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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Second Quarter 2023 Earnings Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chris Stevo, Senior Vice President and Chief Investor Relations Officer. Please go ahead, sir.

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

Thank you, Chelsea. Good morning. Welcome to Pfizer's second quarter earnings call. I'm joined today by Dr. Albert Bourla, our Chairman and CEO; Dave Denton, our CFO; Dr. Mikael Dolsten, Chief Scientific Officer and President, Pfizer Research and Development. Joining for the Q&A session, we also have Angela Hwang, Chief Commercial Officer and President, Global Biopharmaceutical Business; Aamir Malik, our Chief Business Innovation Officer; Dr. Chris Boshoff, our Chief Oncology Research and Development Officer; and Doug Lankler, our General Counsel.

Before we begin the call, I want to remind you of some logistical items. The materials for this call and other earnings-related materials are on the Investor Relations section of Pfizer.com, and of course, my favorite, our forward-looking statements. Please see our forward-looking statements disclaimer on Slide 3 and additional information regarding these statements, and our non-GAAP financial measures is available on our earnings release in our SEC forms 10-K and 10-Q under Risk Factors and Forward-Looking Information and factors that may affect future results. Forward-looking statements on the call are subject to substantial risks and uncertainties, speak only as of the call's original date, and we undertake no obligation to update or revise any of these statements.

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

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

Thank you, Chris. Hello, everyone, and thank you for joining us today. Our second quarter financial results were solid and in line with our expectations. Non-COVID-19 revenues grew 5% operationally compared to the year ago quarter. Total revenue declined 53% operationally, primarily due to the anticipated revenue declines in both PAXLOVID and COMIRNATY. Even with these declines, our COVID-19 portfolio remains a significant contributor to the business with more than \$1.6 billion in combined revenue during this quarter. Of course, our patient impact data are equally important because patients are the reason we exist. Through the first 6 months of the year, more than 356 million patients around the world were treated with our medicines and vaccines.

We continue to make progress towards our goal of executing an unprecedented number of launches of new products or indications. In fact, Pfizer is more than halfway of its goal of launching 19 new products or indications in 18 months' time. In addition to the 6 approvals and 5 launches that occurred prior to 2023, we have 6 approvals and 4 launches in the first 6 months of 2023. For the second half of 2023, we expect 6 additional approvals and 6 additional launches, including the 2 launches that occurred in July.

Then in 2024, we expect 1 approval and 4 launches which, if approved and recommended, would raise the total to 19 new launches in approximately 18 months. As you can see in this chart, for this year's launches, we expect the revenue contribution to occur largely in the second half of 2023 because the first half launches occurred late in the second quarter. And then in 2024, with the additional impact of next year's expected launches, we anticipate an even greater total contribution for our 19 launches. It is important to note that 18 of the 19 potential launches have been largely de-risked from a technical perspective at this point, with the only 1 remaining being our RNA flu candidate.

Equally encouraging is that our pipeline is expected to contribute -- continue generating breakthrough treatments and vaccines long after the 19 we have been discussing. We recently reported milestones from several exciting pipeline candidates with the potential to be significant future value drivers. These include: Phase 3 data from marstacimab, a novel antibody being studied for the treatment of hemophilia A and B; regulatory filing acceptance of our hemophilia B gene therapy candidate; the publication in the New England Journal of Medicine of Phase 2 results for our vaccine candidate for maternal immunization against Group B streptococcus; and first-in-human data from our pipeline of potential next-generation breast cancer treatments, including our novel CDK4, CDK2 and KAT6 inhibitors.

Now I would like to provide some commentary on our COVID-19 portfolio. As you all know, during the pandemic, Pfizer demonstrated impressively the power of our research and manufacturing capabilities by bringing to the world the first and most widely used vaccine and oral treatment for COVID-19. These scientific breakthroughs have played a significant role in bringing the global health crisis under control, and we are very proud of our contribution. The profits that these products have generated today have enabled us to invest in acquiring Arena, ReViral, Biohaven and Global Blood Therapeutics, which together, we expect to contribute approximately \$10 billion of revenues in year 2030.

In fact, the acquisitions of Biohaven and Global Blood Therapeutics are already contributing to our operational growth, while the acquisition of Arena is expected to start generating revenues toward the end of this year. We also remain very excited about our planned acquisition of Seagen, which if approved, is expected to contribute more than \$10 billion in 2030 revenues.

As a result of the positive momentum of our non-COVID-19 revenues and more importantly, the success of our COVID-19 portfolio, Pfizer's overall revenues have increased exponentially compared with our 2019 revenues, pro forma for the divestitures of Upjohn and our Consumer business. This allowed us to increase investments in R&D and SI&A to support this new revenue base and our expected new product launches.

The increased investments we are making in R&D and SI&A this year were sized based on certain revenue assumptions we made in January for both our COVID-19 and non-COVID-19 products. These assumptions also were incorporated in our 2023 financial guidance. Clearly, there is a higher level of uncertainty regarding the demand projections for our COVID-19 products than for the rest of our business. For example, in January, we shared our expectation that approximately 100 million doses of COVID-19 would be administered in the U.S. this year, of which we estimated Pfizer to capture 60% market share. In the first 6 months of 2023, 12.4 million doses were administered in the U.S. While the 12.4 million doses are behind our earlier projections, our market share for COVID-19 is ahead of our previous expectations at 65%.

However, the vast majority of respiratory vaccinations happened during the fall and winter respiratory disease season, which starts in September, and we expect COVID-19 vaccinations to follow this pattern going forward. The uncertainty of the exact timing of COMIRNATY commercialization was largely removed with the decision by the FDA and CDC to request a change in the composition of the vaccine to address the Omicron XBB.1.5 strain. We believe this will allow us to commercialize the vaccine in September, assuming the updated vaccines are approved and available by the end of August, of course.

In the European Union, the uncertainty regarding the vaccine's revenue contributions for '23 and beyond was removed when we renegotiated successfully our long-term agreement. This agreement spread the agreed volumes over 4 years. And while it puts pressure on this year's volumes, we believe it also provides longer-term revenue certainty in this important market.

Similar to what we are experiencing with the vaccine, the second half of the year will play a bigger role in informing our expectations for the long-term demand of PAXLOVID, the utilization of which follows very closely the COVID-19 infection rates. We expect a new COVID-19 wave to start in the U.S. this fall, and this expectation is supported by the increase in infection rates we are already seeing. Obviously, the severity of disease and people's desire for treatment also will be factors, as will the ongoing dialogue with the U.S. government regarding when we will transition to a commercial model for PAXLOVID. These are the uncertainties.

We are acutely aware that all these uncertainties are making it difficult to project the future revenues of Pfizer in this area and largely Pfizer, and also affecting our stock price as a result. The good news is we will have much more clarity and certainty regarding how our COVID-19 products will perform in the commercial market by the time we report our third quarter financial results. And we expect the uncertainties to be largely eliminated by the end of the year. This is because we expect the vaccination and treatment rates from the upcoming respiratory disease season to be a reliable predictor of trends in subsequent years, with some potential upside, of course, if a combination flu and COVID-19 vaccine is brought to market in the future.

Additionally, by that point, the timing of transitioning to full commercialization of both COMIRNATY and PAXLOVID should become clear. Despite this uncertainty, we'll continue to invest in our COVID-19 portfolio this year, in advance of the upcoming respiratory disease season. This is very important. But given the uncertainty, we are also preparing to have the ability to adjust our 2024 total cost base to align with various future COVID-19 disease -- revenue scenarios. In fact, we've already identified specific areas where we can make adjustments, primarily within our COVID-19 cost base, if demand comes in lower than expected. Dave will provide more details during his remarks.

Next, I wanted to share a few quick updates of our planned acquisition of Seagen, which we believe will be a major driver of our future success. Seagen's shareholders recently overwhelmingly approved the planned acquisition, and we have already raised most of the external financing needed to fund the transaction. We also continue to work closely with regulators, including the Federal Trade Commission and the European Commission. In the meantime, our integration planning continues, which will allow us to hit the ground running following an anticipated close later in 2023 or early in 2024, subject to the satisfaction of customary closing conditions.

