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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's First Quarter 2024 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*

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 first quarter of 2024 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 call for questions. Joining for the Q&A session, we also have Dr. Chris Boshoff, EVP and Chief Oncology Officer; Alexandre de Germay, 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 our 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 the statements.

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

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

Thank you, Francesca. Good morning, everyone. Thank you for joining our call. In the first quarter, we had a solid start to the year, and we are cautiously optimistic about what we will achieve in 2024. I'm pleased and appreciate how our Pfizer colleagues are executing with discipline as they focus on the patients and others we serve. This helped us deliver a strong performance during the quarter in our non-COVID product portfolio, drive progress towards our oncology leadership, advance our pipeline and continue to strengthen our business.

Today, we will discuss highlights from the quarter and provide updates about how we are continuing to make progress with the 5 strategic priorities we served with you at the start of the year. We are proud of the positive impact we achieved around the world with our deep capabilities and global scale. Through the first 3 months of the year, we reached more than 119 million patients with our medicines and vaccines. We will continue to build on Pfizer's 175-year history of driving medical and pharmaceutical breakthroughs as we maximize the opportunities in front of us.

Our confidence in the year ahead comes from our focus on executing the strategic priorities that we believe will deliver operational, commercial and financial success across our business. The priorities are: achieve world-class oncology leadership, deliver the next wave of pipeline innovation, maximize performance of our new products, expand margins by realigning our cost base and allocate capital to enhance shareholder value. In the first quarter, we made notable progress with each one, and I will share some highlights.

Many of you joined us in our Oncology Innovation Day in February, and I hope you found it to be a valuable opportunity to see how we are well positioned to achieve world-class oncology leadership. We are pleased with the excellence we have been able to achieve in both integration and commercial execution.

With a strong mix of Pfizer and Seagen colleagues in the newly combined team, we believe we have one of the most experienced and talented groups of oncology leaders in the industry. We''re also already seeing the benefit of strong commercial execution with our newly cross-trained sales and field medical teams.

In the first quarter of 2024, our oncology revenues grew 19% operationally over the same quarter a year ago, driven in part by: the acquisition of the 4 in-line products from legacy Seagen—, —and then particularly, the strong ongoing launch of PADCEV in front-line locally advanced/metastatic urothelial cancer, regardless of cisplatin eligibility, following FDA approval based on the groundbreaking EV-302 data.

We have an increased demand for XTANDI, which continues to be a backbone therapy across the prostate cancer treatment continuum. And we have continued growth from LORBRENA, which could emerge as the potential first-line standard of care in ALK-positive metastatic non-small-cell lung cancer.

Earlier this week, we also announced the full FDA approval of TIVDAK to treat recurring or metastatic cervical cancer. TIVDAK is the first antibody-drug conjugate to have positive overall survival data for patients with previously treated recurrent or metastatic cervical cancer.

Going forward, we are guided by a strategy focusing on our greatest opportunities to make a difference for patients with cancer. With the power of our deep expertise, broad and diverse portfolio and global scale, we are confident we are well on our way toward our 2030 goals of doubling the number of patients treated with our innovative cancer medicines; increasing the number of blockbuster medicines in our portfolio from 5 today to 8 or more; and driving an anticipated tenfold increase in the proportion of revenue from biologics.

This is important because it brings the potential to provide more durable revenue based on several factors, including Inflation Reduction Act considerations and the greater challenges of copying complex biologics. We will look forward to sharing continued updates with you on our progress in accelerating oncology breakthroughs.

Now I"ll turn to our progress with delivering the next wave of pipeline innovation. In Oncology, during the quarter, we had three pivotal Phase 3 study starts, including the first Phase 3 trial for our selective CDK4 inhibitor, atirmociclib; our integrin-beta-6-directed ADC, sigvotatug vedotin—; and the fourth Phase 3 trial for ELREXFIO in multiple myeloma.

At the upcoming American Society of Clinical Oncology Annual Meeting, we will present data spanning each of our tumor areas of focus and core scientific modalities, including new 5-year progression-free survival data for LORBRENA, Phase 3 data for ADCETRIS in diffuse large B cell lymphoma and additional developments from across our deep and diverse pipelines.

We are also driving continued execution beyond Oncology, with a sharpened focus on key value drivers expected to build potential multi-billion-dollar product portfolios. Through the first quarter, we are on track with delivering on our anticipated milestones and have important updates in both our growing Respiratory and Hematology portfolios.

With ABRYSVO, we believe we have the opportunity to further expand what is currently the broadest approved range of patients for the RSV vaccine, including adults 60 years and older and infants from birth to 6 months via maternal immunization. We recently reported positive results from the Phase 3 MONeT trial, evaluating ABRYSVO in adults aged 18 to 59 at increased risk for RSV disease.

The trial met its primary endpoints, and we intend to submit these data to regulatory agencies. We believe ABRYSVO has the potential to become the first and only RSV vaccine for adults 18 years and older.

Hematology is another priority area. With the progress of recent and near-term milestones, we are confident that we could establish a potential multi-billion-dollar product portfolio across hemophilia and sickle cell disease. We recently received the first U.S. FDA gene therapy approval for Pfizer with FDA approval for BEQVEZ, a one-time gene therapy for adults with hemophilia B.

This program builds upon our growing presence in hemophilia. We expect an FDA decision before year end for marstacimab, which has the potential to become the first once-weekly subcutaneous treatment for the hemophilia B market, and the first treatment delivered as a flat dose for both hemophilia A and hemophilia B.

Moving to sickle cell. We recently started the Phase 3 study of osivelotor, our potentially best-in-class next-generation hemoglobin S polymerization inhibitor. We are committed to addressing the underserved needs of the sickle cell disease community, and we are leveraging our capabilities for potential breakthroughs for these patients.

Now, I'll turn to our strategic priority of maximizing performance of our new products. While it may take a year to realize the full benefit of the changes we put in place, as we speak, to bring a more efficient structure to our commercial operations, we are pleased by the impact we are already seeing from our sharpened focus and Pfizer colleagues embracing our high-performance culture.

Earlier, I mentioned the momentum of our Oncology products. Our Pfizer U.S. Commercial and Pfizer International Commercial organizations are also moving ahead in driving progress with growth in their respective markets. We have several potential key growth drivers for this year and into year 2025.

With ABRYSVO, we are very pleased with the positive data in the 18 to 59 age group that differentiates our product, and we are encouraged by our opportunities to continue increasing overall RSV market growth and market share.

Another example of -- is our enthusiasm for the potential of NURTEC to help the more than one billion people living with migraine worldwide. With oral CGRP penetration leaving room for potential significant growth, we will continue to

Focus on reducing access barriers for health care professionals and patients, as well as on education through direct-to-consumer marketing.

With OXBRYTA, we will continue to educate health care professionals and patients on the importance of proactively treating the underlying cause of sickle cell disease by reframing treatment goals to chronic and proactive treatment. VELSIPITY is coming off its initial launch, and we are focused on ensuring patient access as a first-line advanced therapy oral option for moderate to severe ulcerative colitis.

