else to think. But as I said, we will start this process very soon.

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Now for IBRANCE, I'll ask Angela to comment.

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

So yes, thanks for the question on IBRANCE. In terms of our focus for IBRANCE, where we've been, as you know, is really looking at the early breast cancer indications, which disappointingly did not pan out for us in PALLAS and PENELOPE, so we are very much focused on metastatic breast cancer as our opportunity with IBRANCE. And here, we continue to feel really confident about what we've seen with our data as well as what we're seeing from a market share perspective, right?

So first-line use of CDK in metastatic breast cancer as a class, it's still only at 52%, but we have a long way to go in terms of our ability to grow this class. But actually, for IBRANCE itself, it has a very high market share, 87%, in fact. And we've had this leadership position in first-line treatment for many years. And in fact, since May, even post the announcement of the monarchE data, we have seen this consistent market share. So I think that our focus on metastatic breast cancer and our focus on growing the use of the CDK class in metastatic cancer will continue to provide us a tremendous amount of opportunity.

I think just as a follow-up to your question in terms of are there other ideas and other thoughts for IBRANCE, just to remind you that we do have still the PATINA trial that is ongoing, which will read out in the second half of 2022 for a different population, HR-positive and HER2-positive population. So it's a slightly different question, but really touches on additional expansion opportunities for IBRANCE.

Operator

Your next question is from Navin Jacob from UBS.

Navin Cyriac Jacob - *UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic*

And I will be very in line with my colleagues about questioning questions on the COVID vaccines. Maybe let me try this a different way. Versus your original assumptions when you were designing the trial and based on the literature and the data set -- data that are out there, not necessarily in the trial, but just from what you're seeing outside of the trial, how do you think the symptomatic rates for folks that are infected compared to when you originally designed the study? That's question number one.

And similarly, I suppose, also with infection rate itself, I think when you enhance the size of the study from 30,000 to 44,000 patients, one of the reasons -- rationale for increasing the size is because of what you deemed to be a slower infection rate. I'm wondering about that as well as the symptom rate relative to the original assumptions.

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

Thank you, Navin, and again, I understand the interest here. I don't want to comment much more. But what we see is our infection rates, that they're aligned with what we see in the country. That's not something to be a surprise because it's a large study that we try to position geographically in multiple sites that represent basically the country in the U.S. where we have the bulk of the patients.

The increase of 30,000 to 44,000, anyway, wouldn't make any difference in the early readouts. It would only make a difference because of the larger numbers at the very, very late readouts. So I don't think that was the reason, but we did it. It was mainly because we felt very good about the safety profile, so we started -- we opened our vaccination to kids of 16 years old in beginning, then we went to 12 years old, and then we went to people that they are suffering from HIV, from hepatitis B, from hepatitis C. So this is why. And also, we use it to improve the diversity of the study, which we have made it public, so it's very, very good right now. I feel very good about the diversity of our study.

So Navin, thanks for your question. Let's all keep our fingers crossed, but we will have positive readouts.

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Operator

Your next question is from Chris Schott from JPMorgan.

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

I guess my first was on abrocitinib and market development. I guess my question is, if I look at the RA situation, it took some time for the JAKs to gain traction. Obviously, now the class is doing really well. Do you expect a similar situation in AD? So launch that eventually gets very large, but maybe takes some time to build momentum? Or are there differences in this market that could allow for faster uptake here?

And then my second question was on VYNDAQEL and how we think about growth from here. Should we think about the ratio of diagnosed patients to those who receive drug to shrink significantly over time? Or should we think about there being a persistent gap between diagnosis rates and those who actually receive the product?

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

Yes. Excellent questions. Both, I think, are appropriate to be answered by Angela. So Angela, why don't you start with abrocitinib and how you think the market will evolve given the experience on RA and JAKs? And then, of course, in VYNDAQEL, what -- how that change between diagnosis and treatment can evolve over time.

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

Great. Thank you. I think in all the I&I areas, what we're dealing with here are very complex diseases, chronic diseases, where there is a tremendous amount of debilitation for our patients and a lot of suffering. So I think first and foremost, I think both RA and atopic derm share that. But maybe the difference that I see the greatest between the 2 is that RA is a pretty well-established disease for whom -- even at the time when we launched Xeljanz, right, there was a lot of treatment, there was a lot of biologics, there was not an oral, but there was a lot of biologics.

That, in fact, is quite different when we think about where we are with atopic derm in that, in the atopic derm today, there are just not great treatments. We talked earlier today about -- in the opening about the systemic treatment, right? There's a lot of use of steroids. There is a Dupixent that has been a great solution for many patients. But even with all of that, there's just not a lot of solutions at all. And today, there is still a high -- there is really a significant unmet need in terms of what patients are being able to do.

