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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Fourth Quarter 2023 Earnings Conference Call. Today's call is being recorded. At this time, I would like to turn the call over to Francesca DeMartino, Chief Investor Relations Officer and Senior Vice President. Please go ahead, ma'am.

Francesca M. DeMartino - Pfizer Inc. - Chief IR Officer, Senior VP

Good morning, and welcome to Pfizer's earnings call. I'm Francesca DeMartino, Chief Investor Relations Officer. On behalf of the Pfizer team, thank you for joining us. This call is being made available via audio webcast at Pfizer.com. Earlier this morning, we released our results for the fourth quarter and full year 2023 via a press release that is available on our website at Pfizer.com.

I'm joined today by Dr. Albert Bourla, our Chairman and CEO; and Dave Denton, our CFO. Albert and Dave have some prepared remarks, and we will then open the floor for questions. Joining for the Q&A session, we also have Dr. Chris Boshoff, EVP and Chief Oncology Officer; Alexandre de Gernay, EVP and Chief International Commercial Officer; Dr. Mikael Dolsten, Chief Scientific Officer and President of R&D; Doug Lankler, EVP and General Counsel; and Aamir Malik, EVP and Chief U.S. Commercial Officer.

Before we get started, I want to remind you that we will be making forward-looking statements and discussing certain non-GAAP financial measures. I encourage you to read the disclaimers in our slide presentation, the press release we issued this morning and the disclosures in our SEC filings, which are all available on the IR website on Pfizer.com. 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 & CEO

Thank you, Francesca. Good morning, everyone, and thank you for joining us. I'm pleased to discuss some of the highlights from the fourth quarter and full year 2023 and, of course, the compelling year we have had. I would like to begin with a few reflections for -- on 2023. As you know, we missed our initial internal projections and Street expectations predominantly related to our COVID products, which affected our stock price performance. Despite, however, this challenging year, there were a few great things that happened in 2023 that may have gotten lost amidst the missed expectations.

First, in 2023, Pfizer impacted the lives of more than [618 million] (corrected by company after the call) people approximately around the world. We believe there is no other company that can reach as many people and patients as Pfizer. If you multiply this with our brand equity and awareness, it creates a connection with consumers that can be a very strong asset for us.

Second, despite the decline in revenue from our COVID products, as of the reported results of the first 9 months of 2023, we were the #1 pharmaceutical company in terms of revenues from pharma-only products, a marked improvement from our fourth position in 2019.

Next, 2023 was a record year for FDA approvals with 9 new molecular entity approvals from Pfizer and many more approvals for new indications in already approved products, marking a very productive year of pipeline execution for Pfizer.

Finally, we closed the Seagen acquisition. In the current regulatory environment, being able to close such a large acquisition demonstrates our ability to successfully engage with regulatory bodies.

Our deliberate and strategic efforts throughout 2023 created a strong foundation to support us. We are now focused on maximizing the opportunities that have positioned us for success, and our team is driving confidently as we start 2024.

From the advent of penicillin to the development of the COVID-19 vaccine, Pfizer has been at the forefront of medical and pharmaceutical breakthroughs for the past 175 years. This year is our 175th anniversary, that have not only changed patients' lives but have changed history.

Our strategy to continue to build on our proud history of innovation and commercial excellence is supported by the power and strength of our unmatched global scale and footprint spanning commercial, financial, medical, regulatory, manufacturing and government relations. We have a clear view on how we will deliver operational, commercial and financial success across our business.

Our confidence stems from the opportunity we have to bring additional focus to our business by executing 5 strategic priorities. We will get into each in more detail, but the 5 key priorities for Pfizer this year are: first of all, to achieve a world-class oncology leadership; to deliver the next wave of pipeline innovation; to maximize the performance of our new products; expand margins by realigning our cost base; allocate capital to enhance shareholder value. I'm confident that Pfizer is well positioned to execute and that we can deliver meaningful value for our patients and our shareholders.

Let's start with our first priority, which is to achieve a world-class oncology leadership, which I believe we are in a strong position to do. As a reminder, 1 in 3 people will be diagnosed with cancer in their lifetime. Oncology represents one of the largest and fastest-growing therapeutic areas. Completing the acquisition of Seagen doubled our oncology research and resources overnight and meaningfully expanded the reach and medical impact of our U.S. commercial and medical footprint, with a range of portfolio expansion opportunities boosted by Seagen's broad and deep pipeline.

Seagen's in-line medicines are expected to immediately enhance Pfizer's top line growth, and our combined portfolio provides the opportunity to lead genitourinary cancers and be a leader in breast cancer and deliver at least 8 potential blockbuster products by 2030. We look forward to providing more information about our oncology platform at our Pfizer Oncology Innovation Day on February 29.

As we build our leadership position, we have multiple potential key oncology catalysts in 2024 that we are acutely focused on. On the commercial side, the PADCEV launch in locally advanced/metastatic bladder cancer in combination with pembrolizumab and XTANDI launch in nonmetastatic castration-sensitive prostate cancer. We are excited by the strength of our PADCEV EV-302 data and recent FDA approval, as it represents an opportunity to broaden the reach of this potentially practice-changing, platinum-free regimen to even more patients in the frontline metastatic urothelial cancer setting.

Essentially, the recent approval doubles the addressable population, which had already doubled this past spring. We are also looking forward to Phase 3 data readouts from vepdegestrant in second-line HR-positive metastatic breast cancer; and Braftovi in first-line BRAF colorectal cancer. We also plan to advance our late-stage pipeline with Phase 3 starts of CDK4 in post-CDK4/6 metastatic breast cancer and B6A in non-small cell lung cancer. Building on Pfizer's potential medicines, the pipeline across breast cancer, genitourinary cancer, hematology and CRC, our CDK4 inhibitor could be a compelling follow-on to IBRANCE.

And finally, in the early-stage pipeline, we look forward to initiating first in patient studies of 4 new ADC candidates this year, where we believe we have acquired the expertise to be a leader.

Our second priority is to deliver the next wave of pipeline innovation with discovery and development across our therapeutic areas outside of Oncology in Vaccines, Anti-Infectives, Internal Medicine Metabolic Diseases and Inflammation and Immunology.

In 2024, we plan to continue to make meaningful investments in R&D. In fact, Pfizer's R&D budget is one of the highest in the industry and supports our robust pipeline. We are pursuing cutting-edge science across modalities and platforms to deliver the next generation of potential breakthroughs. We are also leveraging AI and other digital tools across the value chain to increase speed and success rates.

Starting first with our fourth-generation PCV vaccine candidate, which recently entered the clinic and received FDA Fast Track designation. Building on our deep heritage with Prevnar, we aim to solidify our leadership in the pneumococcal vaccine space by increasing valency and serotype immunogenicity while maintaining our unique FDA label, which includes both IPD and pneumococcal pneumonia in adults.

Respiratory vaccine combinations are another area where we are poised to lead, building upon our successful COVID vaccine. With the first-generation stand-alone mRNA flu vaccine, data demonstrated relative efficacy versus a recommended flu vaccine in 18 to 64-year-olds, but did not meet success criteria for immunogenicity for the B strains.

Our second-generation flu vaccine was tested in a Phase 2 COVID/flu combination study for 18 to 64-years-old and has shown encouraging results in both the A and the B strains. This new construct has now moved already into a Phase 3 COVID/flu combination trial.