Last week, we announced that Chris Boshoff has joined Pfizer's Executive Leadership team as Chief Oncology Research and Development Officer and Executive Vice President, reporting directly to me. In this role, Chris will lead a new end-to-end Oncology R&D organization and be the single point of accountability for the entire oncology pipeline from discovery to early- and late-phase clinical development. This is similar to the structure we currently have in place for our Vaccines R&D organization, which has proven to be very productive.

Pfizer and Seagen serve a common vision to deliver life-saving treatments for people living with cancer, which is why I'm so pleased that after closing, Chris' Oncology leadership team will include talented, purpose-driven and highly productive leaders from both companies. And we made already announcements about the people that are joining Chris' leadership team. We believe this new structure will help further accelerate the delivery of cancer therapies, which is critical because in the battle against cancer, time is life.

At Pfizer, one of core business principles is the belief that trust is everything. I'm proud to share that in recent months, we have received some wonderful accolades that speak to the trust we are building with external stakeholders. We were named one of the '23-'24 Best Companies to Work For by U.S. News & World Report. We were listed in Newsweek's List of America's Greatest Workplaces 2023. For the third year in a row, Pfizer has earned a top 100 score in the 2023 Disability Equality Index. And our own Rady Johnson received the Disability:IN '23 Executive Sponsor of the Year Award at the National Conference in July. And lastly, our PGS site in Ascoli, Italy is being recognized by the United Nations for the Welcome Award - Working for Refugee Integration. These recognitions are very important because they strengthen the unprecedented brand equity that Pfizer built during the COVID-19 pandemic.

Before I hand it over to Dave, I want to quickly comment on the situation at our facility in Rocky Mount, North Carolina. First, all of us at Pfizer were relieved that no colleagues were seriously injured when the tornado struck. That said, our facility sustained substantial damage as did the neighborhoods where many of our colleagues live, unfortunately. The local leadership team has done an incredible job responding to this devastating event. And we are proceeding with both urgency and caution to determine the best way to get the site back online as quickly as possible so as to minimize any impact on patients. Of course, we are also taking steps to ensure the continued safety of our colleagues and contractors, which remains our top priority.

And with that, I will now turn it over to Dave, and after Dave, Mikael will provide an update on our R&D pipeline. Dave?

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

Thank you, Albert, and good morning to everyone. Over the past 24 months, Pfizer has made important investments to position it squarely on track to achieve profitable and sustainable growth, particularly in the back half of this decade. We have strategically invested to expand our commercial portfolio and our late-stage pipeline, strengthened our market launch capabilities and enhanced innovation through internal R&D and business development actions. These deliberate efforts continue to solidify Pfizer's ability to overcome upcoming LOEs and drive sustainable revenue growth, all while enhancing long-term shareholder value.

To further support our long-term growth objectives, we are executing a capital allocation strategy designed to effectively deploy our cash. Our strategy is focused on 3 main pillars: first is reinvesting in our business; second is growing our dividends over time; and finally, making value-enhancing share repurchases. In the first half of 2023 alone, we've invested \$5.2 billion in internal R&D, returned \$4.6 billion to shareholders via our quarterly dividend and allocated approximately \$43 billion towards the proposed acquisition of Seagen. During the second quarter, Pfizer successfully completed a \$31 billion unsecured debt offering across 8 tranches. The net proceeds of this debt offering will be used to substantially fund the Seagen acquisition. The new debt carried a weighted average yield of 4.93% and a weighted average maturity of 16.3 years, consistent with our expectations.

On a full year run rate basis, the annual financing cost associated with the acquisition is expected to be nearly \$2 billion. With the completion now of this debt offering, the company is positioned to close the Seagen acquisition immediately upon post-regulatory approvals. While we plan to continue investing in our business, we expect to delever our capital structure following the closing of the Seagen transaction. As we delever, it is our expectation to return to a more balanced capital allocation strategy, inclusive of share repurchases.

Now with that, let me briefly cover a few highlights of our quarterly financial performance. As Albert said, our Q2 results were solid and in line with our expectations from both the top and a bottom line perspective, albeit slightly better than EPS consensus. As expected in our guidance, our overall Q2 revenue declined 53% operationally. The contraction in revenue was driven by the anticipated decline in both PAXLOVID and COMIRNATY sales. We expect these products to transition to a commercial market in the second half of this year. Our operational revenue growth, excluding our COVID products was in line with expectations at 5% versus Q2 of LY, with strong contributions from the inclusion of both NURTEC and Oxbryta as well as the continued growth from the VYNDAQEL family.

During Q2, adjusted SI&A expenses were \$3.4 billion and grew 20% operationally versus LY. We continue to invest in support of our upcoming launches and grow our recently acquired products. While it's clear that these near-term investments are dampening our current profitability levels, we are laser-focused on maximizing the longer-term performance of these products.

Now moving to the bottom line, reported diluted earnings per share this quarter declined by 77% to \$0.41, while Adjusted diluted earnings per share of \$0.67 declined 65% on an operational basis. Earnings compressed at a greater rate than revenues, primarily due to the steep and anticipated contraction in PAXLOVID sales during the quarter. Once again, foreign exchange movements continue to unfavorably impact our results, reducing second quarter revenues by approximately \$280 million or 1% and adjusted diluted earnings per share by \$0.05 or 2% compared to last year.

Now that we are at the halfway point of our 2023 financial plan, I'd like to take a moment to reflect on how we are executing across our business while navigating within an incredibly unique and dynamic environment. As a management team, we remain committed to transparency and sharing our assessment of the evolving marketplace, given the magnitude of launches, the ongoing shifting nature of the COVID landscape and the continued integration of acquired assets.

Let me begin by elaborating on our full year '23 financial guidance. We are narrowing our expectations for revenues to between \$67 billion and \$70 billion and maintaining guidance for Adjusted diluted earnings per share of \$3.25 to \$3.45 for the full year. For our more durable and predictable non-COVID revenues, we are updating our guidance range to 6% to 8% operational revenue growth. From a launch timing standpoint, I'll point out that the majority of our 2023 launches are anticipated to occur in the second half of 2023, and our commercialization schedule remains materially unchanged. As a company, we always strive to achieve the highest revenue level possible while maintaining a realistic view of the key input that inform our outlook.

Regarding RSV for older adults, the shared decision-making recommendation by ACIP is likely to slow its near-term uptake in the U.S. In addition, the recent approval of TALZENNA in the U.S. results in a more narrow patient population than originally planned. These factors, coupled with the impact of the damaged Rocky Mount manufacturing facility presents near-term revenue challenges. However, we expect positive revenue momentum as we exit 2023 and head in 2024. And importantly, the long-term outlook for our non-COVID business remains intact relative to our 2030 ambitions.

Turning now to our less predictable and more variable COVID portfolio. Year-to-date, we have booked slightly over 40% of the \$21.5 billion full year revenue forecast for both COMIRNATY and PAXLOVID with the important fall vaccination and respiratory infection season ahead of us. We are acutely aware that COVID demand depends on many evolving market variables, making the range of potential revenue outcomes increasingly large and difficult to predict with certainty. These variables include the overall level of vaccination and infection rates, the speed of drawdown in government inventory levels and the mutating nature of the virus itself, just to name a few.

In the interest of public health and with the important fall season ahead of us, we are maintaining our COVID revenue outlook for the year while continuing to invest largely on a variable expense basis to support our COVID products in 2023. These variable investments are important to support our efforts to reach as many patients as possible, helping to ensure that the most at-risk individuals are both vaccinated and treated while maintaining our leading market share. We are proud of what we have achieved through the COVID portfolio, and this has allowed the company to invest in support of its growth agenda for the back half of this decade. Our visibility into future COVID revenues and demands should improve throughout the remainder of 2023 as we gain clarity on a more typical annual run rate.

