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Company Summary

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PRESENTATION

Operator

(Operator Instructions) Good day, everyone, and welcome to Pfizer's third-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 DeMartino - Pfizer Inc - Chief Investor Relations Officer, Senior Vice President

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 third 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. Members of our leadership team will be available for the Q&A session, including Dr. Andrew Baum, who recently joined Pfizer as EVP and Chief Strategy and Innovation 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 our 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, Chief Executive Officer

Thank you, Francesca. Good morning, everyone. Thank you for joining us today. Our team continues to execute, and we are pleased to report another quarter of strong performance. We are guided by our purpose of delivering breakthroughs that change patients' lives, and I'm proud that we have reached more than 270 million patients with our medicines and vaccines through the first nine months of 2024.

The focus on execution excellence is starting to deliver results, with market share gains in the US and international, as well as robust growth in revenues and EPS. As a result, we are raising guidance ranges for our full-year 2024 total revenues and adjusted diluted earnings per share.

In January, we presented the five key priorities that would guide Pfizer during our year of execution. Today, you will hear how we advanced our business in the third quarter with each of these strategic priorities. I will focus on highlighting -- showing our progress with the first three. Dave will discuss our continued work to reduce our cost base, expand our margins, and strategically deploy our capital.

Then we will review our financial performance during the quarter and explain why we believe we are well-positioned to deliver on our financial commitments and create long-term value for shareholders. And then we will take questions. So with that, I'll turn to our performance against our priorities during the quarter.

Stated simply, oncology is having a great year and delivered another quarter of strong performance, with 31% year-over-year performance growth resulting from solid demand across our product portfolio that includes legacy Seagen and legacy Pfizer products. We set a goal to achieve world-class oncology leaders. In the US, we are already the third largest biopharma company in oncology by revenue through the first half of 2024, and we are proud of the progress we are making toward our goal.

Demand continued to increase for XTANDI, the market leader for four types of advanced prostate cancer, grew 28% year over year. TALZENNA grew by 77% in the quarter versus the same quarter from a year ago. We are encouraged by the opportunity to further advance the prostate cancer treatment landscape based on the exciting overall survival data We announced earlier this month from the Phase III TALAPRO study.

In the study, TALZENNA in combination with XTANDI demonstrated statistically significant overall survival benefit in patients with metastatic castration-resistant prostate cancer, becoming the first and only such combination to do so. Driving scientific breakthroughs in genitourinary cancers is one of the key areas of focus in oncology. The TALAPRO-2

results show how we continue innovating to improve survival for men with prostate cancer, which is the second most common cancer in men and the fifth most common cause of cancer death among men worldwide.

We saw continued momentum during the quarter with the ongoing launch of PADCEV with pembrolizumab for patients with advanced metastatic bladder cancer, regardless of their eligibility to receive cisplatin-based chemotherapy. This combination has quickly become the most prescribed first-line treatment in the US for locally advanced metastatic urothelial cancer.

In thoracic cancer, we achieved 31% operational growth this quarter with LORBRENA, a treatment for adults with ALK-positive metastatic non-small cell lung cancer. Following the release of our five years of CROWN data during the ASCO annual meeting, we are observing an acceleration of first-line new patient starts around the world, and in particular, in our key markets of the US, China, Germany, and France.

Our BRAFTOVI and MEKTOVI combination also achieved strong year-over-year growth in the third quarter of 32%, primarily driven by growth in the metastatic non-small cell cancer indication. And we continue to be pleased by strong performance with the launch of ELREXFIO, which had about 80% sequential revenue growth over the second quarter of 2024.

In the US, we have more than doubled our new patient start since January. In Japan, we were able to catch up with competition and launch as the first to market PCMA by specific, helping to address an unmet medical need for patients with triple-class exposed multiple myeloma. We believe ELREXFIO has the potential to be a transformative treatment option for people with multiple myeloma, and we are continuing to advance development with four ongoing registrational studies in earlier lines of therapy that, if positive and approved, could support serving a way more expanded patient population.

Now I will turn to some select highlights of how we continue strategically advancing our pipeline. We are prioritizing opportunities where we have scientific leadership and deep capabilities to address significant unmet patient needs. Earlier, I spoke to the strength of our market in oncology medicines. Our pipeline, however, is what excites us the most.