And I will mention LITFULO. We will work toward continuing to accelerate the consideration of advanced systemic treatments for appropriate patients with alopecia areata and further unlock access to LITFULO. Additionally, we continue to protect and grow our core brands and key blockbusters, including PREVNAR, VYNDAQEL and ELIQUIS.

In a moment, Dave will provide updates about how we're also making progress with two other strategic priorities, expanding margins by realigning our cost base and allocating capital to enhance shareholder value. When we consider what we achieved in the first quarter, along with our continued progress in executing our 5 strategic priorities, we are cautiously optimistic about the year ahead.

We are continuing to focus on commercial execution, protecting and growing our products and driving strong starts with new commercial launches. With the progress we are making in advancing our cost-realignment program, as well as our confidence in the underlying strength in our business and our continued execution, we have raised our outlook for 2024 adjusted earnings per share by $0.10.

We have confidence in our company. With some of the most experienced and talented colleagues in the industry, we have demonstrated many times before that we are very good at execution, and we expect to continue delivering life-changing medicines for hundreds of millions of patients globally and meaningful value for our shareholders.

Now, I will turn it over to Dave to discuss the financial performance during the quarter as well as our progress in strengthening our business and enhancing shareholder value. Dave?

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

Thank you, Albert, and good morning. As we continue to navigate a challenging post-COVID environment, I"m pleased to share that this year is off to a solid start. We are protecting and growing our core brands while investing in building a more effective organization. Our relentless focus on execution is positioning Pfizer to improve shareholder returns.

This morning, I'll briefly review the highlights of our first quarter results, then I'll touch on our capital allocation priorities. I'll wrap up by outlining our 2024 financial guidance as well as our key priorities for the remainder of this year.

Turning to the first quarter, let me walk down the P&L. Total company revenues for the quarter were $14.9 billion, reflecting an operational decline of $3.5 billion or 19% versus last year. As you know, our business continues to be negatively impacted by a declining COVID environment on a global basis. To that end, we expect our COVID products will continue to have an outsized effect on both our top line and our bottom line throughout this year.

However, I do want to point out that we expect our COVID products will continue to be contributors to revenues and cash flows for the foreseeable future. Strong commercial execution across the enterprise drove 11% operational revenue growth in the quarter when you exclude COMIRNATY and PAXLOVID.

Performance was positively impacted by our renewed focus on key products and markets, refined allocation of commercial field resources globally and further alignment of marketing resources into key priority areas. Contributing to this performance were our acquired products from Seagen, alongside in-line products such as VYNDAQEL, ELIQUIS and ABRYSVO.

Dampening our growth in the quarter was the expected lower global demand for IBRANCE and SULPERAZON, driven largely by lower demand in China in the first quarter of 2024 versus last year.

Adjusted Gross Margin for the first quarter improved by 530 basis points to 79.6% versus Q1 of last year. This improvement was driven by 3 factors. First were lower sales volume of COMIRNATY resulting in favorable sales mix. Second, in the quarter, we recorded a product return adjustment for PAXLOVID associated with our U.S. government contract, and I'll touch upon that in just a moment.

And finally, we executed strong cost management across our manufacturing network. Improvements in our gross margin rate will continue to be an important focus for the company going forward. Total Adjusted operating expenses increased modestly by 1% to $5.9 billion compared to Q1 of last year despite adding expenses associated with the acquired Seagen business.

This disciplined cost control puts us squarely on track to delivering on our $4 billion net savings commitment by the end of the year. Adjusted SI&A expenses increased 3% operationally in the quarter, driven by an increase in marketing and promotional expenses for recently acquired or launched products, partially offset by a decrease in expenses for PAXLOVID and COMIRNATY.

Consistent with our strategy, we are prioritizing our R&D spending to enhance overall returns while supporting growth from our pipeline. For the quarter, adjusted R&D Expenses were $2.5 billion, a decrease of 1% operationally versus LY. The slight decline was driven primarily by a lower spending resulting from our cost realignment program and lower spending on certain vaccines program, largely offset by increased investments mainly to develop certain assets acquired from Seagen.

Q1 Reported diluted earnings per share were $0.55. Our Adjusted diluted earnings per share was $0.82, which exceeded our expectations due to favorable gross margin performance as well as strong cost management across the enterprise.

As I stated earlier, during the quarter, we recorded a favorable product return adjustment associated with our U.S. government contract for PAXLOVID. Recall that during Q4 of last year, we estimated the U.S. government credit for PAXLOVID was $3.5 billion.

Earlier this year, the U.S. government announced that the EUA labeled product was no longer authorized for CUs and the agreed-upon return period had now expired. Given those facts, we can now finalize the total value of the U.S. government credit. This resulted in a favorable adjustment to revenues of $771 million for PAXLOVID and contributed $0.11 to the company's earnings per share.

Now let me quickly touch upon our capital allocation strategy, which is designed to enhance long-term shareholder value. Our strategy consists of maintaining and growing our dividend over time, reinvesting in our business at an appropriate level of financial return and making value-enhancing share repurchases after delevering our balance sheet.

During the first quarter, we returned $2.4 billion to shareholders via our quarterly dividend, invested $2.5 billion in internal R&D and, as expected, business development activity was minimal in the quarter. We are committed to delivering our capital structure with a gross leverage target of 3.25x, which we expect to achieve over time.

In support of that goal, during the quarter, we paid down approximately $1.25 billion of maturing debt. And in May, we will pay down another $1 billion of outstanding notes. And importantly, during the quarter, we began to monetize our Haleon stake through an initial sale of $3.5 billion, which reduced our equity position in the company from 32% to approximately 23%.

Looking ahead to the next couple of quarters, I'd like to point out that we expect operating cash flow to be significantly below typical levels, largely due to the timing of certain payments. Despite this near-term pressure, clearly, our objective is to return to a more balanced capital allocation strategy over time.

Now let me spend just a few minutes on our outlook for the remainder of this year. As we entered 2024, the company was highly focused on delivering on its financial commitments, and our performance in Q1 demonstrates that we are off to a solid start. With that objective in mind and the fact that it's still early in the year, we are modestly updating the earnings outlook for this year.

We are raising our full year Adjusted diluted earnings per share guidance range by $0.10 to a new range of $2.15 to $2.35. Looking ahead, this increase takes into consideration both our improving line of sight to our cost savings targets and continued strength in our underlying business. As a reminder, our EPS guidance also includes an anticipated $0.40 of earnings dilution from the Seagen acquisition, largely due to financing costs.

While the PAXLOVID revenue return adjustment moves us to the upper end of the revenue guidance range, our top line revenue expectations remain unchanged for the year. We continue to expect revenues in the range of $58.5 billion to $61.5 billion. In addition, even though COMIRNATY revenues continue to perform consistent with our plan, it is important to remember that we expect approximately 90% of our sales to occur in the second half of the year, mostly in Q4, given the seasonal nature of these products.

Lastly, we remain on track to deliver at least $4 billion of net savings from our cost realignment program by the end of the year. Improving our cost base will put us on strong footing towards margin expansion and improved financial returns as we move forward.

As you know, over the past 2 years, the company has made significant investments to drive growth in the back half of the decade, and we remain encouraged by the long-term growth outlook for Pfizer. 2024 is clearly a year of focus, execution and delivering on our near-term financial commitments. The foundation that we establish this year sets the stage to deliver on our commitment to enhance shareholder value, both this year and through the end of the decade.