We are well aware that our 2023 profit outlook is currently being dampened by incremental cost in support of our launches as well as higher R&D investments aligned with the company's current revenue base. We remain committed to both defending and growing our overall level of profitability. As Albert mentioned earlier, we expect this fall's performance of our COVID-19 products to help us more effectively forecast future sales performance.

To that end, if our COVID-19 revenues are less than what we have assumed, we are prepared to launch an enterprise-wide cost improvement program aligned with the longer-term revenue projections for our business. This program will be designed to support our objective of growing our operating profit margin and we'd expect to begin to yield results in 2024. And we look forward to sharing the specific details of this program in our upcoming earnings call.

In closing, this is an extraordinary time for Pfizer. Our confidence and our commitment to our strategy and to achieving our 2030 goals is unwavering. We will continue to focus our efforts to drive growth while enhancing long-term shareholder value.

And with that, let me now turn it over to Mikael.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development

Thank you, Dave. Today, I will provide updates on a few different therapeutic focus areas, starting with breast cancer. We are working to deliver the next wave of innovative therapies for estrogen receptor-positive breast cancer. The pillars of this strategy are threefold: establishing our investigational CDK4 inhibitor as a next-generation cell cycle therapy backbone, establishing vepdegestrant as the next-generation endocrine therapy backbone; and establishing novel mechanisms like our investigational CDK2 inhibitor and KAT6 inhibitor candidate as next-gen combination partners to enhance efficacy.

Our clinical strategy entails first, developing assets for the metastatic setting, in which IBRANCE is currently the leader and unmet need is high, followed by an opportunity to expand to earlier-stage breast cancer, including the CDK4/6-naïve population and adjuvant or neoadjuvant settings.

Data presented at ASCO from 3 key investigational medicines from our next-gen portfolio demonstrated antitumor activity heavily pretreated populations for patients with breast cancer. As a reminder, the majority of hormone receptor positive breast cancers express low CDK6, while CDK4 is likely to be a major cell cycle driver. We have seen that CDK4/6 inhibition can lead to neutropenia, which requires more frequent blood test monitoring, mostly driven by CDK6 inhibition. Across the CDK4/6 inhibitor class, approximately 30% to 60% of patients experience severe neutropenia.

On the left, in a Phase 1 dose escalation study in patients with hormone receptor-positive HER2-negative breast cancer, all of whom have previously received a CDK4/6 inhibitor, treatment with our CDK4 inhibitor in combination with endocrine therapy resulted in a confirmed objective response rate of 29%, clinical benefit response rate of 52% and a median progression-free survival of nearly 25 weeks. The combination was well tolerated, which may enable maximum CDK4 inhibition. We are actively planning the Phase III randomized study.

In addition, I'd like to highlight encouraging data from the Phase 1 dose escalation study of our novel CDK2 inhibitor, which showed monotherapy activity, including confirmed partial responses in breast cancer patients who had previously received a CDK4/6 inhibitor. Also, durable confirmed clinical responses were observed in a Phase I trial of our novel KAT6 inhibitor as a monotherapy and in combination with endocrine therapy in heavily pretreated patients with breast cancer.

Turning now to blood cancer. ELREXFIO, also known as elranatamab, subject to regulatory approval, is expected to be the anchor of an anticipated multibillion-dollar franchise. An FDA decision for the potential first indication in the triple-class relapsed or refractory multiple myeloma population is expected this year, and we continue to advance the MagnetisMM clinical programs to expand into earlier lines of treatment. In addition, development of maplirpcept, also known as TTI-622, is underway, including in combination with ELREXFIO to support potential mutations in myeloma and acute myeloid leukemia.

Here, we show ELREXFIO data presented at EHA from the MagnetisMM-3 trial in patients with triple-class refractory multiple myeloma who had no prior exposure to BCMA-directed therapy. On the left, we observed highly meaningful survival with ELREXFIO monotherapy with a 15-month overall survival of 57%. In patients who achieved a complete response, 15-month survival was remarkably 93%, underscoring the potential for deep and durable responses.

We can see evidence of broad activity in multiple myeloma on the right, with the graph showing a single agent complete response rate of 35%, which rises to 46% in the subset of patients with 2 to 3 therapy. Our ongoing randomized trials are in less pretreated to newly diagnosed population.

Subject to approval, ELREXFIO may have key differentiators such as 50% low hospitalization time during the step-up dosing period per protocol and an extended dosing interval that moves from once weekly to every other week dosing beyond week 24.

Turning now to hemophilia A and B, the pivotal trial of marstacimab met its primary endpoint with statistically significant and clinically meaningful effect on annualized bleeding rate or ABR. There was a 35% reduction in ABR compared to prophylactic factor replacement and 92% reduction in ABR versus on-demand factor replacement. Marstacimab offers a differentiated mechanism of action and dosing regimen compared to standard-of-care therapy. If approved, it has the potential to be the first once-weekly subcu hemophilia B treatment for patients without inhibitors and the first hemophilia A or B treatment administered in a patient-friendly pen as a flat dose. Regulatory submission is expected in the second half of '23.

Next, LITFULO, also known as ritlecitinib, is the first medicine to receive FDA approval to treat severe alopecia areata in both adults and adolescents 12 years and older. It also recently received a positive opinion from the European Medicines Agency's CHMP recommending body, but it's not yet approved. It has the potential to redefine the standard of care for alopecia areata. LITFULO is the first-of-its-kind kinase inhibitor with a unique mechanism that inhibits both the TEC kinase family and transiently JAK3 pathways that have been implicated in the alopecia areata pathophysiology. In addition, we're exploring how its unique mechanism of action could potentially be applied across immune disorders, including vitiligo, in which a Phase III study is ongoing, and other potential indications.

Finally, we're making excellent progress on the milestones we have set out through the first half of '24. As Albert noted, we recently received FDA approval for Prevna 20 in the pediatric population. We have robust strategies in place to potentially improve the protection provided by current pneumococcal vaccines. I look forward to sharing more about this in the coming quarters.

In addition, we recently published Phase 2 data in New England Journal Medicine, showing our Group B streptococcus maternal vaccine candidate was generally well tolerated and generated robust antibody levels. The Journal also published a natural history study, which was used to determine protective antibody levels at birth. These 2 studies indicated that the vaccine candidate may offer meaningful protection to infants born to immunized mothers. We were highly encouraged that Dr. Carol Baker, an infectious disease expert from the University of Texas Health Science Center, wrote an independent NEJM editorial highlighting the important future prospects of our GBS vaccine candidate.

The progress of the GBS vaccine candidate dovetails nicely with the positive result and anticipated upcoming regulatory decision for our RSV vaccine ABRYVO for administration to pregnant women. ABRYVO recently received a positive opinion from European Medicines Agency's CHMP for both older adults and maternal immunization to help protect infants. ABRYVO is approved for older adults all in the U.S. and under regulatory review for the maternal indication.

In addition, we remain excited to see the Phase 2 data from danuglipron by end of '23, which we expect will enable us to finalize our Phase 3 plan. Finally, I'll call out the Phase 3 trial start of our anti-interferon beta candidate for the treatment of inflammatory muscle myopathies, which has received Fast Track designation from FDA.

Thank you. Let me turn it over to Chris to start the Q&A session.

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

Thank you, Mikael. Chelsea, if you could please queue up the callers. We have at least 30 minutes for our Q&A session now.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question will come from Robyn Karnauskas with Truist Securities.

Nicole Germino - *Truist Securities, Inc., Research Division - Associate*

This is Nicole on for Robyn. So just a quick question for us. Can you share what you expect the shared decision making to slow the uptake in the U.S. would be in? What we want to know if they can elaborate -- if you guys can elaborate on why you think this is the case and with peak annual sales is lower than previously expected? And how do you think ex-U.S. sales might be impacted if at all, give the ACIP decision?

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

Thank you. Maybe Angela can answer that. The question was, do you expect respiratory disease season to have a big impact on RSV, and also do we expect -- in the U.S. and also do we expect any impact, excluding the U.S.?