Moving next to GBT601. Our next-generation and potentially best-in-class HbS polymerization inhibitor represents a potential step-wise evolution over Oxbryta for sickle cell disease. Recent data presented at ASH 2023 demonstrated multiple blood parameters approaching normal ranges with treatment, suggesting GBT601 may have the potential to deliver strong efficacy with the convenience of a once-daily pill. We have reaffirmed our commitment to our emerging cardiometabolic programs, with several early clinical development compounds.

On the other end of the weight management spectrum, we have ponesegromab, our GDF-15 neutralizing antibody for cancer cachexia with Phase 2 data expected later this year. Ponesegromab has the potential to be first-in-class and the first FDA-approved treatment for cancer cachexia, which accounts for 20%, 30% of all cancer deaths, a significant statistic.

Our third priority is, of course, to maximize the performance of our new products and core franchises through a relentless focus on execution to continue growing our top line. To do this, we are prioritizing and focusing while leveraging data to make changes quickly and adapt. Our Pfizer U.S. Commercial and our Pfizer International Commercial organizations will leverage a more focused, efficient structure to drive executional excellence in their respective markets and expand reach to drive growth over the next several years.

To discuss a few examples, we continue to be very enthusiastic about the potential of Nurtec to help the more than 1 billion people living with migraines worldwide. As access and prescriptions in the U.S. and globally continue to increase, we will continue to focus on direct-to-consumer marketing and reducing barriers to access and affordability for health care practitioners and patients.

With Oxbryta, we will continue to educate health care practitioners and patients on the importance of proactively treating the underlying cause of sickle cell disease by reframing treatment goals to chronic/proactive treatment.

With Abrysvo, we are focused on increasing overall RSV market growth and market share by establishing RSV vaccination as a year-round discussion and expanding our retail contracting and offerings.

With ELREXFIO, we are focused on educating health care practitioners in both academic institutions and in the community, awareness building and new patient trialists.

Coming off the initial launch of VELSIPITY, we are focused on helping ensure patient access to VELSIPITY as a first-line advanced therapy oral option.

With LITFULO, we continue to accelerate the consideration of advanced systemic treatments for appropriate alopecia areata patients and further unlock access to LITFULO.

In addition, of course, we continue to protect and grow our core franchises and key blockbusters, including Prevnar, VYNDAQEL and Eliquis, while exploring further opportunities to advance a number of innovative combination regimens. We believe we are well positioned to bring our global commercial manufacturing and supply capabilities to accelerate current and future marketed products.

We believe all these components support our growth potential through 2024 and drive growth potential into 2025. We plan to provide updates throughout the year on how we are advancing these strategic priorities.

And with that, I will turn the call over to Dave, who will discuss our financial performance, our initiative to realign our cost base and our capital allocation strategy to enhance shareholder value. Dave?

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

Thank you, Albert, and good morning, everyone. As we enter 2024, we are clearly focused on a small number of critical priorities. These priorities include building a world-class Oncology organization; ensuring the next wave of pipeline innovations; maximizing our new product portfolio performance with a more efficient commercial structure; and finally, rightsizing our cost base.

With that said, I'll start this morning with our full year and our fourth quarter results, then I'll touch upon our capital allocation priorities. I'll finish this morning with a few comments on our 2024 guidance and the near-term expectations that set this year as a foundational year to drive our growth potential in the latter half of the decade.

For the full year 2023, we recorded revenues of \$58.5 billion, achieving 7% operational growth, solidly in line with our expectations when excluding contributions from both COMIRNATY and PAXLOVID. The significant sales decline in our COVID products, including a \$3.5 billion revenue reversal for PAXLOVID, were the primary driver of an overall 41% operational decrease year-over-year. And with the expectation that Seagen will be a substantial growth contributor in 2024 and beyond, our full year and fourth quarter results include approximately \$120 million in Seagen product revenue after the close of the acquisition on December 14.

On the bottom line, we reported full year 2023 diluted EPS of \$0.37 a share, a 93% year-over-year decline and adjusted diluted earnings per share of \$1.84, down 72% versus LY. This decline is primarily due to a significant decrease in sales for both COMIRNATY and PAXLOVID; the impact of the \$3.5 billion reversal for PAXLOVID revenues in the fourth quarter related to an expected return of an estimated 6.5 million unused EUA-labeled treatment courses from the U.S. government; and finally, a noncash inventory write-off and other charges of \$5.6 billion recorded in the third quarter for PAXLOVID and, to a lesser extent, COMIRNATY.

Now turning to the quarter, I'd like to highlight that we delivered a solid 8% year-over-year operational revenue growth, again, excluding COMIRNATY and PAXLOVID. Contributing to the strong performance were our newly approved RSV vaccine as well as VYNDAQEL and Eliquis, partly offset by lower revenues from IBRANCE and the Pevnar family. However, our Q4 results, both top and bottom line, continued to be significantly and negatively impacted by our COVID products on a year-on-year basis. Revenues declined 42% operationally, the result of a significant decrease in both COMIRNATY and PAXLOVID sales.

Adjusted cost of sales as a percentage of revenues increased by 12 percentage points, driven primarily by the \$3.5 billion noncash PAXLOVID revenue reversal and, to a much lesser extent, unfavorable changes in sales mix. Overall, our adjusted operating expenses declined 10% compared to Q4 of last year.

Adjusted SG&A expenses increased 1% operationally in the quarter, primarily driven by the timing of marketing and promotional activities, including those related to recently launched and acquired products. And consistent with our strategy, we have been focused on reprioritizing our R&D spending to enhance overall returns. Adjusted R&D expenses decreased 24% operationally, driven primarily by lower spending across both vaccine programs and certain acquired assets as well as lower compensation-related expenses.

Both our Reported diluted loss per share of \$0.60 and our Adjusted diluted earnings per share of \$0.10 for the quarter were negatively impacted by the \$3.5 billion PAXLOVID revenue reversal, which dampened EPS by approximately \$0.54. Continued declines in both COMIRNATY and PAXLOVID sales also negatively affected our performance in the quarter. Foreign exchange movements had an immaterial impact compared to last year's fourth quarter.

As we are increasingly focused on prioritizing our investments to drive forward-looking growth, our GAAP results include a \$1.4 billion intangible asset impairment charge associated with etrasimod, based on changes in the development plans for additional indications and overall revenue expectations. But I will point out that this product is still projected to contribute over \$1 billion in peak annual sales. Additionally, we recorded a nearly \$1 billion intangible asset impairment for Pevnar 13, reflecting a transition to vaccines with higher serotypes coverage.

As discussed in prior quarters, our capital allocation strategy is designed to enhance shareholder value and is based on 3 core pillars: first is growing our dividend; second is reinvesting in the business; and finally is making share repurchases after delevering our balance sheet.

For 2023, we returned \$9.2 billion to shareholders via our quarterly dividend; we've invested \$10.7 billion in internal R&D; and finally, we've invested approximately \$44 billion in completed business development transactions, net of acquired cash, essentially for the acquisition of Seagen.

Our expectation is to maintain and grow our dividend while delevering our capital structure, with a gross leverage target of 3.25x and a goal to preserve our credit rating and access to Tier 1 commercial paper. Upon achieving our delevering goals, we anticipate returning to a more balanced capital allocation strategy, inclusive of share repurchases.