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

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

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We'll take our first question from Louise Chen with Cantor.

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

I had a question for you on your RSV vaccine sales. Just curious what drove the downtick versus the fourth quarter. It looks like GSK had a similar downtick. And then how do you think about potential competition coming into the market for vaccines and treatments? Does that impact your future growth projections for this franchise?

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

I think, Aamir, that's a question for you, then maybe Alexandre also, you can add because now we started already to register and approve the product in international markets. Aamir?

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

Louise, thanks for the question. So it very much appears like the RSV vaccination market is following a seasonal trend, so you expect the dynamics in Q4 versus Q1 to be different. In Q1, what we saw for the market is for older adults, it certainly attenuated over the course of the quarter. So there was a peak in the second week of January, and then a steady week-by-week decline since then.

Now in terms of the dynamics for our business and ABRYSVO, our performance was in line with what we expected. We think this will follow a seasonal trend. And we think we're very well positioned for the fall season for several reasons.

One is we're progressing our retail contracting. Second is we have a real strength in the nonretail channel. You referred to GSK. They reported their revenues. When you look at the mix of U.S. revenues as reported, it's about a 60-40 mix. Our retail share is lower than that, but our nonretail share is much higher. And that portion of our business really doubled between Q4 and Q1 from about 9% to 17%.

And I think that just speaks to our strength in doctors' offices and relationships we have with organized customers. And I'll also note that later this year, if approved, we will have a new presentation of ACT-O-VIAL, which demonstrates ease of administration, and also our clinical data, which Albert referred to in his remarks, for label expansion for ABRYSVO for 18- to 59-year-olds as well as -- that are at risk as well as durable efficacy through 2 seasons. I think the combination of these commercial efforts as well as potential label expansion really position us well for a fall season.

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

Okay. Thank you, Aamir. Now, Alexandre?

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

Yes. So Louise, thanks for the questions. On the international front, we actually made great progress on ABRYSVO. As you know, we got approval in the second half of 2023 in Europe and in the U.K. And since then, we've been working with the health authority and the experts to provide medical evidence and health care system benefits associated with the protection against lower respiratory tract infection, as with RSV, and through immunizations of maternal after the immunization of all the others. So we're making good progress.

And actually, we have already received the recommendation in the U.K., in Australia, in Norway, and we are progressing and waiting some recommendations from the vaccine technical committee in many other European markets. We also had good progress from a regulatory standpoint because it was a milestone with the approval of older adults and MI during the maternal immunization in Japan in the first quarter as well as Kingdom of Saudi Arabia.

So overall, they don't yet translate into financials because it takes time to get to the approval to get VTC and to get funding for those campaigns, but we see significant opportunity that we can address unmet medical need in the international. Just to give you 1 example, in Europe, for instance, half of the hospitalization due to respiratory tract infection in the first year of life were caused by RSV.

So there is definitely a great opportunity. And the majority of those hospitalizations occurred for the first 3 months of age. And as you know, ABRYSVO is the only maternal vaccine that help protect infants from lower respiratory tract infection caused by RSV immunization from birth through to 6 months. So we see a great opportunity.

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

Thank you, Alexandre.

Operator

We'll take our next question from Terence Flynn with Morgan Stanley.

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

Maybe just a 2 part from me. Just wondering if you can comment at all about potential impact in 2025 from the Part D redesign. We've heard a couple of other companies already comment here. And then one on the pipeline. Can you give us any update on danuglipron and your plans more broadly in obesity?

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

Yes, thank you. Clearly danuglipron is of interest. Let me take that one so to clear the way. It's not new. We don't have news on danu. Everything is as we have discussed before, so we are waiting around mid-year to get the totality of the data that relates to the once-a-day formulation. And then based on the data and everything else, we will make decision for future plans. So we'll speak about them when we have more to say. However, now let's go to Aamir about the Part D redesign in 2025. Did you expect them?

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

Sure. Terence, thanks for the question. And as you can imagine, there's many moving parts to Part D redesign. I think relevant to our business, I think it's important to first note that as part of what already went into place with the redesign, there is no cost sharing imposed on vaccines. So that, given our significant vaccines portfolio, is a positive. And then, obviously, over the course of '24 and '25, there's other dynamics with out-of-pocket cost caps, which create better access for patients, and that is helpful to volumes, and we're starting to see that in '24 in some parts of our business, including on VYNDA.

And then there's things to come, including a change in that cap as well as patient smoothing. So we'll see how that plays out. And obviously, there's also changes in how costs are shared between plans, manufacturers, government and patients. So how all of that gets implemented, we're tracking that very closely. We're not offering any specific guidance in terms of direct dollar impact on our business in 2025 because there's still a lot to come on this. And when we are ready to do that, we certainly will.

Operator

We'll take our next question from Akash Tewari with Jefferies.

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

On tafamidis, really strong quarter, but I wanted to ask on patent life. Given we've seen the EU patent office write-down multiple invalidity oppositions and on the U.S. side, it looks like defendants are conceding infringement. How should we think about IP for this product? Why shouldn't this patent

fit out to 2025? And then number two, really strong quarter for PADCEV and you do have the pending TIVDAK launch in first-line cervical. Is there any possibility we could see Seagen become accretive to Pfizer earnings by next year?

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

That's very good questions. Why don't we go first to you, Dave, to speak a little bit about is doing very well. If you expect that can become accretive earlier. Also, I would like to hear some comments from Chris about the progress of the portfolio, and then Doug can comment on the IP situation, our customers.

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

Yes. So just maybe on Seagen from a financial perspective, obviously, clearly a very solid quarter and a very solid start to the year. I think we're not changing our expectations, both short term and long term for Seagen, but I think we're cautiously optimistic as we look forward. So probably nothing to update financially other than our continued commitment to the financial metrics that we've already established. And again, we're probably cautiously optimistic on the trends that we're seeing underlying that business at this point in time.

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

You want to make some comments also, Chris, about the performance of the Seagen business?

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

Yes, I think just to add to what Dave has said, it's early days for as he pointed out, the 302, the data was -- we just launched early this year. We've already seen 164% year-on-year pro forma growth. It's early but we're very pleased that we've got NCCN Guidelines Category 1. We've got a New England Journal publication. We've got uptake in both academic and community settings. In fact, 70% of the current accounts on the community. And we're looking forward now because I think we're well set for the future in the muscle invasive bladder cancer setting and those 2 studies that we'll read out late in 2025, '26, '27.

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

Thank you very much, Chris. Doug, what about the situation with the IP disputes?

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

Yes. VYNDAQEL and VYNDAMAX currently has U.S. patent exclusivity, excuse me, through the end of this year. But we have a patent pending patent term extension, which would take it out to December of 2028. And we may be filing additional requests for patent term extensions while that is pending. In major European markets, our patents expire in November of 2026. And in Japan, the patent expires in 2026, but there's regulatory exclusivity through March of 2029 for cardiomyopathy.

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

Thank you, Doug. Thank you, Akash.

Operator

We'll take our next question from Evan Seigerman with BMO Capital Markets.