Angela Hwang - *Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business*

Sure. So first of all, we're really excited about the approval for our RSV older adult vaccine. And the way I would see the shared clinical decision-making is just that it is a step towards the full routine recommendation that we anticipate. So I think that there is -- the way to look at it is that it's a short-term effect.

We do expect that with more data that will emerge -- be emerging out of our clinical program, that we'll have an additional opportunity to go back to the ACIP and actually get the routine recommendation that we hope for. So over the next year or so, as we collect and finalize our data, that is really the anticipation of it. So it doesn't change the full opportunity for this particular vaccine. It doesn't change the peak. It just means that it takes us a little bit longer to get to the peak because of the shared clinical decision-making that was -- that extra step that we have to take right now.

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

And what about the ex-U.S.?

Angela Hwang - *Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business*

Ex-U.S., actually, we had a different filing. We were able to get both maternal and older adult at the same time, so I think you see slightly different dynamics there in that here in the U.S., our maternal vaccine will be launching later. But in ex-U.S. they'll be -- and in Europe, they will be launching at the same time. And those vaccine technical committees have not opined yet on those recommendations, in particular in terms of the utilization. And so we'll await that. But I think what you have that's different and that's really a great upside is the fact that we have both indications at once.

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

Thank you very much, Angela. I hope we gave you what you asked, Robyn. Operator, the next question please.

Operator

Next, we have Umer Raffat with Evercore.

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

I know I heard 2 different things on the cost cut just now. One was that it would be enterprise-wide, while Albert, I think, used the word within the COVID cost base. So I was just trying to reconcile the 2. And also on danuglipron, is it reasonable to expect that if it's below mid-teens weight loss, you wouldn't move forward?

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

Let me clarify. Of course, it will be enterprise-wide, but what I said is that the COVID part is going to be the biggest one. Right now, you need to know that R&D and SI&A cost of COVID is big, it's not a small amount. So it's -- there's a lot of events. Mikael, can you speak a little bit about the prospects to move ahead danu?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development*

Well, we really look forward to get the data. And as you know, we have in parallel developed activities also for modified leads. I think we really need to look at the totality of data, its performance on important metabolic permit in diabetes, its ability to deliver weight loss as you alluded to, and also, of course, its tolerability in general. These 3 complicate how well the drug can perform.

And I remain optimistic that oral drugs in this class can have a profound effect on weight loss. Of course, one needs to be maybe a little bit cautioned to drive weight loss too far, as you have seen also some concerns in public media about side effects that may arise on that. So we will really integrate all of that data and make a decision, and we really look forward to that moment.

Operator

Our next question will come from Evan Seigerman with BMO.

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

Kind of a follow-up from Umer's, I want to focus on the GLP-1 franchise. Can you talk about the competitive profile of danuglipron in its current form, considering safety, twice-daily dosing and efficacy? And maybe remind us on the timelines to potentially get more on a once-daily formulation of this asset?

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

Mikael?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development*

Yes. As I said in my prepared remarks, we expect data at the later part of this year. We are absolutely encouraged and confident that it has a different profile when it comes to adverse events as the drug lotiglipron that we stopped. So we don't see that as an issue. And I also spoke to that we will put together the totality of data to -- pending readout, prepare a potential Phase 3 program. And it's a very big sector, diabetes and obesity. We have considerable expertise in treating cardiometabolic patients. So we look forward to share more data and more plans with you as we move through the quarter. Thank you for your great interest. It is important to us.

Operator

Next, we have Terence Flynn with Morgan Stanley.

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

Maybe 2 for me. Dave, I was just wondering how we should think about steady-state operating margin here. Looking back pre-COVID, the company was around mid- to high 30% range. So is that how we should think about this when you gave us some of the parameters, but just maybe how to think about steady state?

And then on the messenger RNA Phase 3 seasonal flu vaccine program, it looks like that trial was upsized based on clinicaltrials.gov. So just wondering, Mikael, if you can talk through timing of data and help frame expectations there.

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

Thank you, Terence. Let's start with Dave.

David M. Denton - *Pfizer Inc. - CFO & Executive VP*

Yes, so great question. As we think about our operating margin long term, clearly, our objective is to expand that over time. Clearly, it is our expectation to get back to, at a minimum, pre-COVID levels with one caveat is that we -- as we go forward, we do have a different mix of products within our portfolio, particularly the vaccine related to COVID.

As you know, the vaccine, given the cost share that we have or profit share that we have with our partner, does dilute that product from an operating margin perspective. So with mix adjusted, you should see us back to those levels over time. But obviously, as we cycle into '24, we'll give you a lot more clarity on all the puts and takes as we integrate Seagen, as we roll forward from a COVID franchise perspective, how that looks, as well as all the developments that we have coming out the pipeline at this point in time.

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

Thank you, David. Mikael, mRNA, flu.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development*

Yes. First, the totality of experience we have with mRNA for flu makes me very encouraged that this will be the new modality as it was for COVID but now for flu, that engages [through mechanism] the B cells and the T cell that we should aspire for, having better efficacy than what we have seen with the old flu. We are continuing with the study because we just wanted to have more events and particularly have addition of a flu V type of events, which were scarce in the newest part of the trial.

And we look forward to update you, hopefully, be able to conclude the study later this year. But we also are putting mitigations as adding immunity studies that can be supplementary for getting a total good data package of activity against flu A and flu B. But as I said, I remain very optimistic that the mRNA is going to be the next important platform to deal with flu. Thank you.

Operator

Next, we have Chris Shibutani with Goldman Sachs.

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

Two questions, if I may. On the potential enterprise-wide cost program, you would have some opportunity outside of the COVID programs to consider? Can you help us with the relative weighting potentially of R&D versus SG&A or some other component of that? And I ask that in part because you've announced some changes, for instance, in kind of the structure at the top tier of management of the R&D with the anticipation of the oncology and Seattle Genetics.

And then secondly, if I could, on the Rocky Mount facility, it's reassuring to hear in terms of your own staff. But I think folks are looking to get a sense for the scale of the damage and perhaps what potential gating factors for getting more information on timing? I know that you guys have communicated with some of your hospital-based customers, but any additional insights in terms of magnitude, impact and timing of the recovery, and what that could look like from a progress standpoint would be helpful.

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

Let me say a few words about the Rocky Mount, and then I'll ask Dave to answer the question about the cost adjustment program in case we have a significant reduction on our revenues because of the COVID. The Rocky Mount, it was severe the damage of the hurricane, but the damage was mainly concentrated on the warehouse, which means that we lost a lot of inventory that was about to be sent to the market. The facilities per se, the production facilities were not impacted by the hurricanes, so the buildings are standing there. However, because the utilities were discontinued, the facilities had to stop operating. And in this highly sensitive sterile environment, when you are losing power, it's not easy to switch on and switch off. It takes time and a lot of processes so that we can start it.

And the additional challenge will be some of the inventories of materials that were also destroyed, particularly glass and other startup, we need to make sure that we will replace in time. So what I want to say is that we feel very confident that the whole thing will go back to life. But still, we are assessing how long that will take. And we are doing anything we can to make sure that we will minimize the shortages in the marketplace because of that. Now let's move to some more color on the cost adjustment program.

David M. Denton - *Pfizer Inc. - CFO & Executive VP*

Yes. So thank you for the question. Clearly, as we develop this program in the back half of '23, we look forward to sharing a lot more details as we cycle into '24 and give you a lot of, I'll say, milestones as you think about both our cost and investment structure going forward. Importantly, as you know, we're extremely excited about the Seagen acquisition that's upcoming here.

Upon approval, this will allow the company to refocus its efforts and its investments to make sure that we're squarely focused on battling cancer going forward. And we think there's a big opportunity as we align our resources against that franchise and that battle to fight cancer, and an opportunity for patients and importantly, an opportunity long term for Pfizer.