So I think with all market development, with all new treatments, it takes time for you to reach peak. But we believe that given the significant unmet need, and in particular, for atopic derm patients, where I think, typically, we've been focused on skin clearing, but what we also know for patients is that the #1 condition they're suffering from is psoriasis. And that when you have agents that can really resolve that and resolve that very quickly, it will open up opportunities that didn't previously exist before in AD.

So that's how I see the market. I think we're really excited about it. We see a great ability to really meet patient unmet needs, and that is going to drive our growth.

Your second question was around VYNDAQEL and how to think about diagnosis versus the people that receive the drug. And I think on this regard, what you should expect to see is there will be some gap, right? So between those who are diagnosed, there is always a difference between those that are diagnosed and those who are deemed eligible to receive treatment. And then there is a difference between -- or a gap, then the next step that you have to take is for those that are treated, how many of them actually get the prescription and receive a prescription.

And I think that actually, on that front, we've been doing rather well. This quarter, in Q3, 82% of those who were deemed treatment-eligible were able to receive a VYNDAQEL prescription. And that is, in fact, up from last quarter where it was actually 78% of those who were deemed eligible

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for treatment received a script. So the gap is not all that wide, and we've seen improvements from last quarter to this one. So I think along the entire patient funnel for VYNDAQEL, we have great opportunities to improve how the patient flows on diagnosis to treatment to receiving a script, receiving a script to actually getting the medicines in the hands through specialty pharmacy. It's still a new condition and one that's early in its launch, so I think that we have great opportunities to improve every step of the way.

Operator

Your next question comes from Steve Scala from Cowen.

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

Albert, with all due respect, could you please be absolutely clear whether the 32 events have been reached already? It seems that the answer is yes, Pfizer has the 32 events, otherwise I think you would say no.

And on to the DMD gene therapy, will Phase 3 start this year? And has Pfizer and FDA agreed on a potency assay?

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

Yes. Steve, I appreciate the curiosity and I appreciate the creativity, and everybody can try every possible angle, but I think I have answered this as fully as we are prepared. Now you used a very creative way of asking, so I will tell you clearly, no, we don't have the 32 events right now. So that's what I can say. So -- and I have to say, Chuck, can you remind me what was the second part of the question?

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

Yes, question was in DMD, has the FDA agreed on a potency assay.

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

Mikael, maybe you can take that?

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

Absolutely. I think, Steve, you first asked will Phase 3 start this year. We expect and I believe Phase 3 will start this year and relatively soon. As you know, the profile through modification of the steroid dose from 1 mg per kg to 2 mg per kg looks really great now. And Albert spoke in his introduction to the 19 treated boys, in which in the recent -- after the steroid change, we have had no cases with complement activation, so we're very excited about the current plan.

Now for the assay, yes, as part of our final protocol development with FDA, we changed from an initial inverted terminal repeat methodology to a transient method, as suggested by FDA, along with the weight of the patients to determine those. And that's all in place and made the initial dose of what was expressed as 3E14, go down to the 2E14. It's the very same dose that we use all the time. It's just that the different assay gives a different readout. But all of that is in place. We have a terrific technology platform that I think is the leading in this field, how to measure the various endpoints, including the concentration of the virus gene therapy.

Operator

Your next question comes from Tim Anderson from Wolfe Research.

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

I have a non-COVID question, which is following the initial news where you said you'd spin out Upjohn you described the company as likely to pay less of its free cash back to shareholders in the form of dividends and buybacks. And I'm wondering if that's still the current view, especially if you can achieve the revenue growth targets you've given of at least 6% over the next several years. And that question ties into another question on M&A. What's the upper limit on the size of the deals you might be considering? Should we assume these will likely be sub-$10 billion transactions? Or are larger deals also potentially on the table?

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

Thank you, Tim, for asking a non-COVID question. Appreciate it, really. And also, it came at the time that I thought Frank will not have a chance to speak, but now we are giving him the exact right forum. So Frank, take it from here.

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

Thank you, Albert. And Tim, thanks for the question. So on M&A, we always say, we never say never because one of the nice things about being part of Pfizer is we have the firepower to pretty much do any kind of a deal we want, and I think we've been able to demonstrate that in the past. So I wouldn't limit us or cap us on some specific dollar amount given the firepower that we have. Albert mentioned earlier, our focus has been mid-phase, Phase 2, Phase 3, kind of things that would impact our revenue base '24, '25, '26. But in terms of capacity, quite frankly, we're very much unlimited, strong balance sheet, strong capital structure, strong investment grade, we generate lots of operating cash flow. So we're in a very good position, quite frankly, to be very proactive as we need to be on M&A.