Lung cancer is the number-one cause of cancer-related death around the world. At the recent ESMA Congress, we saw long-term follow-up results from FOREST trial evaluating BRAFTOVI and MEKTOVI in patients with BRAF V600E mutant metastatic non-small cell lung cancer, which demonstrated compelling efficacy for patients. We are also rapidly advancing to next-generation ADC candidates with the potential to make significant impact on the more than 300,000 patients with non-small cell lung cancer in the US.

The first is sigvotatug vedotin, which is now in Phase 3, and we are planning additional pivotal trials in the coming months. The other one is a PDL1-AV-ADC. We are equally encouraged by the updated Phase I data we presented at ESMO for this ADC, and we are planning registration-enabling trials in 2025.

Our genitourinary pipeline is expanding. We are studying another novel ADC, disitamab vedotin, in two ongoing registration-intent trials in urothelial cancer. And mevrometostat, our novel EZH2 inhibitor, is another example of the progress we are making throughout our pipeline. This has been studied as a new potential treatment for men who have metastatic castration-resistant prostate cancer, and we are enrolling currently patients into Phase 3 studies.

Finally, to build on the foundation for our drugs, we are making progress with development of two candidates we believe can replace the current backbones of ER-positive HER2-negative breast cancer. Atirmociclib, our potential first-in-class CDK4 inhibitor, is enrolling a second-line Phase 3 trial, and we expect to start a first-line Phase III study by early 2025. And we expect the first Phase III data in the coming months for vepdegestrant, estrogen receptor degrader that we are co-developing right now with Arvinas.

Our fourth-generation PCV candidate, now in Phase 2 adults and pediatrics, covers 25 serotypes, including improved immunogenicity for serotype 3, very important, which is one of the largest remaining contributors of disease. We are focused on building on our leadership in the industry by continuing to expand balance sheet with our fifth-generation candidate, which is in pre-clinical development that covers over 30 serotypes.

In the last several months, we have advanced a potential new vaccine against C. diff, which is considered an urgent public health threat that lacks any approved vaccines. Leveraging experience from our previous C. diff program, we have

developed a new formulation for a second-generation candidate. After encouraging Phase I data with this new formulation, we have advanced to our Phase 2 study already.

We are also working to support significant needs for about 90 million Americans and 200 million Europeans in areas with high incidence of Lyme disease. VLA15 is a vaccine candidate we are co-developing that is intended to protect against the six most prevalent serotypes in North America and Europe. A Phase 3 trial is underway. And pending positive data and regulatory approval, VLA15 would become the only vaccine available to help prevent the acute, severe, and long-term health consequences of Lyme disease globally.

Paxlovid is the standard of care COVID-19 oral treatment for those at high risk of progressing to severe disease. We believe, however, that it is an opportunity to expand both our therapeutic impact and market position with our next-generation oral antiviral candidate, ibuzatrelvir. In a Phase 2 study, we have demonstrated robust antiviral activity at all doses and without the need for ritonavir boosting.

We have addressed the drug-drug interactions and the metallic taste associated with Paxlovid. We expect to start a Phase 3 study in the coming months. We are also moving forward with our Phase 3 program in non-segmental vitiligo with ritlecitinib, a candidate with a differentiated JAK/STAT mechanism developed in-house at Pfizer that has the potential to be an expansion of indications for LITFULO, which is currently approved in severe alopecia areata.

Vitiligo, like alopecia areata, is an autoimmune disease with high unmet need. It is the leading cause for skin depigmentation and affects nearly 3 million patients in the US alone. We are also enthusiastic about our two first-in-class trial-specific antibodies with early data demonstrating excellent 3-in-1 patterns. We believe this program has the potential to deliver improved efficacy in atopic dermatitis with an ongoing Phase 2 study evaluating safety and efficacy.

We had a Phase 2 redoubt of ponsegromab, which is another in-house discovery and development asset. We are encouraged by the potential for a breakthrough for patients with cancer or cachexia who lack treatment options for this life-threatening, wasting condition that currently has no FDA-approved treatment. The Phase2I study met its primary endpoint of change from baseline in body weight compared to placebo across all doses tested. And at the highest dose evaluated, saw improvements for baseline in appetite, cachexia symptoms, physical activity, and muscle mass.

Based on these positive results, we expect to advance to a registration-enabling study next year. Our Phase 2 study in patients with heart failure-related cachexia is ongoing. We remain on track with our dose optimization studies for danuglipron, our oral GLP-1 receptor agonist candidate, and look forward to discussing more about this in early 2025. In our broader obesity portfolio, we continue to advance our early-stage candidates, including our oral small-molecule GIPR antagonist, which is advancing to Phase 2 in 2024 this year, and an additional once-daily oral GLP-1 receptor agonist in Phase I.