Having said that, we will be informed in the back half of the year of our revenue performance, specifically as it relates to COVID. That will inform us the level of opportunity we have to expand our margins into '24 and '25 and beyond. That will allow us to step back and make sure that all of our costs, all our investments are aligned with those Seagen objectives as well as aligned to maximizing the performance of our in-line portfolio as well as the launches that are occurring as we speak in the back half of this year.

So again, we look forward to sharing a lot more to this -- from this. This will be balanced, as you well know between SI&A and R&D, and we'll give you that specific breakdown and that specific information later this year and into next year.

Operator

Next, we have Louise Chen with Cantor.

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

Wanted to ask you first on these COVID scenarios that you think could unfold in the second half '23. Any way you could share some of the big ones that you anticipate could potentially happen? And then secondly, seeing a lot of headlines in the ATTR-CM space. I'm just curious if you anticipate any potential competition or meaningful competition to VYNDAQEL, VYNDAMAX?

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

All right. So on the COVID, I will say a few words and then I will ask Angela to comment on both. Look, the COVID scenarios, it depends. What are the uncertainties? I think I articulated. Let's start with the vaccine. The biggest uncertainty is vaccination rates. I think market share is pretty much, I think, well established. Vaccination rate is what we are going to see in the fall that is coming. So that will be a big concern.

Another uncertainty was the time of commercialization in the U.S. because, of course, you go with new inventories, new sales to the market and with higher prices. That has been resolved. We know that it's very likely that we will launch in September because FDA and CDC they asked us to change the inventories basically by creating a new vaccine. So that will happen.

And also, the other uncertainty that existed about the COVID vaccine was the European contract. That was a very long -- very big contract. And now we have ascertained that it has been negotiated, a little bit less for the year because it's spread over 4 years, but it's renegotiated. So all of that are the key uncertainty. Of course, there is how much LatAm, Latin America, and other countries, would prefer this. It's not the only ones, but we think those are the fundamentals.

And we will know pretty much the trend in the third quarter. And we will know pretty much, quite accurate, what is the situation in the end of the year, that I think will be a very big predictor of what you should expect going forward with the only upside if we have a combined vaccine with flu or with RSV that, that will increase the vaccination rate.

On PAXLOVID, a little bit more uncertainty because, of course, we are having the uncertainty of treatment rates and infection rates. And we don't know how that will behave. We don't have any benchmarks to see how that goes. We know that the treatment rates are following very closely the infection rates, and the infection rates are rising right now. But remains to be seen how that will work. Of course, also the same with PAXLOVID arising and receive the market, the scripts on a weekly basis as always do when the infection rates are going up.

But we have some more uncertainties over there, which is the timing of launch, which will depend on how we will agree for the interest of public health to transition this launch with the various governments. So all of that remains to be seen. And these are the scenarios that we see for COVID. And the key message it is the uncertainty will go away at the end of the year. We will know what COVID will contribute on a stable basis in Pfizer's revenue and we will go from there.

Now Angela, maybe if you want anything to add to that and talk about the next question -- the other question.

Angela Hwang - *Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business*

Louise, I think when you talk about VYNDAMAX or VYNDAQEL, the biggest and our biggest differentiator that we're extremely confident about is just the totality of our data, really, along 4 dimensions. And whether that's clinical data or real-world data. We have all-cause mortality and CV-related hospitalization data. Our data also relevant in both hereditary and wild-type ATTR-CM, so that's unique.

We've also demonstrated significant survival benefit at 5 years through our real-world data. So whichever way you look at it, and if you compare that with any competitor program, I think that we have a highly differentiated and an extremely valuable molecule that stacks up well against any competition.

Operator

Next, we have Mohit Bansal with Wells Fargo.

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

And maybe a follow-up to this one a little bit. So thank you for all the transparency, by the way. So is it fair to say that in COVID trends that you have seen so far, at least sales trend that had been below your expectations, and you want to see 1 more quarter before you adjust expectations. I'm asking this because if I look at the -- it seems like you still expect 88 million or so vaccinations in the second half of the year in the U.S. and the number was actually, by our conversion, 44 million or so in terms of administration, 111 million in terms of shipments. So just trying to understand, is it like -- is it something where you are -- where we could get better update in third quarter on the COVID numbers?

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

Yes. Thank you for the question. I think the answer is yes, we should get way better still. It's not that we just want to see another quarter. We want to see the big quarter of the respiratory season. COVID, we always said and everybody, I think, thinks that, that is a common sense. But we'll follow going forward the seasonality of the other respiratory vaccines. That's becoming more and more clear, right?

And the majority of these vaccinations are happening in the third and fourth quarter for the year. So it's not that we are just another quarter. We're awaiting the main quarter. If COVID vaccinations go anywhere close to the flu vaccination rates, then we have a very big bit of what we expect to have. If they are a small fraction of what will happen for flu, then of course, we have a miss. So that's why we are going to see how that will evolve. So it's a very, very important quarter.

The rest, although for the first half of the year, we have got significant contribution towards the total growth. So we don't need that much of inventory if we have the utilization over there to make sure that we know how big the COVID franchise will become. And as I said, in the EU, we have adjusted very well. We know we'll have high certainty. PAXLOVID because China is a very, very good market. We don't know how in the next wave the PAXLOVID will be used.

We have the rest of the world, but the inventories, they were also last year. So we are now expecting that the products will start being going out or (inaudible) product will start more reordering from many more countries. So that's why the infection rates on the PAXLOVID will be extremely, extremely important. And all of that are happening now. So once we know them, we can predict way more accurately. Thank you very much.

Operator

Next, we have Trung Huynh with Credit Suisse.

Trung Chuong Huynh - *Crédit Suisse AG, Research Division - Research Analyst*

You commented the long-term outlook for your non-COVID business remains intact relative to the 2030 ambitions. How are you thinking about the midterm 2025 guide because if you assume the midpoint of your ex-COVID '23 guide at 7%, in order to achieve the 6% 2020 to 2025 guidance ex-COVID, on our calculations, you need to do high single-digit growth for that base business for '24 and '25. That looks tough especially as you'll have more LOEs. So do you remain confident in that midterm guide?

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

Yes, thank you. The LOEs are coming basically from year '26, right? So all the way to '25, I think the impact will not be that high. Also, the guidance that we gave was 6%, if I'm -- yes, we feel quite confident that we will be there. So we'll continue and we are at 6% right now all these years, right,

year-to-date. So yes, the non-COVID business, I think clearly, the success of the launches is very important. So we'll see a lot of things coming ahead of us. But it is way better predictable. And I think we are there, so I don't think there will be any variability. Thank you for the question, by the way.

Operator

Next, we have Colin Bristow with UBS.

Colin Nigel Bristow - *UBS Investment Bank, Research Division - Analyst*

Another follow-up on danuglipron. I just didn't have the answer in terms of when we'll hear about the once-daily formulation. And I'd just like to understand your level of confidence here that you can make this a once-daily formulation without negatively impacting the AE profile, presumably given an increase in Cmax.

And then more broadly, can you just talk more about how you're going to compete here, given I think it was previously referenced you're behind the competition, the clinical differentiation, the potentially less convenient dosing and essentially a therapeutic category in which you don't have a major presence. And then just maybe one other quick one on a pipeline item, on DMD gene therapy. It's a late-stage asset that doesn't seem to get much airtime. Is your enthusiasm waning on this program? Or is it just that others are sort of a bigger priority?

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

Yes, thank you. So Mikael, again, clearly the obesity market and the size of it is creating a lot of interest in danuglipron and -- so the question was about the 1-day formulation. And then also tell us a little bit about where we are with DMD.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development*

I hear your interest in a once-daily product, and I would say I don't see any particular barrier for us in creating that. We have tremendous experience in modified release formulation. And our early data, as we now have initiated a while ago, tells us we should be encouraged that when it relates to once-a-day modified release for danuglipron, I believe we will have such a formulation in a reasonable future in our hands.