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

I want to touch on gross margin. Obviously, a nice improvement in this quarter. And I believe, back in December, you had said, for the full year, it would be around 70%. Do you expect that we could actually see a better gross margin for the full year, given kind of the benefit we've seen? Or are there some other puts and takes that we should be aware of?

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

Yes, so this is Dave. We're always looking to improve our performance from both a gross margin and operating performance perspective. So I'll say we'll continue to focus on that. Obviously, as you know, there's 3 things that improved our gross margin rate in the quarter. Some of those are temporal. Some of those are more permanent. I think what is encouraging within our gross margin performance is the fact that our cost control element across our manufacturing platform was really strong. We expect that to be -- continue to be a focus.

But keep in mind that our COMIRNATY volume is very back half weighted. COMIRNATY, as you know, carries because of our profit share carries a very low gross margin rate. So that mix will reverse itself in the back half of the year, compressing and putting pressure on our gross margin rate. So you should expect that dynamic to occur as that product plays itself out through 2024.

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

Thank you very much.

Operator

We'll take our next question from Vamil Divan with Guggenheim Securities.

Vamil Kishore Divan - *Guggenheim Securities, LLC, Research Division - MD of Healthcare Research & Senior Equity Research Analyst*

Congratulations on the quarter. The 2 products I want to just kind of touch on in terms of the sort of newer growth drivers. So one is NURTEC, which came in a little bit lighter than we expected. Obviously, the first quarter there tends to be impacted a lot by gross to net. I'm just trying to understand if you can just give a little more detail on what the dynamics in the quarter and any sort of change to your sort of expectation of that product outlook.

And then the second one on the myeloma side, ELREXFIO. Just noticed in your slide presentation that used to be listed under the sort of key growth drivers in prior quarters. This year, on Slide 9, when your sort of key growth drivers is no longer listed there. So I'm just curious if -- it looks like it was an intentional change. I'm just curious, sort of what drove the decision to move that from the group of key growth drivers?

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

Thank you very much, Vamil. Aamir, NURTEC, and then Chris, myeloma.

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

Thanks for the question, Vamil. So I'm happy to talk a little bit about NURTEC. We'd like to accelerate the momentum of NURTEC, and we're taking several steps to do that. For the quarter itself, what we're encouraged by is the demand and the volumes that we saw. And then on the flip side, as you already alluded to, the performance in the quarter was impacted by gross to net.

So on demand, a few points to just keep in mind. NURTEC continued its market leadership within the class with a 49% TRx share, and that was up 28% from Q1 of last year. Secondly, NBRx share, which we keep a very close eye on, that volume, as a whole, hit its high point since we closed the Biohaven acquisition at the end of '22.

So that was up versus last year, but also, importantly, up versus Q4 of '23. And there were about 11,000 new NURTEC writers in Q1, and this is 90% of all the new writers within the oral CGRP class. So there's a lot about the volume and the demand that we're encouraged by.

Now on gross to net, there were 3 issues this quarter. One is you typically tend to see this dynamic in the first quarter of every year. We saw that last year, too, just given the benefit design dynamics. Secondly, we did have some payer mix issues between government and commercial channels this quarter. And then finally, there was an unfavorable onetime prior period adjustment to our GTNs in Q1.

Your question about the rest of the year, for NURTEC, we expect continued growth. We've talked about the fact -- the fundamentals in terms of untreated patients and undertreated patients remain strong. We also think that some of the gross to net that I described is going to be temporal and will slowly abate over the course of the rest of the year. And then we have made a number of changes in our commercial execution in terms of what we're doing with patient engagement and focusing our field force resources on physician awareness in a different way and also working to reduce friction for patient access. So overall, we do expect continued growth from NURTEC in the balance of '24.

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

Thank you. Chris, about ELREXFIO?

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

Thank you, Albert. So the reason Albert didn't list ELREXFIO as a major growth driver, just to remind, so he pointed out LORBRENA, XTANDI and PADCEV as the immediate biggest growth drivers for Oncology. But we're absolutely confident that ELREXFIO will become, over the next couple of months and years, a major driver for Oncology.

Just a reminder, we've seen very promising efficacy data in highly refractory patient populations with deep and durable responses. And we've reported the longest reported median progressive-free survival in the recurrent relapsed/refractory setting of 17.2 months. Now of course, recognizing there's no definitive conclusion as there's no head-to-head studies. We're currently encouraged by what we've seen with the uptake, with the build of new patient starts as we have planned. And we remain very optimistic with the future from the current indication as well as from the future indications.

And a reminder that we have 4 ongoing registrational studies in the next 12 months. The first Phase 3 study would read out multiple -- in the MM5 study. We've also recently received J-code for access, and we're smoothing the reimbursement process and continue to gain favorable positions on various pathways, and in some, the most favorable pathways. We're looking forward to update you very soon on more things from ELREXFIO.

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

Thank you, Chris. And maybe Alexandre, you have anything to add about the product in international markets?

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

Yes. On ELREXFIO, we actually have -- it's progressing very nicely because, as you know, we got approval in Europe in December of 2023 and in the U.K. in January, and in Japan in March 2024. So we are now moving into reimbursement, ABRYSVO. And we've got early access, considering the clinical profile, the exceptional clinical profile of the product. So that's why we got, in some market, early access, and that's why we started sales in the first quarter.

But we are very satisfied by that. We could close the time-to-market gap versus competitor. And in some cases, like in Japan, we actually indeed became first-in-class approved. So then we are moving into registrational -- reimbursement discussion and introduction of the product later in the year.

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

Yes. Overall, in most international markets, there is a gap between the approval and the access round. But because of the profile of the product, we saw early access, which is basically something that happens on an exceptional base if the product is unique. But some countries, before they approve the price, they are allowing you to have access to your own price and that they may be adjusted. So -- but there's a very good signs for this product. We are really feeling very bullish when we see the clinical profile and the opinions of the key opinion leaders.

Thank you.

Operator

We'll take our next question from Dave Risinger with Leerink Partners.

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

Yes. So how many questions am I allowed to ask?

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

You, Dave, you don't have a limit.

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

Okay. So I have -- I'll keep it to 2. So first, regarding the company's cost structure. I'm just trying to get a sense of whether it bottomed out in the first quarter or if there are additional cost reductions ahead after March 30 such that the cost structure of the company is coming down after the first quarter. And then second, with respect to VYNDAQEL. I appreciate the comments in response to the question earlier, but I'm just trying to get a little bit better understanding of how to think about it.

So there was a comment about patent term extension potentially applying beyond December of '28. So if Pfizer is successful, what would the date be instead of December '28 for the U.S.? And then for the EU, the comment was November of '26. But I've heard that there was a positive EU patent development, and I'm trying to understand what that would extend the EU to.

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

Thank you very much, Dave. So Dave Denton, please, you take the cost structure.

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

Yes. First, as you well know, rightsizing our cost structure is incredibly important for us from -- as we think of forward for margin expansion and improving our financial returns. As we look through Q1 and through the balance of the year, keep in mind that the cost changes that we've made in the U.S. are largely complete. Obviously, in ex U.S., some of those changes lag, but you will see changes in the cost structure ex U.S. for the balance of the year.