Now given that we issued our full year 2024 revenue and Adjusted diluted earnings per share guidance on December 13, let me just hit a few of the highlights. We expect total company full year '24 revenues to be in the range of \$58.5 billion to \$61.5 billion, which reflects our expectation of strong contributions across our product portfolio. Importantly, excluding COMIRNATY and PAXLOVID, we anticipate operational revenue growth of 8% to 10%. We remain confident on delivering at least \$4 billion of net savings from our cost realignment program by the end of this year. We believe rightsizing the cost base will put us on a strong footing towards margin expansion and increased operational efficiency moving forward.

We expect Adjusted diluted earnings per share to be in the range of \$2.05 to \$2.25 a share for the full year of 2024. And as a reminder, this range is inclusive of an anticipated \$0.40 of earnings dilution from the Seagen acquisition and again, with the vast majority of this dilution resulting from the financing costs associated with the deal. Cycling into 2024, we have significantly invested in our business to fuel our long-term growth, and the foundation is set to deliver on our commitments to enhance long-term shareholder value. We are acutely focused on driving near-term performance while solidifying our growth expectations for the back half of this decade.

And with that, I'd like to turn it back over to Albert to begin our Q&A session.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you. With that, let's start the Q&A session. Operator, please assemble the queue.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

And our first question comes from Robyn Karnauskas with Truist Securities.

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

So maybe I'm stupid on this question, but if I'm doing your math for your guidance of margins in low 70s for fiscal year '24, by my math, the margins for other biopharma would have to drop to about 60% in order to balance out the other margins. Can you just help me understand your guidance and triangulate that with your top line and bottom line guidance and triangulating that with your margin guidance?

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

Yes. So maybe -- this is Dave. Correct. Our guidance for gross margin, although we don't provide it specifically, we've given some color around the fact that it's approximately 70%. Obviously, our focus going forward is to improve our margin rate and, more importantly, improve our operating margin rate to the bottom line. I would -- as we look here at 2024, there's a few things that have compressed our margin rate versus as COVID has declined year-over-year, that has served to, I'll say, delever, if you will, the P&L as COVID takes up and cover some fixed overhead.

But importantly, what's happening is we are in-sourcing products that we've recently acquired. Those -- that in-sourcing requires time before we get up to peak yield and performance so that in the short term, dampens gross margin rate but has a trajectory to improve gross margin rate over time. And then secondly, we have new launches that are coming online late in Q3 or -- late in the second half of 2023 and moving into '24. Again, those are not at peak performance yet. That will ultimately improve gross margin rate as we cycle into later years.

And then finally, I will say that over the last several years, we have absorbed some amount of inflation within our cost of goods sold. That is an area of opportunity for us as we think about improving performance longer term. So I hope that gives you some color.

Operator

Next, we have Carter Gould with Barclays.

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

Maybe another kind of finance question here. Certainly, R&D in 4Q was meaningfully below kind of where you guys had set the guide there. How should we think about that? Does it just reflect sort of faster cost cutting? Is it just more an artifact of the later integration of SGEN? And clearly, you're reaffirming your guide but just maybe if you can just sort of check that box for us, that would be helpful.

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

Sure. Probably not much to read into that. Obviously, R&D came in a little favorable than our expectations previously. Part of this is the fact that we are very focused on our -- realigning our cost base, so consistent with the program. And then secondly, there probably is some timing that's dampening R&D in the fourth quarter that will slide into 2024 and into 2025. So there is some timing implications to that performance level.

But I think importantly, back to my prepared remarks, is our focus is on delivering net savings of \$4 billion. And if you look through the end of 2023, about half of that we've achieved already. We're now focused on achieving the additional \$2 billion or so as we cycle into 2024, and all eyes are on that objective.

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Thank you, Dave. We have high confidence on the number that we gave.

Operator

Our next question will come from Louise Chen with Cantor.

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

Wanted to ask you on your Prevnar franchise. First of all, for the fourth-generation PCV, could you give more color on how it compares in contrast with Prevnar 20? And then just on the Prevnar order timing issue, was that U.S. or ex U.S.?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Thank you. Aamir, why don't you take the Prevnar question? And then maybe Alexandre, you can add a little bit color on the situation in the U.S. So what is the situation in Prevnar with the orders?

Aamir Malik - Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP

Yes. So Louise, with regards to Prevnar, with the pediatric business, we often see some lumpiness in quarterly revenues given the timing and impact of CDC orders, so it's difficult to kind of map that all out quarter by quarter. So you should expect that on the pediatric business. But the pediatric business, otherwise, we're very happy with how our launch is progressing and the growth momentum that we see there.

On the adult business, I think it's different in the sense that we have a 96% market share that we closed the adult business with at the end of the year. But it's really important to keep in mind that we are operating in a market where the patient pool is steadily decreasing. There was a big catch-up opportunity versus the prior recommendation, and we've worked through that catch-up opportunity already. So the remaining patients are generally those that are aging into the 65-plus population as well as those with underlying medical conditions, and those are harder to activate patients. So we expect that business to continue to face that smaller patient population going forward. And we also expect competition with V116 emerging that will make the adult market more competitive, but we see a lot of growth potential in the pediatric market.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you. Alexandre, how was the Prevnar situation in the last quarter or in the year in international markets?

Alexandre de Germay - Pfizer Inc. - Chief International Commercial Officer, Executive VP

Yes. Louise, good question. As you know, the majority of our ex U.S. business is driven by tender. And of course, we book the sales when we ship the product. It doesn't reflect utilization. And then the government schedule their campaign in their respective markets. The reality is that we continue to have an IP exclusivity in 113 markets around the world. And at the same time, we continue to progress both on the pediatric, as you saw last week, the CHMP positive opinion, and now we're going to go into the final approval and then vaccine technical committees and pricing in all those markets, so that will take a bit of time.

But at the same time, we see some positive traction on the adult franchise, where we have launched in over 30 markets. And we see some very good developments with the recommendation of the vaccine technical committee. To give you an example, we used to have very limited access on our Prevnar 13 in country like Germany or France and U.K. And we just received a recommendation from the VTC in Germany that actually recommended usage of Prevnar 20 in old adults over 60 as well as at-risk population from 18 to 59, which we believe we have a significant growth opportunity in increasing vaccination in the adult population ex U.S.

Albert Bourla - Pfizer Inc. - Chairman & CEO

And Mikael, to conclude what about the fourth-generation Prevnar?

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

Yes. I'm very pleased that the fourth generation has entered clinical studies. It has a Fast Track designation from U.S. FDA, indicating a unique product offering. And it includes some of the new technology we have developed that gives us a really cutting-edge toolbox, whether it's chemistry, carriers or reformulations. And of course, it relies on the unique Pfizer platform to have potential prevention of both invasive disease, which is the smaller disease burden and pneumococcal disease, which causes more than 150,000 hospitalizations. And to the best of my knowledge, we are the only one that can address both of them. So we feel very good about that entry.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you, Mikael. So to summarize the Prevnar, which I know it is in the minds of all, let's start with the commercial front. In the U.S., clearly, the adult opportunity, we have taken the cream basically of the catch-up opportunity. This is happening once you are getting a recommendation from

CDC for a catch-up. This market, the pool of patients has been largely exhausted. We have already 96% market share of that. So this is not a market, the adult from now that we expect that will continuously grow in the U.S.