And then in terms of your Upjohn question. From my perspective, we get the Upjohn deal done, we form Viatris, we're going to get $12 billion in cash. Our intent with that $12 billion in cash is to pay down debt given we're transferring, give or take, about $4 billion of EBITDA to Upjohn. But our capital deployment priorities don't change as a result of that transaction. We'll still return capital to our shareholders as we have been doing. We'll continue to invest in the business and our pipeline, obviously, and capital, and then we'll continue to invest in M&A.

So from my perspective, capital priorities don't change. And in terms of M&A capacity, we're fortunate enough where we really have lots of capacity and lots of firepower.

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*

Great. Albert, you guys -- can you talk about the post EUA or post-approval plan around communicating safety data to the public on the -- your vaccine, just to get people more comfortable? Because one of the concerns is going to be the percent of people willing to take a vaccine earlier maybe lower than it had been in previous months. And obviously, those numbers should be higher to get the herd immunity.

And then a second question for Frank. Going back to the enabling-function costs, you guys called out in January, $4.5 billion there. Maybe just help frame that for us. How much of those savings have you already realized? How quickly can you realize additional savings in 2021? Just trying to understand the margin opportunity there.

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

Let me take the first before I pass it to Frank. And actually, I will ask the help of Angela here also in answering this question. I do see, because we are watching the polls and also I speak to people, my neighbors, my friends, and I do see that there is some skepticism that has been mainly because of the politicization of the vaccine. So this is real, and I think we need to address it. But we started addressing it long time back. We are doing for this disease -- for this vaccine things that we have never done before. And those are, first of all, things that have to do with transparency. We have published our protocol. We have -- we are publishing real-time our Phase 1 data so our community and the public, but also the other scientists and the other companies that are developing COVID vaccines can see them and learn from them.

We have announced the first readouts of our pivotal study, unblinded data, of course, on the safety. We signed a pledge but make very clear to the world that we are going to follow the high ethical and quality standards. And we will continue being very transparent and very quality science-driven, which I think it is the best way to overcome the public's opinion. So by the way, we didn't even take money from the government. So to make sure that Pfizer will stay out of the politics. And this vaccine at our risk, financial risk, would not be characterized as the Republican vaccine or the Democratic vaccine. It's not -- it is a vaccine for the world that we are developing.

Now going forward, I think we will do also -- will continue doing things. Our safety data, according to the FDA, will be reviewed publicly by an advisory committee, so that will be another additional good step. As for transparency, Angela, you want also to add a few things that we are planning to do?

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

Sure. Well, over and above what Albert said, obviously, having clear public education and a well-supported public education effort is going to be critical, right? We need to educate the public on the importance of actually getting the vaccine and then, of course, around the safety processes and creating confidence around the development process that has gone into developing these vaccines.

And so this happens sort of at 2 levels: first is about how Pfizer is working through intermediaries and opinion leaders to provide this education; and then secondly, what we can do ourselves. So on the first front, we have already been and are continuing our efforts to work with industry partners, patient organizations, government and other public health institutions to share with them our expertise so that they can create and build content and also deliver education as they need. So just as I said, this is well underway. There's a multichannel approach. That includes ETC, and these experts are already deploying a wide range of channels and forms of communication to educate and to educate specific communities.

On the other hand, for us, once we have authorization and once we have a label, we'll be able to do additional communication and more education around our vaccine, specifically. We also recognize that, of course, there are certain communities that have been -- minority communities specifically that have been more affected by this disease than others, so we're also supporting the development of specific content and education that can more effectively reach these communities and be more customized with sort of the approach and the content that we are sharing. So this is a very big effort that is already underway, and I think you're going to see more and more of this buildup towards the end of the year.

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

Thank you, Angela. And before I ask Frank to take the question about cost of enabling functions, I would like also, Mikael, to comment about our pharmacovigilance program that we have put in place and how that also could play a significant role in ensuring that the vaccine is safe. Mikael?

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

Thank you, Albert. So we have the pharmacovigilance platform in the industry that has experience to handle the largest number of the adverse event report by far. And we have started very proactively and been in open dialogue with the Operation Warp Speed and FDA about putting this pharmacovigilance platform to play -- to monitor sophisticated participant, whether viewing a potential EUA and later approval. And that includes

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building control cohorts already now for understanding continuous disease reporting of what we expect to be the first group of responders, such as health care workers and first-line responders.