Those are probably not quite as large as we look forward compared to what has already happened at this point. But I would just say that this will be a constant focus for us as we think about cost and margin enhancements going forward. This is a -- now we're on a continual cycle of thinking about how we invest and what is the appropriate cost structure in support of our revenue objectives for this business going forward.

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

Thank you, Dave. And Doug, can you please clarify a few things about VYNDAQEL to Dave Risinger's question?

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

Sure. Just to be clear, Dave, we shouldn't think beyond December 2028 on VYNDAQEL and VYNDAMAX. So we've got a patent term extension that is filed and is pending. And all I was saying was that, in addition to that patent term extension, which would take it out to December 2028 that we filed and is pending, we may file additional patent term extensions, again, though, just to take it out to December 2028. I hope that's clear.

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

Thank you for clarifying that.

Operator

We'll take our next question from Trung Huynh with UBS.

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

Trung Huynh from UBS. One on the ACIP meeting coming up and just a clarification on the guide, if I may. So on ACIP in June, what's your expectation on the recommendation for the 50 to 59 population? Could this be a shared clinical decision like the 60-plus? Would you think this is going to be risk-based? Is there any chance you can get the 18 to 59 data on the agenda for this meeting?

And just on the guide, a clarification here on the credit for the quarter bec you've kept your $3 billion guide for PAX. I appreciate the comment you're now going to be at the upper end of guide. But on PAX, do you expect to have $770 million less PAX sales than you imagined at the start of the year, given that you updated your EPS guide. Or was this expected?

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

Well, maybe I'll take that first. From a guide perspective, I would not -- we obviously did not expect this final adjustment. It was an estimate that we did at the end of the year. We're now finalizing the adjustment based on the returns that we've seen, and it is now complete. I would say that, as we look forward for the full year, both for PAXLOVID and for the full year of all of our products, we're cautiously optimistic about where we are.

I think PAXLOVID started off from a very solid utilization. And keep in mind that product will trend consistent with infection rates across the globe. And we're still cautiously optimistic that we will achieve our objective, and we do not expect anything less than our original expectation at this point in time.

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

Thank you, David. And Mikael, on the ACIP meetings and the June-October recommendations, et cetera.

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

Yes. First, to punctuate, good to hear you interested in our RSV vaccine. We have a lot of positive and informative data that's coming in 18 to 59. We have already been out sharing a robust outcome for that. And filing is imminent to happen in U.S. FDA. We also have data coming on second season, full second season and data so far that have been available show robust and probably best-in-class profile for us. And you heard AAMIR mention, we also have new delivery format. So there is a lot of positive things happening to further strengthen ABRYSVO.

For a formal decision on recommendation, ACIP normally wait until a product is FDA approved. We don't know exactly when FDA will potentially approve. We think, clearly, given this unique age range that it can happen to be meaningful for the fall, but that needs to be, of course, pending FDA's views. But we will certainly be very open to share data from several of these new important data sets that could help ACIP to understand the planning of the various RSV products. And we think that would be very helpful for ACIP as Abrysvo data set are robust and, in some sense, unique in a positive way. Thank you.

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

In general a couple of comments for those -- both of these questions. On the ACIP, we always don't speak for ACIP. So it's not appropriate, so ACIP will do what they think they can do. Of course, typically, as we say, they wait to see FDA approvals, and we hope that they will ask us to present the data in June, but it's something that we don't know. What we know is that whatever they decide, whenever they decide we have prepared our marketing and commercial plans in the U.S., as we do, of course, in other countries so that we can maximize the approvals or the recommendations or the data that we have. So that's 1 thing.

The other thing, David explained that we are cautiously optimistic, of course, about -- that comes through the entire line of guidance that we gave. We are cautious in our revenues, cautious about margins. And of course, we improved, again, cautiously that we think the EPS. You need to see all of that in the context of who have been there last year with a big misalignment between what we were expecting to come for COVID and eventually what came.

And that it is something that makes us to be double cautious when we speak about projections. We know credibility is extremely important for us. So everything we say, we feel rocket solid, but we will achieve. And we don't say anything more than that, we prefer to achieve rather than be safe. So that as a context to all the guidance that we have provided this time.

Operator

We'll take our next question from Umer Raffat with Evercore ISI.

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

A couple of financial focused questions, if I may. First, on gross margin. Dave, I remember last time you mentioned 2 specific things: in-sourcing of recently acquired products as well as new launches as being a drag on gross margin. Considering both those things were presumably baked into

1Q, and 1Q looked more like what the historic margin build would have implied, wouldn't that suggest full year margin is tracking meaningfully north of the full year guidance of 70%? Or were there one-offs like some inventory work down from recent acquisitions in 1Q that helped it?

And secondly, and maybe this is for you and Albert both. Is there a potential for a significant monetization for some of your excess manufacturing capacity from over the years, be it fill finish or beyond, just considering what the broader environment is and some of the questions on dividend?

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

I think David can take both of them. Dave?

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

Yes. On the gross margin side, as I said, there is a couple of things that impacted favorably our performance in Q1. The items that you listed of both new product launches and in-sourcing, the in-sourcing is probably a longer-term implication to us because those don't happen in an immediate quarter. So as you think about Seagen, it's probably a multiyear phenomenon that we have here. But I don't think that was an outsized impact to that.

And obviously, the new launches, we plan for those to be compressing our gross margin rates, of which they did. I think we're off to a very solid start. But keep in mind what I said earlier, in the back half of the year, COMIRNATY sales will begin to ramp up. They compress our gross margin rate fairly significantly, given the partner contribution and payment that we have to our partners. So I would expect that to dampen our gross margin performance in the back half of the year.

Umer, as you well know, we're focused on overdelivery, if we can. So I think we will do everything we can to continue to improve our performance there.

And then finally, as we think about the balance sheet, first and foremost, I just want to reiterate that our #1 priority from a capital allocation perspective is both supporting and growing our dividend over time, and that is not at risk. Secondly, yes, we always look at the assets that we have across our platform and understand what's the best way to capitalize on those assets, and some of that may be monetizing some of that. Some of that may be operating more effectively. So everything is on the table from that perspective.

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

Thank you, David. And although your answer was very complete, I will just reiterate something that you said because it seems like that some people, they want to hear it again. The dividend is a sacred cow for us. Dividend, it is secured, and we will continue our policy on dividend as we have promised repeating. And we don't have to monetize things to be able to see that. The reason why we are looking at all our assets is because we want to maximize return on the capital.

And of course, we will see opportunities. I don't know when it makes sense, like the ones that we described, there is serious now issue with the sterile capacity that people are looking to acquire. We will look at everything, but it's not that we are looking right now on this or that because we need to support the dividend, all really to support the delevering opportunities or need to support the investments in the business, right? We can do that without doing any much. Thank you very much.

Operator

We'll take our next question from Geoff Meacham with Bank of America.

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

Just have 2 quick ones. The first is now that Seagen has been fully integrated, and you'll see some commercial leverage from the deal, would you expect to see more of a gradual impact on the PADCEV and et cetera, trajectories looking out a few years? Or could you have a more near-term inflection? And then the second question, Dave or Albert, the capital allocation commitment to the dividend is super clear. What we view on Slide 12 as dividend and deleveraging as the 2 highest priorities, or is bolt-on BD still in the mix for this year or next?