Pediatric, very different story because our market share is now growing, and we have indications that we'll continue growing very strongly. So we expect in the U.S., the Prevnar situation to be a strong growth story in pediatric. International, both, we expect to see growth because the products have just been launched, and then the recommendations are following. So there is a delay in international higher than usually there is in the U.S. So we expect to see growth in adult and in the pediatric.

I want to reemphasize that we have basically exclusivity of Prevnar 13 in more than 100 countries, 113 countries in NI of tenders. And we plan to convert that now to 20. And then on the fourth generation, we are moving full speed. We think that our expertise will allow us to build a polyvalent vaccine that will really compete very, very nicely as a fourth generation and we will do that successfully and fast. So that's the story.

Operator

Next, we have a question from Trung Huynh with UBS.

Trung Chuong Huynh - *UBS Investment Bank, Research Division - Analyst*

Trung from UBS. Two, please. So in your prepared remarks, you noted you took a \$1.4 billion impairment charge associated with etrasimod. Can you add more color here? What prompted that reevaluation? And any feedback of how that launch has gone? Secondly, on Abrysvo, so can you give us some color on how your contracting has evolved in '24 versus '23? And based on that, what's your market share do you think you can capture this year versus the 35% last year?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Thank you very much. Why don't you take, Dave, the impairment question and then I will move to commercial guys?

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

Yes. So on etrasimod, keep in mind that this product, we still anticipate to be over \$1 billion in peak sales. As you know, there are multiple indications attributed to this medicine. And financially, as you look at that medication, there were additional indications that met the financial criteria for an impairment of which we took in the quarter. Clinically, obviously, clinically, there's still some work that will be ongoing in support of the asset. So with that...

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Thank you very much. So Aamir, maybe etrasimod commercially, how the launch is doing and the Abrysvo.

Aamir Malik - *Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP*

Sure. So I'll start with etrasimod or VELSIPITY, as we call it. So just in terms of the product value proposition, we think this is a very promising oral option for moderate to severe UC patients. It's got strong efficacy that patients and physicians that we've exposed this to. They want to start transitioning from conventional therapy to advanced therapy. And it gives them an option also to maintain once-a-day oral routine, which many are already on instead of beginning with an injection or infusion. So about 80% of those patients that haven't progressed to an advanced therapy prefer an oral option, but only about 10% of those patients actually get one.

So there's a very clear need here that VELSIPITY can help us fit. And the benefit-risk profile for VELSIPITY is also very, very strong. So we approved -- we received approval at the end of last year. And so we've invested efforts in building HCP and patient awareness on the label and on the value proposition. But I just want to remind you that with any immuno-inflammatory product, it takes time to get broad national access. And that is where our focus is right now is ensuring that we secure VELSIPITY access as a first-line advanced therapy oral option, and that's going to take some time to put in place. And when we have that in place, we see upside momentum from the launch.

Albert Bourla - Pfizer Inc. - Chairman & CEO

What about Abrysvo?

Aamir Malik - Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP

On Abrysvo, I'll comment briefly on the adult and then on the maternal. On the adult vaccine, I think the market was clearly ahead of everyone's expectations and not limited by shared clinical decision-making versus a routine recommendation. We would like to do better than the 30-some percent share that you referred to as well. So we're very focused going forward on retail contracting for the '24, '25 season. But I will also mention that we are doing that with real thoughtfulness on ensuring that we secure a profitable share in those contracts and also differentiating using our maternal indication.

We also see opportunities in the nonretail setting, where for example, with the VA system and with IDNs, we have strong share. And we're going to also focus on new opportunities that we're currently studying with Abrysvo, adults aged 18 and older with underlying medical conditions as well as a new packing presentation to better fit our customer needs. So we see momentum there.

And on the maternal side, we're only a few months in but we're encouraged by what we're seeing as the first maternal vaccine to prevent infants from birth to 6 months when they are the most vulnerable. More than 65% of women prefer to get the maternal vaccine versus having their infant immunized with a monoclonal antibody. And we think that the label provides us opportunity to grow that segment as well.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

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

Two for me. I guess the first one is just COMIRNATY rest of world was ahead of consensus expectations this quarter. Just wondering if there were any onetime benefits in that number, if that's a fair go-forward sales level to think about through 2026 given the existing EU contract? And then the second one is, I noticed that danuglipron wasn't mentioned in the PR or the prepared remarks. Just wondering if that once-daily PK trial completed yet and what the next steps are there.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you very much. Maybe very quickly on the danu, we didn't mention because we don't have anything to say more. So that's the only thing. There is a program, which is composed with a lot of experiments that we are doing now in terms of moving it to once-daily and we will speak only when we have data. We don't want to become now the focus again of another earnings call. But that being said, I'm moving it to Alexandre to discuss about COMIRNATY in the rest of the world outside the U.S. What are the dynamics over there then?

Alexandre de Germay - Pfizer Inc. - Chief International Commercial Officer, Executive VP

That's why there are several elements playing out on the COMIRNATY franchise. First, what we see is restrictions on vaccination guidelines, right? So versus the previous years, we see that the guidelines are really focusing on the older population as well as the at-risk population. But we have, as you know, already signed several contracts with the European Commission, Canada, U.K. and Australia. And following the approval in August last year, we started to execute on our contract with the European countries. As a matter of fact, some countries have decided to advance some of their order in 2024 into 2023 so that they can execute their vaccination campaign properly.

The other trend that we see is that actually, we don't see major vaccination uptakes in the future year. We think that what we have seen in 2023, 2024 campaign is really the type of vaccination we will see, and that will be carried on the next few years. The only area where there is a potential future growth in terms of vaccination uptake is if we can increase our co-administration with the flu vaccines where in all our key markets, the rate of vaccination in flu is actually higher than it is for COMIRNATY. So we believe that there is potentially here an opportunity.

The last point that I want to say is, as you see that the COMIRNATY self pattern is evolving towards a seasonal pattern. So you saw you have a very strong Q4, like you expect in flu vaccination type of market. And that's what we see also to be expected in 2024. And actually, as I was reading some of your models in the financial community, I think there is some confusion that we will have higher Q1, Q2, which I believe will be more towards the second part of the year, but of course, in line with the guidance.

Operator

Our next question will come from Umer Raffat with Evercore ISI.

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

Albert, so I was looking at SEC filings from Cerevel and they disclosed that Pfizer was open to putting out a bid on Cerevel after Phase 3 data, which would have been in 2024, meaning I also noticed that you were saying you're not open to a buyback in 2024 and deleveraging remains a top priority. So I just want to balance those two, especially also in the context of where the stock stands.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Well, look, I will ask Dave to speak about it. But the fact that we are looking at everything and we are engaging in everything doesn't mean that, that's our obligation. We are doing all the work. It doesn't mean that our intention is to deviate from the capital allocation strategy that we have just articulated. And that is the #1 priority is our dividend and the growing dividend. Then it's a year of execution. We try to delever, as David said.

And then once we bring our deleverage to the levels that we are aspiring, we will start also moving into share buybacks and, of course, M&A, which means that for '24, we will see everything in existence because we never say never to business development opportunities could come. But our strategy, it is that you will not see anything major in business development in terms of dollars. David, did I say it well?

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

You said it well. You are correct.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you very much. You are a good teacher. Thank you. And the other question, Umer? I think that was it, right? Yes. Thank you, Umer.