When could it come to the market if the drug continues and makes a great Phase 3? Well, I think we can have it at launch or shortly after launch. So I wouldn't worry about that. But I agree with you that once-daily modified release can sometimes actually improve the tolerability profile by (inaudible) and the variability and exposure, which typically reduce GI side effects that have been seen as limiting this drug. So that's why I can see a potential twofold advantage of an MR goes from twice a day to once a day, and may also help uniquely to create a tolerability profile within the structures of oral GLPs.

DMD gene therapy I'm encouraged that the FDA took a very positive angle on that drug when it comes to its urgency to get into the market. Chris, you and I have worked very closely on that, and we expect today relatively soon to conclude the trial. I'll also ask Chris to pitch in on it.

Chris Boshoff - *Pfizer Inc. - Executive VP and Chief Oncology Research & Development Officer*

Thank you, Mikael. So the DMD program is obviously very important for us not just for the importance of gene therapy but for patients and families with this absolutely devastating disease. And we do have an interim analysis later this year for the CIFFREO trial. The CIFFREO trial, all patients have now been enrolled in the study. The interim analysis will be based not on a surrogate biomarker end point but on truly functional end point. So we believe that's the best way to measure the benefit of gene therapy in this disease is with a functional end point. And that should come later this year, and we'll update you with the final analysis for the study then in 2024.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development

That was terrific. I just wanted to add that we have, like you heard Sarepta [enroll] biomarker data that look very robust in our hand. But as Chris said, we want to provide patients with even more experience about the potential benefit.

Operator

Next, we have Kerry Holford with Berenberg.

Kerry Ann Holford - Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst

A couple of questions (inaudible). It's clear that demand for your COVID assets will influence whether or not you go down this rig. But given the potential you've highlighted previously for a COVID-flu combination vaccine, I'm interested to understand whether the upcoming Phase 3 data from your mRNA flu vaccine trial will influence your decisions on that cost saving program in any way.

And then secondly, on hemophilia, your anti-TFPI say you're filing second half of this year for noninhibitor patients. Should we assume you would seek to launch in that patient group only next year? Or would you wait for the detail in the inhibitor patient group before you proceed to market? And perhaps you can just discuss how big an opportunity you see in that drug.

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

Let me start with the COVID and then Mikael also can comment. But for example, we are very excited about the combinations, right? And the combinations will be flu and COVID and then also flu, COVID and RSV. And we are working on that. And we believe actually that the fact that if we have a combination with the non-mRNA included although that we have likely that we expect to have the benefit of better safety profile because we don't have to load 3 product's RNA into a single injection, but we will be using only 2, COVID and flu, and then we'll use the protein-based vaccine (inaudible). All of that are working very well.

Now the question is what will happen if the COVID market is seen to be very -- is monovalent. It's very, very low. I think that will play here in our decision about controlling the cost because if it is very, very low, although we expect an upside in the combination, we will assume at this stage that the medical need for COVID is not that high. And as a result, we will reduce our investments in the area and also temper our expectations for sales. And then if the combinations come and we are way more successful, then we restore. You want also -- what was your second question? Yes, about the marstacimab. Mikael?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development

I'm very excited about marstacimab. I follow this project for a long time. And as you know, we reported out a very encouraging data. We had 92% reduction in annual bleeding rate versus on-demand. We had really no safety events that has been associated with other products, including Hemlibra. It's active against both A and B. It's administrated with a prefilled pen. I think it can be, from a medical point of view, a very large product, a single option for hemophilia A and B. Of course, when I think about how Hemlibra has been such a promise for heme A patient and I see this profile that looks so good, I'm optimistic that it can do well in both segments.

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

Thank you very much. Let's move to the next question, please. And we are a little bit -- the time is flying. So a lot of interest. So let's try to be more -- one question, please.

Operator

Our next question will come from Geoff Meacham with Bank of America.

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

Just had 2 real quick ones. Angela, on Pevnar, what does long-term growth look like? Clearly, you may have a tougher competitive environment. Just if you lose share, what do you think the [TAM growth] could look like to offset that? And then Mikael, you talked a little bit about next-gen CDK. I know it's super early in development. But is there a risk-benefit hurdle you have in line? I'm just thinking about cost benefit post-IBRANCE LOE and also considering the competitive landscape.

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

So Angela, how concerned you are with the competitive environment, with respect to our competitors, but we have some realities that maybe you want to discuss. And also, I will ask -- actually, it will be Chris Boshoff to answer the question of CDK4 since we have him here in his new capacity. Angela?

Angela Hwang - *Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business*

Well, I mean, I want to begin by just saying how I'm incredibly proud we are of the performance of the entire Pevnar franchise. If you look at the adult indication, we have grown -- not only have we grown 23% since last year this time, we are doing all of this growth prior to the full vaccination season, which is what you typically see. So the fact that we've been able to bring these vaccinations tell us a lot about the work that we've done in pneumococcal disease, how well appreciated it is, but also how well our machinery is working, not to mention the fact that we have 96% share of the adult indication.

In peds also, of course, being that we went from being 100% of the market, today, we share some of that market share with PCV15. But I just want to remind everyone that, that is to be expected, and we are exactly where we thought we would be. And so from that perspective, we're also really proud of how Pevnar 13 has competed with Pevnar -- PCV15. I think the important thing here to realize is that given the ACIP recommendation that we've just got for Pevnar peds, what we are beginning to see now is a sort of reversal of that decline and the reclaiming of market share.

And so we have -- the fact that we've seen some accounts purchasing PCV20 peds now, we've seen some account switching from PCV15 to our own Pevnar 20, the fact that our federal contracts had added Pevnar 20 to their register, which means that public vaccinations can begin. And then maybe the one thing I will mention about Pevnar peds which is unique compared to any other pneumococcal vaccine, which is that we were given the recommendation to vaccinate adult -- well, kids 2 to 18 immunocompromised. So that is a whole new population that we've never had before.

So when you kind of bring all of this together and you factor that this quarter alone, Pevnar franchise generated \$1.3 billion in revenue, just this 1 quarter, I think that order of magnitude gives you a sense of the scale and the competitiveness of our portfolio, and we're really excited about what Pevnar can do over the next coming quarters.

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

And that is under the competition of PCV15 which I think was around \$150 million, if I'm not mistaken. Chris, can you please speak about the CDK4 and the franchise in general over there?

Chris Boshoff - Pfizer Inc. - Executive VP and Chief Oncology Research & Development Officer

Thank you for the question. So as you know, ER+ breast cancer is the most common cancer globally for women, and we're very proud that we can build on our leadership in cell cycle inhibition with IBRANCE. And with 3 first-in-class potential assets, CDK4-specific inhibitor, CDK2-specific inhibitor and a KAT6-specific inhibitor, all 3 with significant potential to transform treatment in the future for ER+ breast cancer.

For CDK4, we have seen more complete and continuous CDK4 target coverage and potentially improved tolerability due to reduced CDK6 inhibition. And as Mikael has pointed out, CDK6 leads to the hematological vulnerability. We know that epithelial cells specifically, highly expressed CDK4, and that's why it's so important to specifically target CDK4. And what we've seen, as Mikael has pointed out, is grade 3 neutropenia of 15% with our CDK4 inhibitor and that's versus 60% as expected with other CDK4/6 inhibitors.

We've also not noted any grade 3 diarrhea. And again, that's very different from what you know from some of the other CDK4/6 inhibitors. We're accelerating our registration strategy with the first study in second-line post CDK4/6, where we've recently shown 30% overall response rate in a heavy pretreated population, and we're also starting populations with CDK4 plus CDK2 as well as CDK4 with our potential next-generation backbone, ARV-471 or vepdegestrant, which we are codeveloping with Arvinas.

Operator

Next, we have Tim Anderson with Wolfe Research.

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

If I could go back to the COVID guidance. Investors have been cautious not only on the level of your prior guidance for '23 but also the shape of the future revenue curves beyond '23. So my question is on the latter, let's say, for the future curve. Are you confident still in saying that 2023 should be the trough, and then you'll rebound to some higher level of sales in 2024 and beyond and see kind of continued growth from that point forward? Or is that now more uncertain, too?