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

Yes. Let's go to Chris to understand the commercial impact on Seagen and how that will take time.

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

Thank you very much. So as you know, we had a number of months planning prior to close to ensure we had a seamless integration. And we completed cross-training of our commercial field force teams in January, especially for breast cancer, between TUKYSA and IBRANCE, but also hematology between ADCETRIS and ELREXFIO. And we should start seeing that further playing out now over the coming months.

As we've mentioned, we're obviously very pleased that there's been tremendous colleague retention, so we haven't had an issue with colleague retention, both from the legacy Pfizer and the legacy Seagen organization as we build a new business.

We expect PADCEV to continue to do well. There's significant enthusiasm from health care providers, from patients, from patient advocacy groups because of the groundbreaking data, double the overall survival. So we are confident that we'll continue to see PADCEV growth.

We've also seen TUKYSA, for instance, 21% year-over-year pro forma basis growth. And in fact, the last quarter was the highest performance of TUKYSA. So overall, great confidence, and we started the first new Phase 3 study with an NME from the Seagen portfolio with a secret attack. and we hope to update you on other Phase 3 studies from the legacy Seagen portfolio.

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

From my perspective, yes, of course, we have invested so much into this business, and we think that this is an area that we can make a huge difference to the world. I'm monitoring that very closely. I'm very impressed actually, I would say, nicely surprised on the positive side how well both on the Pfizer impact of day 1 plus 1 equals 3 rather than 2. But already, we'll start seeing it both in the research organization because we are putting now a lot of Phase 3 on starts.

And you don't see but I have high visibility on what's going on in earlier stages where we put a lot of stuff in the clinic. And then also in the commercial, that you can see now stabilization for IBRANCE on the Pfizer side, and then high growth of the seeds and assets despite the fact that, as I said, you should expect a decline in the first 6 months.

When you have an integration, always, we have a decline. I haven't seen a single integration that we have done, but it didn't face challenges because people are changing territories, people are changing let's say, jobs, marketers are moving around.

All of that creates, let's say, a disruption here. We can be of -- we have very, very strong growth on both sides. So I'm really, really pleased. Not of course, will take time to see the full benefit. But certainly, under Chris' leadership, and he has formed a terrific team, we are off to a very good start.

Now Dave, why don't you take or the next question?

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

So as it relates to your question regarding capital allocation, clearly, our first priority, our #1 priority is supporting both the dividend as well as delevering our balance sheet. So that is job 1 from my perspective. As it relates to bolt-on acquisitions, in the near term, you would not expect us to do much there. We are -- that is a lower priority in the near term until we get ourselves. I hope that helps.

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

Thank you.

Operator

We'll take our next question from Srikripa Devarakonda with Truist.

Srikripa Devarakonda - *Truist Securities, Inc., Research Division - Associate*

Congrats on the progress. I have a question about your breast cancer franchise from the IBRANCE perspective. You have pivotal data from the estrogen receptor, PROTAC, the collaboration with partnership with Arvinas expected later this year. One is, what are your expectations for these data? And how important are these data for you to make decisions around either continuing or initiating combo Phase 3 trials, like whether it's CDK4/6 combo or CDK4 combo or both of them?

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

Thank you very much. Chris?

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

Yes. Thank you very much for the question. Just a reminder to point out with IBRANCE that over 773,000 patients have now been treated globally with IBRANCE. So it is currently still the CDK4/6 leader. We're very excited about 2 programs: vepdegestrant, which we believe to be best-in-class next-generation receptor degrader and also atimociclib, next-generation CDK4 specific inhibitor.

For, as you point out, we'll get the data later this year for VERITAC-2, but we are planning additional studies at ROTH. You can expect to see first-line studies, both first-line study with atimociclib and standard of care endocrine therapy as well as a termocyclib-plus brand. (inaudible) as you've seen in a heavily pretreated population, we've seen an overall response rate of 32% with medium progressive survival of 8.1 months. We're therefore highly encouraged.

I'm definitely very encouraged by the safety profile and we see more continuous dosing, very good compliance and more complete coverage of CDK4, and that's why we're confident to accelerate CDK4 into a registration strategy and the first study has already started, as you know, the second-line study.

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

Thank you, Chris.

Operator

We'll take our next question from Carter Gould with Barclays.

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

I wanted to ask a follow-up as I think it's important, and I fully respect the focus on '24 and Albert's commentary on conservatism around guidance. But to come back to the IRA impact for thinking about '25. When do you think you'll be in a better position to comment a little bit on you're contracting discussions are underway pretty late in the earnings season here, and most of your peers have already made comments and your Part D exposure isn't exactly a surprise. So any color there on time line would be helpful. And I guess for David, you talked about the operating margin improvement being sort of a multiyear process. Is there a risk that the IRA sort of presents a little bit of a hiccup to that in '25?

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

Aamir, do you have any comments on that?

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

Sure. So Carter, I think you heard us describe the dynamics. And later this year, we will have more clarity on what that means. And so we can certainly share that. I think there's also a specific question that comes up often about Eliquis, so let me just address that now because we are clearly in a live negotiation on that.

BMS, our alliance partner, is leading that process. You've heard them describe, and we also described that there will be transparency around the outcome of that for impact in '26 in the September time frame. And so at that point, we'll be in a position to share more.

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

Yes. And I guess, as it relates to 2025 and the impact of the IRA from a margin expansion perspective, I would say, without giving any specifics on that is, as we look forward, we obviously run multiple scenarios around how our business might perform. And in those scenarios, we would model different impacts to the IRA because it's still unclear because it's still a lot of moving parts, specifically as we just spoke about. Under those scenarios, we will work hard to offset any implication we might have through improving our cost structure.

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

And I want on the IRA, and also, we said something, but clearly, in 2025, we will have 2 events that are happening, which are -- we will have to contribute to -- as a pharmaceutical industry, so that will put pressure on the pricing, let's say. But also, because of the significant pains in the out-of-pocket dynamics, and which I hope that will be implemented, as the law says, immediately because I'm hearing efforts to try to play with that.

But if that is the case, which we are certain because that's the law, we will see significant drug uptake, right, for everyone, not for us, of course, for everyone because there is a huge number of abandonment that is happening at the pharmacy level when people are asked to pay this very high out-of-pocket, particularly the first 1 quarter and maybe 2 when they need to exhaust their, let's say, their co-pays or the deductible.

So that, I think, dynamic, you know that the industry always asks that we contribute to the out-of-pocket payments as long as the patients are paying less because there is a significant benefit for all: for health care system, for the patients, for us. And so I'm not that concerned about that for the industry as a whole. I'm very concerned for the industry as a whole with the mandatory cost reduction. There is no negotiation there. They are just cutting prices, but are occurring for biologics and for more volumes, particularly.