We also recognize the big need for many stakeholders, from pharmacists, nurses, patients, physicians to have access to rapid information. We have a very strong medical information platform across the globe, and we have now augmented it both with staff and with self-serving WebEx platform to be able to respond to many aspects of how we store, distribute the vaccine and expected so far mild to moderate tolerability, et cetera, seen with this vaccine and similar vaccines. So I think we feel we are very well prepared for that.

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

Thank you, Mikael. Now Frank, back to you.

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

Yes. And Randall, the way I'll do this, let me run some numbers and provide some, I'll call it, financial context. And then I'll drill down, and I'll answer your question. So just first on SI&A, because you're talking about the enabling function, so on SI&A, for the quarter, we were $2.87 billion. We were down 10% year-over-year. It was really driven by 3 things: the Consumer separation, which was, give or take, about half the reduction; reduced spending in enabling functions; and some of it was COVID-driven. I called that out because a piece of that is enabling functions, which was probably what triggered the question.

Now let me run the overall numbers, and then I'll drill down and answer the question. So our previous guidance on SI&A for the year was $11.5 billion to $12.5 billion. We tightened the range to $11.5 billion to $12 billion, and that was really driven by COVID savings because, obviously, we knew about Consumer, we had enabling function spending already in our plan. So it was really driven primarily by COVID spending. Then of that $11.5 billion to $12 billion, I think $4 billion to $4.5 billion is the enabling functions, which is now getting to your question.

The way I think about this is you look at that $4 billion to $4.5 billion as an either/or, an expense-to-revenue ratio of the total company as it exists today and the new company, when we're a smaller company because of the revenues that move to Viatris. We want that expense-to-revenue ratio to be the same or less than what it currently is today. So that's kind of a simple way to think about how we're thinking about this and how we are planning in terms of what to do with our enabling functions.

Then the question you asked was, Frank -- you asked me a pacing question. In terms of '21, '22, we'll obviously go as fast as we can and get as much of it as we can into 2021. Obviously, some of it will fall into 2022 just because of the nature of some of the places where we do business, and certain things taking more time than others. And I'll provide more clarity on this when we provide our 2021 guidance, including the SI&A guidance on our next earnings call.

Operator

Your next question comes from Geoff Meacham from Bank of America.

Scott Daniel Puckhaber - *BofA Merrill Lynch, Research Division - VP*

This is Scott on for Geoff. You disclosed last quarter that the FDA indicated an AdCom meeting was not anticipated for tanezumab, but it seems like they want one now in March '21, so that will push out the December PDUFA. So what changed? And maybe you can give us some more insight into your discussions with the FDA. And then maybe as a follow-up, the assay itself wasn't highlighted as an assay with peak sales was from Investor Day. So what do you expect kind of internally peak sales upside to be here if you receive approval?

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

Angela, why don't you take those two? And then also maybe Mikael can comment later on the tanezumab and FDA, but you first, Angela.

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

Sure. So we are -- the tanezumab trial represents probably 1 of the biggest submissions that Pfizer has ever provided the FDA. Our data are extensive, and there's a lot to understand. So we're not surprised by the request to have an AdCom. And in fact, we're looking forward to having this opportunity to really review and to discuss what we have seen in our data and in our clinical trials and to discuss this opportunity with the advisory committee. So we see that as something that will create a good discussion.

In terms of the way to look at the opportunity, this is how we see it. This is really, like many conditions, but this one in particular, a significant unmet need in the treatment of osteoarthritis. There are about 27 million Americans that suffer from this, 11 million of whom have moderate to severe OA. And in the U.S., 80% of those moderate to severe OA patients have already trialed and tried and failed 3 or more analgesics. So we know that these patients are unable today to achieve adequate pain relief.

And so while there are options out there, what we also know is that the options are inadequate. And so when you look at the patient population that's ahead of us, the opportunity to provide a novel and a non-opioid form of pain relief, we think that this is the kind of opportunity that I think patients will be very interested in.

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

Thank you, Angela. Mikael, anything to add about tanezumab filing and FDA's request for advisory committee?

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

I thought Angela answered great. Maybe I can punctuate 2 things. As a potential first-in-class treatment, it's not uncommon for the FDA to hold an AdCom to discuss the submission. So in a way, it was expected. And of course, the discussion will be focused on those many patients that are not well controlled or unresponsive, not eligible, who do not want to take any of the existing pain medication and as an alternative to longer use of opioids, that's where the discussion will be. And as Angela said, we always welcome AdComs in order to share our experience and get external perspective.