Operator

Next, we have Tim Anderson with Wolfe Research.

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

Maybe for Aamir. So Eliquis is the biggest drug on the initial list of 10 drugs for IRA. CMS has until February 1 to provide you the initial proposed negotiated price, so that's 2 days away. So 2 questions here. Can you confirm you haven't already received that initial proposal yet? And second question, can we expect that at some point between now and September 1, which is the deadline that they have to make the final price public, that you'll give some investors some sort of directional information on how those discussions are going? Are we going to be kind of in the dark until September 1?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

So Aamir, are you planning to give light to Tim more? Give us.

Aamir Malik - *Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP*

So Tim, as you can appreciate, this whole price setting authority in Medicare, this is new and pharma companies obviously beginning to understand this process of the federal government. The rules are complicated, so we're wrapping our mind around it. Our alliance partner, BMS, is taking lead and engaging with CMS in an official process to determine the price for Eliquis in Part D that will begin in January 1, 2026. And also as I'm sure you can appreciate, we're not going to comment on an ongoing price-setting process and negotiation.

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Yes. It's very difficult to comment on these things because they are ongoing. So it's very inappropriate and absolutely could complicate things. I understand that there is a need for people to understand because that's an important product. And we will try as soon as possible and practical to be able to provide the level of details that we are looking at, everybody is looking so that they can model it appropriately.

Operator

Our next question will come from Andrew Baum with Citi.

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

A couple of questions, please. First to Aamir, under your new leadership and commercial focus, what key products would you guide us to of recent launches that we should look for in terms of acceleration of rollout trajectory? And it doesn't have to be recently launched, established ones as well. And then second to Mikael. Could you just share a little bit more information about your next-generation PCV vaccine, specifically how many serotypes? And I'm assuming that given it's a new technology, you will lose the ability to grandfather the pneumonia claim from the CAPiTA trial into the product profile as it matures. If you could confirm, that would be great.

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Thank you very much, Andrew. Your assumption, I don't think it is correct, but Mikael will answer that. But let's first go to Aamir to basically give us a view how you see in '24 the priorities of the commercial execution in the U.S.

Aamir Malik - Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP

Yes. So Andrew, I'll take a step back and let me start by saying I've been very excited about this role and this opportunity. And also to do it with the team that we've built, which is a mix of both seasoned Pfizer leaders as well as experienced leaders from outside of Pfizer. I mean my focus and we can talk about specific products, we've touched on many of them already. But my focus overall is on execution excellence, right? So in our primary care and specialty care portfolio, we have a lot of great brands. We have some really enduring franchises, VYNDA, Eliquis, Prevnar. I spent quite a bit of time talking about that. Our focus there is to defend and grow where we can, and we do see some opportunities.

And we also have to acknowledge that we have some brands that have great value propositions, but they happen to be in highly competitive categories with some very, very well-entrenched competitors. So in a situation like that, my focus is principally let's really prioritize the actions that can grow each of the brands and we can talk about the individual launches. There's a lot of operational focus on blocking and tackling, including contracting.

And then when we look at our main resources, we have our field force, our advertising and promotion dollars and our medical capabilities just prioritizing exactly where we put those. That is what I'm focused on with me and my management team. And as I mentioned, we see opportunities in some of the core franchises and defending and growing our share but then also in a number of our launches. And Albert mentioned in his opening remarks what we hope and expect to do with Abrysvo, with Nurtec, with LITFULO, CIBINQO. Those are all brands that we're going to continue to focus on, including some of our recent acquisitions like Oxbryta as well.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you, Aamir. Andrew, let me take the liberty to ask also the other commercial leaders to comment a little bit on their priorities because that will give you better sense of the whole picture. Alexandre, in international, as you are taking over, what are your key priorities?

Alexandre de Germay - Pfizer Inc. - Chief International Commercial Officer, Executive VP

Thanks for the question, Albert, and the opportunity to share my priorities. My main focus is really to focus on the area where we can generate material growth with improved return on investment. This is my mantra. How are we going to do that? My top 4 markets in the order: China, Japan, Germany, and France represents 40% of our international division. So it's quite concentrated. Those 4 markets will report directly to me so that we can have the resources and support the country to execute on their plan at best and to generate the most growth.

Our top 15 countries represents 70% of our total international. So it's, again, quite concentrated. What I'm actually doing currently is in each of those markets, we are selecting our drivers of growth. What are the key in-line and the key new products where we can have material impact with improved return investment? So to give you an example, of course, it's going to be different from one country to the other because the archetype and the dynamic of those markets are different. So last week, I was in Japan. And so for instance, VYNDAQEL, diagnosis rate is half the diagnosis rate that we have in the U.S. and in France. So we reviewed last week the plan to go and catch those increased diagnosis rate. And we're going to continue to, of course, track on execution.

In Germany, Eliquis has a very strong Eliquis franchise. We believe we have growth to untapped opportunity. And I'm next week in Germany to actually review the plan on the Eliquis precisely. And we'll do the same thing on the new product. And it's going to be, for instance, LORBRENA in China. As you know, lung cancer in China is unfortunately affecting a large proportion of the population. And as a matter of fact, the proportion of the lung cancer that can benefit from LORBRENA in the worldwide community is about 1.7%. In China, it's actually 7%. So we believe we have a huge opportunity.

What are we doing is actually developing a plan last week when I was visiting China to quickly get LORBRENA to those patients that could benefit from the clinical outcome. So this is really what I'm doing in each of our top 15 countries. Then frankly, the rest of the year will be simply tracking our execution, tracking all the metrics both from activities, medical activities and KPIs for each of our key products.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you. And then maybe, Chris, also on the commercial front. How do you think of the oncology in the U.S. evolving?

Chris Boshoff - Pfizer Inc. - Chief Oncology Officer, Executive VP

Thank you, Andrew, Albert. Our biggest priority right now is obviously continuity of the business. We've done a lot of work during the last 9 months during integration planning. And we don't want to miss a beat and it's now moving towards flawless execution with immediate priorities, obviously, the PADCEV launch for advanced metastatic bladder cancer from the EV-302 study, the launch of XTANDI in nonmetastatic, castration-sensitive prostate cancer from the EMBARK trial, the early launch, and also focus on access and awareness during 2024 for ELREXFIO in late-line multiple myeloma. And for TALZENNA where up to 25% of patients with metastatic castration-resistant prostate cancer would be eligible in the U.S. for the -- from the TALAPRO-2 indication.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you, Chris. And then let's go to Mikael Dolsten, if you can make some comments on the next generation as much as you can share about sales.

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

Yes. I think we have a very strong position with good momentum in the PCV conjugate. And I think Alexandre, you mentioned just the positive recommendation we got for PCV20 in Europe. Now we're building on that unique platform. And as Andrew did say here, we are able, what you call, grandfather in unique claims for the adult segment for pneumococcal pneumonia. It's really the major burden with 150,000 U.S. hospitalizations. And to the best of our knowledge, the Pfizer platform with a new fourth generation, as was with the third generation, will be the only one that can carry that claim based on, as you said, the original CAPITA studies.