One good thing for us, it is, first of all, that we have good exposure on vaccines, that they are a part of that, actually, they are benefiting from the IRA because there is no cost sharing. So we can see that in the volumes again. But on the small molecules where we do have exposure, I would say that we were like only 1 product that was selected for '26, we would have 3 or 4, and only 1 was selected. So Eliquis, as Aamir said, we will wait to

see. We know, of course, but we can't discuss in the middle of negotiations about anything that's happening. And so we'll see the impact of whatever about this in 2026.

Then if next year, they bring some of the other products that they've been included and they were not in this year, that will be the IBRANCE of the world, that will be the XTANDIs, those are products that anyway, they are approaching their LOE. So even if they come into the IRA, the MPV risk that we have in place is not that big because really, we cut the price for something, but it will not be for a very lengthy period of time, but will be for smaller than others period of time. This doesn't mean that this is not very bad for the industry and for innovation, and we clearly opposing and he will try whatever we can to defend it.

Operator

We'll take our next question from Rajesh Kumar with HSBC.

Rajesh Kumar - *HSBC, Research Division - Analyst*

First question is you very helpfully provided some color on the gross margin. What are the takes and puts there? If we look at your early 70s guidance and the gross margin you've achieved in Q1, do we see below 70s gross margin some point in some quarter this year? Or you sort of will get to early 70s with throughout the year, maintaining over 70% margin? And then the bit which is quite difficult to work out from the disclosures is, how did the PAXLOVID number impact the gross margin? So any help there so that we can model that right would be much appreciated.

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

Okay. Great. So yes, I think we just gave some color around gross margin being closer to 70% versus closer to 80% when we entered 2024. We are maintaining that color at this point in time. I would say that it's unlikely for our gross margin rate to fall below 70% in any given quarter. But I want to just emphasize the gross margin rate will fluctuate a bit, primarily given the mix of sales, specifically within the vaccine portfolio, which carries a lower gross margin, number one.

Number two, when you look at our performance for gross margin in Q1, a dominant effect of that versus last year is the mix, the lower sales volume of COMIRNATY in the quarter in Q1 versus last year's Q1. Obviously, the final adjustment of the PAXLOVID reserve actually did also have a onetime positive impact on the gross margin rate in Q1, but that was less of an impact compared to the mix. So I hope that helps.

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

And as I want to emphasize that on PAXLOVID, what really makes me pleased it is the underlying demand of the product, right? So it was approximately in the first quarter only in the U.S., 2 million scripts, right? So that's significant. And keep in mind that this was the quarter that we moved from a previous way of go-to-market approach to a commercial model, right? That had a lot of minefields in execution, but we didn't step into any of them. So it was Again, I'm very pleased how Aamir and the U.S. team executed on that. Meticulous execution. So we have a very smooth transition with very low co-pays on the commercial plans.

For the vast majority of the insured lives and then at the same time, very good execution with thousands of participating, almost 90,000 pharmacies, if I remember Well, of 90% of the is participating into the Medicare part. And that went extremely well. And also I want to remind that the Medicare that goes clearly with different price level because it is through the credit of the U.S. government compared to the commercial plans, that they are at 1,000, it's a different list price. And that difference exists for this year. Next year, everybody moves to the list price, and of course, the discounts that we give any. Let you over to Case, please.

Operator

We'll take our next question from Chris Shibutani with Goldman Sachs.

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

Two questions, if I may. The first on pneumococcal vaccines with Prevnar as well. Last quarter, you provided some commentary about your thoughts on the tone of the markets, particularly for adult being somewhat more mature. And obviously, competition is coming across the different categories, adult and pediatrics. Can you comment about your view, given that performance was relatively strong and how you're preparing for competition?

The second question I have is on commercial models. There has been some nascent efforts in the industry to go more direct to consumers, for instance, Lilly has direct for their obesity products. Aamir, I'm curious about your thoughts about integrating this type of approach, particularly as I think about certain product categories that you have like migraines and NURTEC, how might this work? Where is Pfizer in terms of exploring these opportunities?

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

Aamir?

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

Okay. Chris, thanks for the question. So on Prevnar, you alluded to the commentary we provided around dimensionalizing the market, and I think it's worthwhile just reiterating that. So the adult market continues to contract and that's for 2 reasons. There are increasingly fewer eligible 65-plus adults. And then the 19 to 64 underlying medical conditions, population is obviously more difficult to activate. So that is a dynamic that is true for our business, but it's also true for any competitor that's going to come into the adult vaccine market. So I think that's important to note.

Now for our overall franchise, we continue to expect growth. We did very nicely in Q1. We saw 6% growth. And the big driver of that is increased uptake as well as market share growth in the pediatric. So pediatrics in Q1 saw a lot of conversion, PCV 13 to 20. And our share exiting Q1 was at 80%, and that was from 71% at the time of launch of PCV 15. So we see good momentum on pediatrics.

Now back to your question about the adult segment and competition. We're continuing to see very good performance where we are. We have 98% market share. We acknowledge that V116 is coming. And as Albert alluded to earlier, we're not going to speculate on what the regulatory outcomes or recommendations are going to be. But there are a number of things that we can do to defend our business in the adult segment. Firstly, we have a portfolio approach to contracting that we're deploying in the retail setting but also in the nonretail setting.

And it's also important to note that in the nonretail setting, many organized customers have a preference for workflow management to stock 1 vaccine that satisfies all the current ACIP recommendations. So until we know more, I think the best way to defend our share in the adult segment is to continue to do what we're doing. And that's to be laser-focused on maximizing the opportunity that we have in the adult segment, albeit contracting and then continue to drive growth in pediatrics.

On your second question around consumers, look, engaging and activating consumers is, as you pointed out, a very, very important part of our business. It's true in vaccines. It's true in categories like PAXLOVID and NURTEC, just to name a few examples. And we're always looking at ways to enhance that connection. One example I'll point to is the work that we've done on VAXassist as a mechanism to help consumers determine their vaccine eligibility but also book appointments. And that's a really good example of value that we can bring. And to the extent that we can do more of that, create value for patients as well as for our business in other categories, we'll certainly look to explore that.

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

Alexandre, very quickly, anything on PCV in international markets?

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

Yes. No, we had a great quarter. As you know, we grew by 8% operationally. But more importantly, we also have achieved some key milestones. So we got the European approval of pediatric Prevnar 20 in Europe. We also got it approved in Japan, which are very important market in Australia and many others. So this is great because then we want to build on the very successful Prevnar 13 franchise around the world. As you know, we have exclusive NIP standards in 130 market, and now we're going to be able to build on that.

Just 1 comment on the Adults. We still are in the process of getting VTC recommendation in most of the European markets. But when we got it in Germany and in France, we see a very nice pickup. And why? Because they extended the population covered by the Prevnar 20 Adult. For instance, in Germany, gave us 18 to 59 population at risk and all-comers, 60 and above. And since that and we got this recommendation in February, we get very nice pickup in utilization in Germany, and we are about to launch in France as we speak. So in Adults, as well, we see a great potential of growth.

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

It's a very nice cadence of approval and recommendation.

Operator

We'll take our next question from Mohit Bansal with Wells Fargo.

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

Maybe a question for Dave. Just wanted to understand the cadence of margin improvement as you are embarking on the cost management journey throughout the year because I mean, you had a really high EPS because of the onetime item, but if you think about margin profile over the year, how should we think about it? I understand fourth quarter could be impacted with COMIRNATY revenues. And then when we get into 2025, should we think about better leverage or do you think there could be more opportunity to reduce expenses in '25 as well?