The highlights I've mentioned today across important therapeutic areas show how we have made meaningful advancements with our pipeline. As we announced earlier this year, Dr. Mikael Dolsten, Pfizer's Chief Scientific Officer, will depart from Pfizer after 15 years of leading Pfizer's research efforts. Our progress for selecting a successor is now quite advanced, and we look forward to announcing an update soon.

Now I will turn to our commercial performance. Another one of our strategic priorities is maximizing the performance of our new products. I am pleased that the decisive actions we took to enhance our commercial organization at the beginning of the year are yielding satisfactory results. With NURTEC, we saw 28% total prescription growth and continued leadership in the oral CGRP class.

Importantly, 85% of primary care clinicians writing CGRP prescriptions for the first time choose Nurtec. This shows the progress we are making in primary care as well as our work with payers to remove barriers for timely patient access to treatment. Among our vaccines, we are very pleased with our performance since the launch of Prevnar20, which has already achieved 83% market share in pediatric and 97% in adults. With last week's recommendation by the Advisory Committee on Immunization Practices to expand adult pneumococcal vaccination to include all adults aged 50 and older.

We believe Prevnar20 is well positioned to serve an expanded population in the United States. Outside of the US, we are predominantly serving the pediatric market and following the recent first quarter approval in Japan and the EU, we are gaining vaccine technical committee recommendations and several market introductions.

With ABRYSVO, we continued improving our US market share position with strong commercial execution. Our market share of sales to retailers and clinics out of wholesalers has exceeded 50% for the quarter, and our market share of shots in arms in the retail setting has increased for nine consecutive weeks through mid-October, currently reaching 43%. Last week's FDA approval for ABRYSVO for patients 18 through 59 who are at increased risk of low respiratory tract disease caused by RSV could help us serve an expanded population over time.

With the rise in COVID-19 infection in the summer and early fall, we have responded to increased demand for Paxlovid as we launched in the US commercial market at the beginning of the year. Our better-than-expected growth during the quarter for Paxlovid reflects higher inflection rates and the strong commercial execution of our team. Our ability to execute effectively includes improving patient access, raising awareness of this treatment option, expanding use of alternative sides of care, and also continuing to educate healthcare providers.

The demand for Paxlovid seems to have stabilized. In the slide, you can see the total number of patients treated with Paxlovid in '24, which is very similar to the same period in '23. It appears to be closely correlated with its weight of COVID-19 that also appear to have very similar pattern in '23 and '24.

The 63% operational growth in the third quarter of our VYNDAQEL family of products is a direct result of our progress in expanding the healthcare provider base and supporting clinicians in identifying more patients who can benefit from this therapy, as well as our work to improve patient access and adherence to therapy. International VYNDAQEL is reimbursed in 44 markets right now, and more are expected next year.

While diagnostic rates vary across markets, the unmet medical need remains significant, as illustrated by the 10% increase of patients on treatment in the third quarter versus the second quarter of 2024 in the US.

We were pleased by the 74% quarterly operational growth and continued progress with expanding access with CIBINQO, a treatment for patients 12 and up with moderate to severe eczema who didn't respond to other treatments, and 27% growth in the US in the second to third quarters of 2024 with LITFULO, the first and only FDA-approved prescription pill for both adults and adolescents as young as 12 with severe alopecia areata.

And I will turn it over to Dave.

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP

Thank you, Albert. And good morning, everyone. I will build on Albert's comments by reinforcing that we are very pleased with the financial results for the third quarter of 2024. These results demonstrate that our focus and our execution against our five strategic priorities are driving positive patient outcomes and continued financial and operational strength.

In addition to our strong top-line performance, our cost-reduction programs are creating a more efficient organization, setting the stage for increased capital returns and supporting our commitment to both maintaining and growing our dividend, all while enhancing shareholder value.

This morning, I will briefly review our Q3 P&L performance, I'll highlight our capital allocation priorities, and touch upon our full-year 2024 financial guidance. Additionally, as we approach the end of the year, I will also share several modeling considerations as we begin to plan for 2025.

Turning first to the third-quarter performance versus the same period of last year, let me walk down the P&L. Total company revenues were $17.7 billion, representing an impressive 32% operational growth. Our COVID-19 products were significant contributors, with Paxlovid generating $2.7 billion in revenue. This included $442 million related to delivering 1 million treatment courses to the US government strategic national stockpile.