Now the new generation will contain more serotypes, has applicability for adult and possibly pediatric, as we have done with all of ours. And it also will include improvement on existing serotypes to, altogether, get a very good increased coverage versus the PCV20. And I do think we are the one that really can continue this expansion of more serotypes, but you need conjugation chemistry carry some reformulations. And I am cautious to abandon any serotype where you work on infant and adults as the characterization what caused disease, for example, pneumonia is not very well described so maintaining the coverage as we have uniquely and it's not really happening with the other product is a unique differentiation. So I feel very good about the fourth generation.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you, Mikael.

Operator

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

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

Albert, the Oncology franchise following Seagen, I suspect, will probably be one of your bigger growth drivers for Pfizer going forward. The question is, is there an intermediate or long-term target as a percent of revenue that you're looking to achieve for this segment? And then are there technologies beyond ADC that you think could be additive to the pipeline?

Albert Bourla - Pfizer Inc. - Chairman & CEO

Yes. Very general, then I will ask Chris to comment a little bit on the technologies that we are having here. I can't say how much Oncology will contribute. But clearly, we have given expectations about Seagen, and we say that we expect it to be at \$10 billion by year 2030 from \$3.1 billion that we gave guidance in 2024. And actually, we feel very good about the \$10 billion. The more data coming -- when we gave the \$10 billion, we were not aware of some of the readouts that follow that projection. So we feel very, very good about that.

Now I have to say that the Pfizer pipeline in Oncology I think was also among the strongest in our entire therapeutic areas. So I think the combination, in general, is giving us, let's say, a lot of strength. But Chris, why don't you comment a little bit about how you see the R&D evolution of oncology, the platforms you are going to base your strategies?

Chris Boshoff - Pfizer Inc. - Chief Oncology Officer, Executive VP

Thank you. So with the modalities we want to focus on for now are those where we see we have significant strength and capabilities, including with medicinal chemistry, our protein engineering as well as our strength in cancer biology. We therefore want to focus on small molecules, especially from our La Jolla; bispecifics, both La Jolla and the new Seattle site; and ADCs in Seattle. So small molecules, biologics.

As you know, we do have an interest also in allogeneic CART cells with the formation of Allogene, the company we still follow and have a significant interest in. But for now focusing on those 3 modalities where we see significant opportunity also for combinations, for example, doing small molecules, ADCs, but also potentially in the future between ADCs and bispecific.

Operator

Our next question comes from Mohit Bansal with Wells Fargo.

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

Maybe a question on Nurtec, the trends in market share as well as pricing. Just wanted to make sure that is there a significant price delta between Nurtec price versus the competitor price? I mean the discounts that they are offering, given that your competitor has multiple offerings in the headache market. And if there is a delta, do you expect this to grow or decline over 2024 on pricing?

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you, Mohit, very much. Aamir, about Nurtec and in general, the migraine franchise.

Aamir Malik - Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP

Yes. So Mohit, thanks for the question. So we were encouraged by Q4 for Nurtec, and I'll also include some comments on ZAVZPRET as part of my response. We were up more than 30% versus the prior year and 20%, over 20% versus the prior quarter. And there's a few things that are encouraging. Nurtec continues to be the #1 prescribed CGRP, so we have leading TRx volume and share. Interestingly, more than 90% of new prescribers in the category, many of whom are primary care physicians are prescribing Nurtec.

And our pills per Rx has also, over the last several quarters, been steadily writing. So we continue to see opportunity, and there's a few things to keep in mind. One is there's still a lot of unmet need. Albert referred to it in his written remarks. But there's a lot of patients undiagnosed. Very few get an Rx therapy. Oral CGRPs are still only less than 20% of the Rx market. But as you point out, this is also a very competitive category with QULIPTA and UBRELVY. And I won't comment specifically on their pricing strategies versus ours and GTNs play a role in all of it.

But our focus for Nurtec, one, I think we want to be sharper and more competitive in our patient engagement and activation. Two, we have an opportunity with our field force to focus on both the most relevant CGRP writers, and as I said, PCPs. PCPs write 2/3 of triptans but only about a little over 1/3 of CGRP, so there's an opportunity there. And then patient access and experience, there's an opportunity to really reduce the friction there. And I will also mention ZAVZPRET because with an intranasal, we think we can have a very nice complement to an oral for either rapid pain relief, and there's also an unmet need for patients that have nausea and vomiting from the use of an oral. So we want to continue to invest in growing our Nurtec and ZAVZPRET franchise.

Operator

Our next question comes from Steve Scala with TD Cowen.

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

Two questions. First on danuglipron, I know Pfizer doesn't want to provide an update. But clearly, the company has greater insight than we do into how the once-daily version is performing in the Phase 1 PK trial. So I'd like to ask how would you characterize that performance so far? In the absence of any visibility, it's kind of hard for us to be confident in the outlook for this program. Second question is a new weight loss agent was added to Phase 1, designated 6016. Can you tell us what the mechanism is, please?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Yes. Steve, I'm going to disappoint you because you are asking things that we have said we are not willing to disclose at this stage for multiple reasons. Clearly, on danu, we have more information than us is very normal with everything that we are doing because we're having a very complicated, as I said, multiple experiments plan right now. But because we don't have new data, we're not going to comment on that.

And on the new weight loss molecule also, we said that unfortunately, we are not able to disclose the mechanism of action. The reason is because, first of all, it's too early and we don't want to take competition, nothing strange about that. So I'm sorry to disappoint you but there is not much to offer at this stage. Hopefully, as we said, midyear is where we expect to have more information on that.

Operator

Next, we have David Risinger with Leerink Partners.

David Reed Risinger - *Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst*

Thanks for all the updates. So I have 2 questions, please. First is for Dave. Could you please discuss the '24 gross margin prospect in some detail? I think on the last call, you had discussed potentially a low 70% gross margin. But if you can comment on that in more detail, that would be helpful.

And the second question is for Mikael. If danuglipron once-daily does have a profile that you're looking for, would the company then conduct a Phase 2a dose-ranging study to assess the efficacy and tolerability in order to design a dose to advance Phase 2b or Phase 3?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Thanks, Dave. Very quickly, Mikael, resolve danu and then we'll go to Dave.

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

Yes. You heard Albert say that we are running a number of clinical experiments to gather insight in that molecule, and we have a second GLP. Pfizer has always been open to consider different types of clinical study design. And in general, we tend to move into directly whenever data is supportive, if there is a large safety database into Phase 3 with a lead-in phase. But we have to look at each program by program. So when we have all the data, we will be able to share with you.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Yes. Let's go to the gross margin where we can share a little bit more information.

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

So David, this is Dave Denton. I'll be very brief here. Obviously, we've indicated our '24 gross margin expectations are in the low 70s, as we discussed previously. As you know, as we cycle into '24, there's a few things that are happening, as I indicated earlier. One is, as COVID comes down, we're kind of deleveraging as COVID had absorbed a lot of fixed overhead. So that's compressing gross margins. Secondly, we're in the process of insourcing many of the acquired products over the last couple of years. And as we insource, the short-term effect of that is dampening on gross margin, which gives us an opportunity to improve gross margins as yields improve over time.

And then finally -- or 2 things finally here is new launches have that same characteristic. As we launch a new product, yields and performance are not at peak performance. That will be an opportunity for us going forward. And then finally, we have absorbed some inflation over time. That is an opportunity for us to take out over the next several periods. So again, an opportunity for us to enhance performance over time. But again, we're in this roughly low 70s for 2024 is our expectation.