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

Yes, thank you for the question. I would say that without giving -- since we don't guide to quarterly expectations for gross margin, I would just say that the focus that we have around improving our cost of goods sold is a multiyear journey. And these costs that we are working to improve take time to adjust and to further implement ways to be more effective and efficient in this infrastructure.

So I wouldn't think of that having a significant impact on 2024 but more -- if it would, it would be late 2024 but more '25 and '26. But more to come. As we know more and as we develop our plans more specifically, we'll be certain to share some specifics around that.

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

Thank you.

Operator

We'll take our next question from Chris Schott with JPMorgan.

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

Just 2 ones for me here. Just on Abrysvo, just really quickly following up on the earlier commentary. Can you just update us on where we are in terms of contracting efforts and progress in the retail channel, just addressing some of the market share issues you highlighted last year? I guess my specific question is, do you have line of sight on contracting at this point? Or is that still something that's going to evolve as the year progresses?

And then the second quick 1 was just on VYNDAQEL. Obviously very strong numbers. Maybe just a quick update in terms of where we are with penetration in that market. And where do we -- how much higher can this go? Just how much more of a growth runway is there for that drug?

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

Aamir?

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

Thanks, Chris. So on Abrysvo, as I said, we're progressing our contracting conversations so we'll have more to share on that as we do later. And in terms of your question on VYNDA, VYNDA had a really strong quarter. We were up 96% year-over-year, but importantly, also 41% over last quarter. When you look at the drivers, I think there's a few things. Some of that is temporal. So there were some purchasing patterns with wholesaler and specialty pharmacies.

And we also made a lot of efforts towards the end of last year to ensure that the re-enrollment process for patients was very smooth at the beginning of this year. So all of that leads to a little bit of a Q1 bolus. But importantly at the heart of it, part of our strong performance on VYNDA is that the fundamentals around diagnosis and demand are really strong. So we saw a 33% quarter-over-quarter increase in new patient starts.

And diagnosis rates over the last several years, we had talked about getting into the 30% to 50% range. We're approaching the top end of that. And there is still significant opportunity to identify more patients. That's the biggest unmet need, and that's where we're concentrating our commercial efforts going forward. So we do think that we will sustain this momentum, probably not at the same rate that we saw in Q1 but we will continue to perform well with VYNDA.

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

Thank you. Alexandre, anything to add?

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

Yes, very quickly. On the international front, we also had a very strong quarter because we saw a 28% operational growth but a 43% volume growth, which is comparable to what we see in the U.S. Exactly as Aamir said, there is still opportunity because we basically have established VYNDAQEL as the standard of care. And we've worked with the health care professional to establish robust infrastructure so that we can screen, diagnose, and treat faster.

And the reality is we still have opportunity to grow because, yes, in markets like France, we are talking 50%, but in other like Italy, we are around 30%, Japan, 28%. So there is still opportunity to grow and increase rates.

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

Thank you very much. Next question. We'll take 2 more questions because we are running out of time.

Operator

We'll take our next question from Tim Anderson with Wolfe Research.

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

So it's a busy pipeline readout year. I'm wondering, Mikael, can you just point to perhaps the 1 or 2 bigger upcoming readouts that excite you the most, where your confidence is high as that could be value creating? So I'm not looking for a description of everything reading out. Just maybe 1 or 2 that excites you the most.

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

Thank you. Mikael, excite us all.

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

Yes, yes. I'm excited about the potential approval for marstacimab for both hemophilia A and B to continue to grow our hematology franchise momentum. DMD gene therapy, we actually today got the equivalent of Breakthrough Designation RMAT based on the early clinical data available, so we are super excited about that. And relatively near term, the readout is coming. COVID/flu combination vaccine, [859] readout Phase 3. And then one mid pipeline ponsegromab cachexia which I think pending readout has really a breakthrough mechanism.

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

Anything from your side, Chris?

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

Perhaps just to mention again the potential unprecedented new 5-year data for Lorbrena, which will be presented oral at ASCO. We could define the growth of Lorbrena over the next decade. There's 2 other upcoming readouts.

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

That's good if we are talking to that enthusiasm.

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

And there's 2 other readouts that's important to us, the 1 is Breakwater, which is the first-line opportunity in BRAF-positive colorectal cancer. A reminder that, that's up to 12% of colorectal cancer. Particularly poor prognosis so we're looking forward to that readout, Breakwater and then also, as mentioned earlier, VERATEC 2 in second-line ER-positive breast cancer, which can define also the to define the future path for.

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

Thank you very much.

Operator

Our last question will come from Steve Scala with TD Cowen.

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

I have 2 questions. In the Pfizer mRNA flu vaccine efficacy trial, was superior efficacy versus approved flu vaccine shown in the 65-plus cohort? This data was to have been presented last year but I don't believe we've ever gotten an update. And then secondly, your interest in obesity more broadly. So the outlook for danuglipron is not good. Bolt-ons don't look likely, but -- and this is just 1 very simple data point. There are postings on pfizer.com for obesity clinical lead position suggesting something is moving forward. So what exactly is moving forward in obesity at Pfizer?

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

Yes. On the obesity and Mikael also can comment, of course, together with the mRNA flu vaccine. But I said multiple times that first of all, metabolic is an area that we have traditionally very big strength in terms of, and this is an area that we have the right to win. So we are strong and to keep investing in the whole area because we have the infrastructure. And obesity is a very big part of it, even the of the market. So we will be very active in the obesity with current mechanism of actions and new mechanisms of actions.

We said repeatedly that we had 3 agents right now in the clinic, and we have multiple on the upper clinical that we are progressing. But we don't have anything to say per se right now because we are waiting, some data and on the other ones, it's too early to speak about them. So that's why we are not commenting much of that. And we will, let's say, continue being very active in the obesity space and one we're in now. Now what about the mRNA vaccine and anything you want to add also to the obesity line?

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

I think you said it so well on obesity. I'll focus on mRNA vaccine and just say that we did share that we had a very robust data for 18 to 59 in the outcome event trial on the first generation flu mRNA platform. We actually further refined that product in order to expand activity against these serotypes although the disease is dominated by A, we saw an opportunity to do that. And that technology is now with the COVID/flu combo vaccine running for 18 to 59 years old and relatively soon, we'll have a readout. We think that's really the near-term opportunity to bring both of the viruses under 1 simple administration approach. For the 65-plus, what you referred to was an early trial with the first generation. We have now moved focus to the second generation and are in preparation of subsequent clinical studies from them.

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

Thank you, Mikael. So thank you, operator, and thank you, everyone, for your interest. That was a very good call. In summary, we are very pleased with the solid start in 2024. We are cautiously optimistic about the year ahead. And with our continued progress in executing our 5 priorities, we are confident that we will continue to deliver for our patients, shareholders, and our company. Thank you again for your interest in Pfizer. We hope to have -- you have a wonderful day. Thank you.

Operator

This does conclude today's program. Thank you for your participation. You may disconnect at any time, and have a wonderful day.