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*

So I have one question for Albert and one for Frank. Albert, could you please define what you mean when you say you will disclose results when there is a conclusive readout? Does that mean interim efficacy success on the primary endpoint? Or does your definition of a conclusive readout include more than just the primary endpoint?

And for Frank, regarding enabling functions, you've been talking about that for a couple of years, and my understanding is that you've already been driving efficiencies in the corporate cost structure of Pfizer. So could you just update us on where the run rate stands today versus the $4 billion to $4.5 billion you were discussing a couple of years ago?

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

Thank you, David. My definition of conclusive result, positive or negative, it is a futility or a demonstrated efficacy readout in the primary endpoint. That's how things work. So Frank?

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

Yes. Thanks, Albert. So Dave, we have been reducing the enabling functions over the years, and that's obviously been reflected in the guidance that we've provided over the last year or 2. That $4 billion to $4.5 billion should be thought of as a base for 2025. And obviously, we'll go to work on that base and we are going to work on that base as we move into '21 and '22. And the intent is obviously to generate -- to capture as much of those savings as we can as quickly as we can. But the $4 billion to $4.5 billion, think about that as the base that we'll come off of.

Operator

Your final question comes from Andrew Baum from Citi.

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

A couple of questions. Firstly, out-of-pocket caps seem to have been proposed twice once by the Senate and then more recently by the President, prior to the most favored nation Executive Order. Thinking about VYNDAQEL and other high-priced small molecules, obviously, this could be very helpful to your business if this comes to pass. Do you think there's a high probability that regardless of which administration out-of-pocket caps for Medicare patients is likely to feature as a central part of health care reform?

And then second, just to clarify on COVID, the interim analysis. We're receiving questions from our clients repeatedly about the level of disclosure. Will it be a simple we met, we look forward to sharing the data? Or do you actually disclose the data at the time the efficacy readout is given?

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

Thank you, Andrew. Now about the out-of-pocket costs. Pfizer repeatedly, and the industry as a whole, has pointed out that, right now, the way that the insurance benefits are working is not sustainable anymore. Right now, the Americans pay out-of-pocket for their medicines, like if they do not have insurance, although they do have and they took a very expensive, likely very good assuming they didn't have to pay from their own pocket.

So this is something that needs to change. And it seems like there is a general recognition, both -- in both sides of the aisle. We will continue working with all, and we hope that we will see a change in the design of these benefits that will reduce the cost that the Americans have to pay out-of-pocket when they go to collect their medicines. This is not something that needs to be done because it will help the financial bottom lines of the industry. This is because it needs to help the patients and the health care system cost in general. Right now, the fact that some patients don't have the out-of-pocket to take their medicine as a result that we have significant numbers that they do not take their medicines but medicines that are needed, medicines that have been prescribed by the physician. And as a result, patients are ending up in the health care system, in hospitals, and they cause the health care system much more. So there is a need any way you see it, cost-wise or human paying-wise, this needs to be reformed.

Now in terms of COVID-19, and I think that was the last question that we have today. So it looks like it's going to be a COVID-19 in the last question. I think right now, we are planning to, as always, these things to have a press release that we'll speak about top line met the endpoint or not. And then, of course, we plan to publish data in a peer review magazine, so that they will be all available. But keep in mind that once we submit data, if things goes according to plan by the third, fourth week of November, there'll be also -- I think they plan to make them public during the AdCom, advisory committee that they will have.

So I think that concludes our call, Chuck, isn't it?

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

That's correct. Albert, back to you for closing remarks.

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

Yes. So I just want to thank all of you for joining us today, of course, your continued engagement with Pfizer. As you just heard, our continued strong performance speaks to the resiliency of our business and the strength of our portfolio, the ingenuity and the resolve of our people and I think the power of our products. As we indicated during our Investor Day, we are very confident in our pipeline. We like its breadth, we like its depth, and we will continue to be opportunistic about bringing in additional promising assets where appropriate. Now we need to continue to execute and deliver for patients.

Of course, we continue to monitor global economies related to COVID impact. COVID is affecting not only our business, Frank spoke, quantified the opportunity today, what it did to us. But if we try to quantify the opportunity, what it's doing to the global economy, we are speaking about trillions. And now has become more obvious than any time that many things need to be done to control this pandemic. Vaccines are expected, if successful, to play a key role to become a very important tool. We are working very diligently. I understand and appreciate your interest, that became very obvious. I just ask everybody to be a little bit patient. So -- and we all cross our fingers that science would win. Thank you very much, everyone.

Operator

Ladies and gentlemen, this concludes Pfizer's third quarter 2020 earnings conference call. Thank you for your participation. You may now disconnect.

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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.

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