Albert Bourla - Pfizer Inc. - Chairman & CEO

And David, let me add a little bit more color here, but the COMIRNATY and PAXLOVID are big products but they are manufactured in the same facilities, but they are separate facilities so they are not affecting the margins of the other products. So the margins were really absorbing in those facilities when you had such a huge volume production and value reduction, of course, the margins were seriously -- those products are seriously taking a lot of the overhead.

Now as we are reducing our expectations for COVID into very realistic within targets, this doesn't mean that we have eliminated our capacity to produce more if the demand is there because that would be not responsible, first of all, from a public health perspective but also from our investors' money perspective. So that's why so far, we maintain all this capacity although the revenues are down, so there's a significant bit.

The second thing that David said, keep in mind, all basically our new acquisitions that brought so many new products, they were from smaller relative companies. They didn't really have their own manufacturing. So these were all outsourced and outsourced, of course, is way more expensive than when you are able to bring it. There are plans for everything to insource, but in manufacturing, that takes 3 years, right, to be able to reduce the margin. And the last but not least, we have disproportional amount of new loans. And those new loans are coming with a very big cost when you build infrastructure or something new to be developed, but of course, you build it for your peak revenues. But of course, you start with very low revenues and then those are going up.

So as the infrastructure is there, but then higher revenues for these new products are coming, it's always the case with new products, but margins are expected. So it's not something about gross margins. You can see it in months, you see it in years, the improvement. But clearly, this is an area that we know why it's happening what's happening and how we can improve it.

Operator

Our next question comes from Chris Schott with JPMorgan.

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

And maybe just for Dave and Albert, just kind of building on mid- to longer-term margin piece of the equation. It sounds like we should think about margin recovery as a gradual process versus a snapback. Is that fair? And I guess kind of the bigger picture question I was asking is just how do we think about reasonable longer-term margins? Maybe not giving specific time lines, but can we think about kind of like mid- to high 30% operating margins as still a reasonable target for Pfizer? Or just kind of factoring in some of the dynamics we're seeing now, do we need to kind of rethink where margins can go over time?

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

No, I think you're absolutely correct. Mid- to high 30s is a reasonable target for us, with a slight caveat sense that the vaccine program, COMIRNATY, has a shared, as you know, gross margin level with our partner. And so that's dampening to gross margins and operating profit. So I'll say, slightly mix adjusted for that product. And then from a progression standpoint, yes, you can think about this as a gradual steady improvement story over the next several periods.

Operator

Our next question comes from Rajesh Kumar with HSBC.

Rajesh Kumar - *HSBC, Research Division - Analyst*

Just on the medium-term margin profile. Thank you for the color you've provided. If you think about the growth aspirations you have, does that require you sacrificing some of the margins? So if you were to say hit the top end of your growth profile, would we be looking at mid-30s gross margin or lower? Or what is the balance there?

And the second one, you briefly touched on your capital allocation priorities earlier. Obviously, cost cutting and deleveraging is a priority for 2024. In the medium term, which are the therapy areas where you would deploy more capital after 2024 deleveraging exercise done?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

David, why don't you take that?

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

Yes. So maybe on the margin discussion, obviously, what we've said is we have invested pretty substantially in our business over the past couple of years. So largely, the investment phase at least from a business development standpoint is behind us. We have work to invest to improve performance going forward, but the big dollars are already invested now. It's an execution story and a continued improvement story. So you should expect that to occur over the next several periods.

Obviously, the higher the revenue, the better performance because you get to leverage your fixed costs. So clearly, the higher those revenue targets and achievement happen, the better improvement from a margin perspective you should expect from us. And then from a capital allocation perspective, I think you said it right. We are, at the moment, focused on executing our plan, focused on supporting our dividend growth over time, but importantly, beginning to delever as we cycle into an integration of (inaudible) assets. And then from a priority standpoint, clearly, we've made

a significant investment in oncology. You should expect us to put the investment thesis behind that franchise going forward. Clearly, that's number one.

Albert Bourla - Pfizer Inc. - Chairman & CEO

And I would add that following the oncology, where clearly, we have right now the biggest part of our R&D expenses and we have a significant also part of our SI&A expenses. The other areas that we are putting a lot of emphasis when it comes to reserve, clearly, vaccines, it's a crown jewel and we plan to have significant productivity. In internal medicines, our metabolic franchise, it is an area that we are very excited. Obesity is part of that. We do believe that obesity is a big market and it's growing.

And we do believe that Pfizer has the capabilities that allows us to play and win in that area. So that's an area that we will continue investing. Immune inflammation, we have significant investments is the other area. And of course, we have -- we are among the few that have antiviral and the anti-infectives still investments. So those are the areas that we will put money, oncology, number one, then vaccines, metabolic diseases, immuno-inflammation, antivirals are the ones that we are continuing to invest in.

Operator

Next, we have Kerry Holford with Berenberg.

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

Just a couple of pipeline questions for me, please. Firstly, on RSV. Can we expect you to announce the date for Abrysvo following that third season in Q2? And then also on the 2 Phase 3 starts, you've highlighted today B6A in lung, CDK4 in breast. When can we expect Phase 3 data readouts for these 2 products?

Albert Bourla - Pfizer Inc. - Chairman & CEO

I'm not sure -- what was your question on RSV?

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

To understand when are you going to publish the data from the following, the third season, third season of RSV?

Albert Bourla - Pfizer Inc. - Chairman & CEO

Yes. Yes, I got it. Thank you. Why don't you take that, Mikael, on the Abrysvo? And then Chris.

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

We continue to accumulate important RSV data and expansion of how the -- this important vaccine can be used. So you should expect this first half of the year, likely Q2, that we share more from our clinical trials, including full second season but also expansion in traditional age groups, as you can know, on clintrial.gov, we have active trials, and we think that will very nicely allow high-risk groups across a large age span to be addressed.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you, Mikael. And then Chris?

Chris Boshoff - Pfizer Inc. - Chief Oncology Officer, Executive VP

Thank you very much for the question. So the immediate readouts for this year, second half 2024 will be vepdegestrant in second-line hormone receptor-positive metastatic breast cancer, the VERITAC-2 study, also second half 2024. We expect to anticipate results from BREAKWATER, a very important indication, up to 12% of colorectal cancer with Braftovi in first-line BRAF CRC. The new study starting right now is CDK4, B6A and dacetuzumab in Phase 3 programs and then also I hope later this year for EZH2. Those will appear in clinicaltrials.gov and probably completion dates beyond 2025 and 2026. But obviously, there could be interim results with earlier results.

Operator

Our next question comes from Chris Shibutani with Goldman Sachs.

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

Two questions, if I may. Aamir, with your prior role, you had talked about a \$25 billion in revenues by 2030 that the company was looking to deliver based upon M&A. We have the impairment with Arena. Is there an update for that? And now that you're in the role of U.S. Chief Commercial Officer, non-Oncology, non-COVID, what would be on your wish list in your current seat in terms of where you feel an opportunity to expand those revenues potentially through business development that could work to hit that \$25 billion target by 2030?

Then secondly, with the M&A activity across the industry, investors are always paying attention to what's going on with the FTC. Having passed through this gauntlet with Seagen last year, is there anything you can comment about to help us think about how regulators are thinking about the M&A environment in terms of particularly size of deal or any other dimension that you think is worth being aware of that might have been your observations from your experience in '23?