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

Yes. Thank you. Yes, I think that this year's utilization at the marketplace will form the basis that we can predict reliably for the next years. I don't think it will be any much different because there will be no different catalyst in the marketplace. Vaccination rates would settle and then the treatment and infection rates also will be, after a new year, indicative of what we should expect periodically.

Clearly, we will have to deal with some inventories movements and this year was a transitioning year because we are going to give prices, and we are going to absorb some of inventories, et cetera. So that should inform the accurate number for '24 and beyond, but should be the base and likely should be higher than what we should see this year. But that, provided that we have reasonable vaccination and treatment range of PAXLOVID. So that's why I say that let's wait to see what will be the actual in this year. And particularly, what will be the utilization, as I said. Because next year, all these inventories and price adjustment things will be very clear what it will be. So thank you very much for the question.

Operator

Our next question will come from Carter Gould with Barclays.

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

Thanks for all the transparency on your thought process on the COVID side. Plenty great questions asked this morning. I guess one I wanted to -- didn't get addressed is you out-licensed your TL1A late last year. Your partner, then turns around and sells it for quite substantially more. I guess

-- so to be a bit provocative, Albert, were Pfizer shareholders well served by this course of events? I would love to give you the opportunity to address that publicly.

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

Thank you, Carter, for giving us this opportunity. And also thank you for recognizing with Roivant. So I think that's very important thought, particularly when there's uncertainty. We should all know what the scenarios and the parameters are and what the actions that could be potentially triggered with different scenarios. Now let's go to TL1A and let's see what is the situation. Aamir, have we served the shareholders to the best of our knowledge or not?

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

Thanks for the question, Carter. And obviously I'm not going to comment on the rumors and speculation or the potential prices attached to different transactions. What I will say is we're very pleased with our TL1A Telavant partnership with Roivant. And we do think shareholders were well served. So as a reminder, why we entered this. We entered this as an R&D portfolio prioritization decision.

So from time to time, we make decisions as part of our disciplined process to our partner R&D programs, where we think it is better to share the risk or the cost with a partner. And in this case, Telavant, covers all of the R&D costs going forward. And that frees up significant R&D capacity for Pfizer to invest in high priority programs. But we still retain value in this program in 3 different ways. We had a 25% equity stake in Telavant, we have full ex-U.S. and ex-Japan rights and we earned royalties on the U.S. and Japan sales. So taken together, this collaboration allows us to keep more than 50% of the total value of TL1A with 0 incremental R&D spend. And for a Phase 2 program, we feel this is a very sound move for Pfizer shareholders.

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

Yes. Mikael, anything to add here?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development

Aamir said it so well. I just wanted to punctuate among the very many options, we have strong platform in bispecific in many therapeutic areas, including immunology and we do have TL1A p40 antibody. That would be very interesting, where we own even greater shares. We have triple specifics that are going into atopic dermatitis. So this just punctuates it. Even in the very same therapeutic area, we have so many things going on. And near term, we expect soon approval for etrasimod and another readout that would go on. So a lot to start there.

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

Thank you. Thank you, Mikael. Don't tip competition too much about what we have in our pocket.

Operator

Next, we have Steve Scala with Cowen.

Stephen Michael Scala - TD Cowen, Research Division - MD & Senior Research Analyst

I just have an observation than a question, but the observation is that it's still not clear what has changed in your long-term COVID expectations versus when you first gave the \$30-billion guidance 6 months ago, since in the prior 6 months, nothing really has changed other than FDA action, which doesn't impact the long term. So that's just an observation.

But my question is on VYNDAQEL. VYNDAQEL has become a very important franchise, yet its exclusivity is not long in either the U.S. or the EU. Are there any strategies to get around the LOEs? Or is it simply similar to Eliquis where post LOEs, Pfizer will move on to other products?

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

Yes. So why don't you take the question, Angela?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

Yes. Well, it is, as you say, an incredibly important product, and we're just so proud of the fact that it's still growing 40-something percent this quarter. I think when it comes to LOEs, just from the perspective of how we needed, our composition of matter patent expires in 2024, but we have patent term extensions that get us through December of 2028. In the EU, it's 2026. In Japan, it goes right up to 2029.

So actually, I feel like we still have a good runway as it pertains to this product, more diagnoses that we need to do and more patients that we can capture on to VYNDAQEL, especially with the incredibly competitive and differentiated profile that we have. As you say, we're always, and working with Aamir, looking at opportunities as to what might be good fit into -- what might fit well into this franchise, in this portfolio. But I guess from my perspective, with or without it, we see an incredibly strong opportunity for us to continue to capture growth.

Operator

Next question comes from David Risinger with Leerink Partners.

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

So my question is on Pfizer's mRNA flu vaccine candidate, please. And Sanofi had stated at its recent Vaccines Analyst Day that first-generation mRNAs against flu will not deliver sufficient strain B efficacy given mRNA technical issues in targeting strain B. So could you just comment on that and your expectations for your vaccines' southern hemisphere strain B efficacy results later this year?

I know that there wasn't the emergence of strain B in the northern hemisphere, but I'm curious about your expectations for demonstrating that strain B efficacy in the southern hemisphere. And then in addition, if you could just comment on your expected reactogenicity profile for mRNA flu versus COMIRNATY's reactogenicity profile?

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

Thank you very much, David. Very good questions. Mikael, so our -- the technical issues that Sanofi is having, are we experiencing as well?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President, Pfizer Research and Development

Well, I think the difference between maybe the pioneering mRNA compound is Pfizer and of course there is Moderna that have worked on this technology many years. We have ourselves in 5 years into it and make ample improvement across the entire mRNA chain. And I think it just gives us a big leg up and world experience we had with COVID vaccine. So I can't really comment on the issues that Sanofi are facing. I share a much

more positive -- I have a much more positive outlook that we have in our capability to design mRNA vaccines that will be powerful against flu A and also against flu B.

And let's wait. Let's -- we accumulate data and see the outcome, but I'm optimistic about that and realize it's a field that requires a lot of capability [vendor] with moderate reactogenicity. The flu reactogenicity has actually been moderate, been really good. So that's not an issue at all at end of the doses that we have been testing in young or older patients.

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

Thank you for clarifying, Mikael.

Operator

Next, we have Andrew Baum with Citi.

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

Could you talk about the impact of price negotiation under the IRA? Expressly, could you talk to whether you'll be able to collapse the rebate to PBMs in order to offset the impact of, let's say, Eliquis' price reduction, following the price negotiations and therefore, protect your earnings? Or do you think you'll have to still pay the PBMs that kind of a flash even though they're being able to buy the drug at a much reduced price -- or fund the drug at a much reduced price?

And then separately for Mikael, given the recent acquisition of Seagen, to what extent -- or planned acquisition of Seagen, to what extent do you believe that there is a potential to review your existing pipeline in order to make room or further optimize your R&D spend to put behind Seagen's additional assets?

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

Yes. So why don't we go first to answer about what IRA will mean in terms of changing the rebates, et cetera, which it's quite a new situation. So we have to see how it plays. But if you want to speak a little bit about it, Angela?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

Yes, sure. So that's exactly right, Albert. I think there's just -- it's a new policy and lots to understand in terms of how it's going to play out. As you say, there will be price negotiations, but at the same time, I think that what we also have to remember, Andrew, is that there's a mitigating factor of the fact that more patients likely will be able to get on Eliquis because of the co-pay threshold and that sort of cap we're going to have as a function of IRA.

And so I think it's a dynamic situation. There's lots for us to consider as it pertains to pricing, rebates, but also patient utilization of the drug and all of this will play out. I guess, as it pertains specifically also to Eliquis, just to remind everyone that though it's obviously one of our largest drugs, its LOE will be around that '26 timeframe. So whatever the impact is, will not be long lasting on our portfolio because it's losing patent anyway around that time.