Albert Bourla - Pfizer Inc. - Chairman & CEO

Thank you very much. Aamir, why don't you take the question? By the way, let me clarify that Aamir's responsibility includes COVID revenue. So go ahead, Aamir.

Aamir Malik - Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP

Okay. So Chris, there's a lot in what you asked. Firstly, on the \$25 billion goal that we put out there, I'll just remind that we guided to \$20 billion for what we plan on getting to by 2030 for the deals that we had done. And I would also just remind you that the \$25 billion was a 2030 goal, so there is lots of time between now and 2030 to achieve that goal, consistent with our capital allocation priorities that Dave described.

On your second question, I mean, to be honest, yes, everyone's got a wish list, but my focus is on exactly what I described right now and what we talked about as a management team, which is delivering value from our launches and delivering value from the deals that we've done. So that's where my focus is. Now lastly, in terms of FTC, it's not appropriate for us to comment on what the FTC is going to do or not do. But what I can say is that we feel very good about how we have operated with all regulators in all regulatory bodies across the world to get done all the deals that we did. And I think that just speaks to our patient-centric approach and our collaborative nature with regulators.

Operator

Next, we have Akash Tewari with Jefferies.

Akash Tewari - *Jefferies LLC, Research Division - Equity Analyst*

Fair point on the Pevnar comments with the impairment charge and kind of the moving parts between adult, pediatric and international. Consensus had modest top line growth over the next few years for the entire franchise. Is that a reasonable expectation for investors, given the increased competition from Merck and the U.S. pool shrinking? And then do you have an internal view on what the ACIP recommendation will be regarding Pevnar and V116?

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

Look, Aamir, why don't you take the -- is it the Pevnar expectations? We don't comment on what the expectations of the Street are, right? So are we -- and I think we gave a very good, let's say, high-level trajectory how we see this market. In the U.S., the adult opportunity, it is mainly as always with the adult, a catch-up opportunity. So when you come, you have a pool of all the people that are eligible, but some of them would choose to make the vaccine.

Usually, that happens in the first year and maybe a little bit then on the second year. We have exhausted, I think, this opportunity with a 96% market share. So right now, I don't think that we will see in the U.S., in the adult, huge opportunity. Merck competition is coming into that. So this is not a very big growth area for us because, as I said, this is not where we plan to do it. It's huge when you launch them very quickly, goes down because then it is just the people that we are really going to sway, they are going into this cohort in terms of age.

The big opportunity it is the pediatric because it is 4 doses, it's not 1. And because it is a huge cohort every year, way bigger the cohort of newborns than people that are becoming 65 in the catch up. So that's how we should see it. So there is nothing much to add into that.

Operator

Our last question will come from Evan Seigerman with BMO Capital Markets.

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

Two questions from me. One, when you think about the additional \$25 billion revenues by 2030, now that Seagen's part of this business, where are we in getting to that metric? And then my second question is really on Oxbryta on sickle cell disease. When you bought the asset, you really -- you noted that you plan to speed up the distribution of the drug to parts of the world most impacted by the disease. We haven't really seen much OUS, given recent competitive approvals of Casgevy in the Middle East. How do you think about the OUS opportunity in context of the competitive updates there? So Seagen and then thinking about some Oxbryta comments.

Albert Bourla - *Pfizer Inc. - Chairman & CEO*

On Seagen, maybe I can take it because that's an easy answer. From Seagen, we expect to get \$10 billion by year 2030. That was a number that we put out there when we announced the acquisition. Since then, a few things that have reinforced our confidence in this number have occurred. The first one, it is that ADC became the hottest thing on the M&A activity. Everybody wants an ADC, which basically our big bet was in this technology. So it looks like there is an overall consensus among investors, companies, analysts that this is a technology that will deliver a lot. So that gives us a lot of comfort that happened after we announced.

The second thing that also happened after we announced is \$10 billion was that Seagen came out with significant readouts or significant products that were beyond our expectations. But also what you don't see but we see, they are advancing a lot of stuff that some of them we will show you in the 29th of February. So also, it was a bet in the technology, a bet in the company, we feel that we did very well in both.

So the \$10 billion is \$10 billion of the \$25 billion, but we remain -- we don't change it, but we remain confident that we can make it. Then of course, in addition to that, there was an additional \$10 billion for all the other things that we have done, and this \$5 billion that we could execute. Now on Oxbryta, how Oxbryta is doing, Aamir?

Aamir Malik - Pfizer Inc. - Chief U.S. Commercial Officer, Executive VP

Yes. So Evan, with regards to Oxbryta and then I'll comment on the acquisition as well since you referred to that. We're pleased with the U.S. performance. Q4 was up 30% over the prior year and 14% over the prior quarter. The prescription trends are very solid. We've made a lot of investments in customer-facing teams since we made that acquisition. So we like the momentum that we're seeing in the U.S., and we expect to see more.

Right now, the rest of the world is a very small part of Oxbryta revenue, and that is something that will take time to develop and we'll obviously look at that appropriately. And as you think about the GBT acquisition, it's important to look at Oxbryta, but I also would remind you that we're also very excited about GBT601, which we expect can bring a lot of value in addition to Oxbryta. Some of it will -- if it's successful from a clinical and regulatory perspective, some sales will be cannibalized, but there will also be room for Oxbryta in the market to continue to grow.

So when you look at the combination of the momentum in the U.S., an opportunity that's yet to be developed outside the U.S. and 601, where we presented great data at ASH in December, we think that there's a lot of value to be gained from this acquisition.

Albert Bourla - Pfizer Inc. - Chairman & CEO

Yes. And I would add, it is the same exactly with the GBT acquisition. When we did the acquisition, we announced our projections for year 2030. Since then, things have improved in terms of our confidence to deliver these numbers. And I'm not talking only that Oxbryta is performing exactly as we thought it would, but the most important upside it is that we had data that we didn't have when we made the acquisition on the 601 but has the potential to become a transformative therapy in the sickle cell and really, really brings to the next -- it's a step change if that thing -- if the Phase 3, let's say, reconfirms the Phase 2 results.

So also over there, I think what we announced, we feel now we're more confident but we should be able to achieve and hopefully exceed.

So with that, I think we start to end the call. In summary, we are optimistic about the year ahead. We have defined our 5 key priorities that will keep us focused. And I repeat again, this will be a year of execution. I have assembled a team that are hand-picked that I believe are the absolutely right leaders to execute. And I know that the whole world was impressed with the way that we executed our COVID strategies, how we were able to execute on the R&D front, on the manufacturing front and on the commercial front with 2 products, the vaccine with the highest market share and with the product in oral antiviral.

We plan to repeat the same execution excellence level as we are building oncology leadership, as we are progressing the next wave of our pipeline, as we are maximizing the performance of all these new launches that have happened, as we execute our cost realignment program starting this year with SI&A, but also which you will see the results. But also of course, the program to improve the gross margin that you won't see results now because it takes long but we started now as we speak, and laser focused in maximizing value for shareholders with the way that we allocate our capital.

The team is there to make sure that this will happen, and I think we should meet again in 3 months, and we will see how we are progressing against those stated goals. Thank you very much all. Bye-bye.

Operator

Thank you, ladies and gentlemen. This does conclude today's Pfizer's Fourth Quarter 2023 Earnings Conference Call. We appreciate your participation, and you may disconnect at this time.

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