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

Thank you very much, Angela. It's an evolving environment so we need to really go see it. Also, Andrew, very quickly on the pipeline issue. We have made very clear, but the Seagen acquisition will mean nothing to the pipeline assets. So no pipeline assets will be eliminated or reduced or increased as a result of -- actually, would be increased because of the combinations, but will not be any reductions on pipeline assets as a result of this acquisition.

Operator

Next, we have Chris Schott with JPMorgan.

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

Just a 2-parter on COMIRNATY. Can you just help me a little bit in terms of -- I guess with the updated vaccine being commercialized in September, how much of your remaining COVID revenue should we think about in 3Q versus 4Q? And I'm just trying to get my sense of when we get this 3Q update, will that be based on the sales we're seeing in the quarter? Or more your interpretation of the trend we're seeing for vaccinations? So just setting expectations. And the second part was on the EU contract renegotiation. Just any additional color you can provide on how different, I guess, the terms end up being for 2023 relative to what was reflected in the 2023 guidance?

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

Thank you very much. I can take it very quickly. Look, if you see, we will have basically July, August, September in the third quarter. So the vaccinations, with the new, would start in September, hopefully, of course. What we expect is that we will have approval by the end of August. And we are ready with products already now. So we have -- so the production will not be an issue.

So normally, we should have also in Q3, most of it in Q4. But what really will clarify us at the end of Q3 plus also the month that takes after Q3 until we give -- we present our Q3 results, it is really the vaccination rates, right? That is what will inform. And then price, right? Because everything after all, way better working at price. So very big part of this uncertainty for COMIRNATY will go away.

On the EU contract renegotiation, I don't know if you noticed, I did say that when we gave our guidance, we were expecting that we will have incorporated assumptions, that we will renegotiate the new contract and our assumptions, we're assuming that we will do over 3 years. Now we did over 4 years, which that creates pressure to our guidance, but then we had some contracts that we didn't expect guidance in Latin America, particularly, that offset very big part of that. So that's why there's no -- but by itself, it's not a reason to change the guidance one way or another. Really, as I said, vaccination rates, it is what will define what is the potential of this vaccines for the years to come. Thank you very much, Chris.

Operator

Next, we have Rajesh Kumar with HSBC.

Rajesh Kumar - HSBC, Research Division - Analyst

Just one for me. You're doing a lot of acquisitions. You've done a large one, Seagen, recently. It's not completed, but as we look forward, how do you think the -- what are the sort of integration challenges you see both on the execution, commercial side but also on the scientific side? What are the things that get you excited versus worried?

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

For the Seagen acquisition, right? Let me...

Rajesh Kumar - HSBC, Research Division - Analyst

But you had multiple acquisitions before that as well. So just -- you've got multi-integrations going on sort of, that's why I'm asking the question.

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

Exactly. Exactly. Yes. So let me start with what excites us with Seagen and I think it's the science behind this company. The ADCs are playing a key role right now, more and more in our research and in our fight against cancer. And Seagen has 1 of the 2 leading platforms and we believe it's actually a better one. So I think that excites me a lot.

Also what excites me a lot is that Seagen was able to achieve all this greatness with limited results, relatively compared to what we are bringing on the table. And what we are bringing on the table on the results front, of course, is not only the capital but also a significant expertise on designing the molecules. And particularly in the small molecules, we are very, very, very good. So when it speaks about payloads, I think we can contribute significantly into that.

Secondly, we are thinking that there is such a nice way of being able to commercialize those products of Seagen, but already in the market or will come because as we look at global presence, that Seagen is lagging. And also in the U.S., we will almost triple our resources once the whole thing is integrated. So there is a lot of things to be excited.

Now as you rightly pointed out, things happening, integrations, that we need to be very aware. And not only we -- we do have our fair share of things that we did wrong in the past and we have our fair share of things that we did right in the past. So I know what is extremely, extremely important is to make sure that, first of all, there will be no cultural clash as we are putting together the 2 organizations. To that end, we are very, very lucky because oncology companies tend to have very, very similar (inaudible), the oncology companies.

And that was saying that even the chemistry of our scientists compared to Seagen's scientists. Actually, where it is really evident it is how many of the great scientists of Seagen raise their hand to join Chris' leadership team as we are going forward. And those scientists will have published this information who will be coming from Seagen. Actually, many of them will lead the global oncology business, not only our past acquisition, not only the Pfizer one, but they will lead the global -- not only the Seagen one, but the global, which is Seagen plus core.

The second thing that we need to be very careful it is that we don't slow down things, and we don't increase cost of things. This is something that we have seen when big companies are acquiring small. But many times, cost goes double and the timelines goes also doubled. So that's something that we must avoid. And in order to avoid, we are doing tremendous pre-integration planning to make sure that innovation will be enhanced dramatically after we are putting the 2 together. And I have full trust on, of course, Chris, that is leading this integration, on this planning for months now.

And last but not least, many times, when you have an integration, it could go wrong and it's good if a CEO, which is the one who can resolve conflicts in a corporation and make decisions fast, has very high visibility on what is happening. So I think very fast. This is our biggest investment for many decades. That's clearly the biggest investment under my watch.

And we take it very seriously as one of the most potential exciting opportunities to grow. But also, we are very cognizant that we should make sure that nothing goes wrong. So I'm personally on it. And Seagen is going to be one of our biggest bets as you can see going forward. So we are using all our experience and the best people and I'm very, very pleased. And I'm very, very pleased because chemistry of the 2 teams is unbeatable right now. And they are working like one and they are all coming to see the new Seagen/Pfizer oncology portfolio growing faster than when we were alone.

Operator

Our last question will come from Michelle Rivera with inThought Research.

Michelle Rivera - *InThought Research - Analyst*

What's the status of the DMD gene therapy program? Have you finalized dosing patients? I read a statement at a recent conference that you finalized screening patients. So I was not sure whether that meant that the trial had been paused. Just some clarity around that and when we should expect data, would be helpful.

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

Chris, you were running DMD until recently. Now, you, of course, provided Mikael the responsibility. So can you give us a little bit very quickly what is the status of DMD?

Chris Boshoff - *Pfizer Inc. - Executive VP and Chief Oncology Research & Development Officer*

Yes, thank you. So the -- as I mentioned earlier, the clinical trial has now completed enrollment. As you pointed out, the halt dosing for the last couple of patients due to a protocol amendment, but we're very confident that we will go ahead and have the interim analysis later this year based on the functional end point, which will be substituted also or which will be, yes, with the biomarker data. We'll have both functional data as well as biomarker data later this year, and then the final analysis for the full study in 2024. We've also fully enrolled now the earlier age group, patients between the ages of 2 and 3 years old, 10 patients enrolled in that trial. So yes, we're looking forward to share the data later this year for you.

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

Thank you very much. In summary, I think we had a solid quarter, continue to invest, to support our unprecedented 19 potential launches in an 18-month period. These are doing very well. The plan is executed as per the timelines. In our pipeline and in value-creating revenue-generating business development opportunities like Seagen, which, as I articulated just in the question before that, it is clearly our big bet and our very, very big opportunity moving forward.

Over the next 3 months, we look forward to moving beyond the current uncertainty related to our COVID-19-related revenue. So we have better clarity. And by the end of the year, we'll have -- the uncertainty will be removed almost at last. To that extent that any adjustments are needed into our cost base for '24 and beyond, we are ready to make. I want to reemphasize that the biggest uncertainty in terms of the long term is vaccination rate. Some short term uncertainties like when commercialization will be, I think it's just a question of time. But the vaccination and treatment rates that we are going to see, I think, will inform what we should expect for the years to come, with only upside with the combination vaccines.

Putting all these factors together, we remain confident in our ability to deliver a robust operational growth and deliver meaningful shareholder value through the end of the decade and beyond.

And that, we will bring our call to a close. Thank you for joining us, and have a great rest of your day.

Operator

Thank you. Ladies and gentlemen, this does conclude Pfizer's Second Quarter 2023 Earnings Conference Call. We appreciate your participation, and you may disconnect at any time.

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