COMIRNATY, our COVID-19 vaccine, contributed $1.4 billion in revenue. Our COVID-19 products were not the only drivers during the quarter. Our non-COVID products also exhibited robust performance with revenues of $13.6 billion, reflecting 14% operational year-over-year growth. This performance shows that our refined commercial approach is working. We continue to focus on key products and geographies, we've refined how we allocate our commercial field resources globally, and we're further optimizing our marketing resources into key priority areas.

We saw a strong contribution from our recently acquired Seagen products, including PADCEV, which continues its momentum following the results of the EV302 study last year. Other key growth drivers included VYNDAQEL, ELIQUIS, XTANDI, and NURTEC, partially offset by declines in Xeljanz and Ibrance.

Adjusted gross margin for the third quarter is approximately 72%, primarily the result of a net unfavorable mix related to our COVID-19 products, primarily due to the commodity profit split with BioNTech and applicable royalty expenses, as well as a slight dampening due to the associated costs incurred with the withdrawal of OXBRYTA. All of this was partially offset by our ongoing focus on cost management across our manufacturing network.

We continue to expect gross margins to be in the mid-70s for the full year, and as previously communicated, long-term improvements in gross margins will remain a key focus for the company over the next several years. We expect to achieve savings from Phase I of our manufacturing optimization program beginning in 2025 and deliver approximately $1.5 billion in savings for the first phase by the end of 2027.

In parallel, we continue to evaluate our strategy for both Phase 2 and Phase 3, which will focus on network structure and product portfolio, respectively. and we expect to have more information to share on those components of the program once they become available.

Total adjusted operating expenses decreased 2% operationally to $5.8 billion, and I will note that this amount includes spending acquired via our Seagen transaction. And looking at the components, adjusted SI&A expenses increased 1% operationally, driven primarily by marketing and promotional expenses for recently launched and acquired products, partially offset by a reduction in the US healthcare reform fees.

Adjusted R&D expenses decrease 4% operationally, driven primarily by lower spending on certain vaccine programs, as well as our cost realignment program, partially offset by an increase in spending related to the Seagen acquisition. We continue to be disciplined with our operational expense management and remain on track to deliver at least $4 billion in net cost savings from our cost realignment program by year end.

Q3 reported diluted earnings per share was $0.78 per quarter, and our adjusted diluted earnings per share was $1.06, benefiting from our top-line performance and efficient operating structure as well as a favorable tax rate driven primarily by jurisdictional mix. As mentioned last quarter, unique one-time items included in our GAAP results and excluded from our adjusted results this quarter include a $420 million charge related to the expected sale of one of our facilities resulting from the discontinuation of our DMD program earlier this year.

Now let me quickly touch upon our capital allocation strategy, which is designed to enhance long-term shareholder value. Our strategy consists of both 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 delivering our balance sheet. In the first nine months of '24, we returned $7.1 billion to shareholders via our quarterly dividend, invested $7.8 billion in internal R&D, and as we expected, completed business development activity was minimal.

Our commitment to delevering our capital structure to a gross leverage target of 3.25 times remains a key priority. In support of that goal, year to date, we have delevered by approximately $4.4 billion, paying down approximately $2.3 billion in maturing debt and approximately $2.1 billion in commercial paper. And in October, we monetized another tranche of our Haleon shares, which for reporting purposes is a Q4 event.

We received approximately $3.5 billion in net cash proceeds, and our ownership in Haleon was reduced from approximately 23% to approximately 15%. Year to date, we have received approximately $6.9 billion of net cash proceeds from the sale of our shares. We intend to monetize our remaining Haleon investment in a prudent fashion, considering our cash flow requirements and future market conditions.

Overall, in Q3, we generate robust operating cash flows, which combined with the Haleon net sales proceeds of approximately $3.5 billion, resulting in a significant free cash flow generation as we enter the fourth quarter. Our objective remains to delever and return to a more balanced allocation of capital between reinvestment and direct return to shareholders over time.

Now let me spend just a few minutes on our outlook for the full year. Based on our focused execution and strong year-to-date results, we are raising our full-year '24 revenue guidance by $1.5 billion and our adjusted diluted earnings per share by $0.30. We now expect revenues in the range of

$61 billion to $64 billion, and operational revenue growth excluding COVID-19 products is unchanged at 9% to 11% and takes into consideration reduction of sales associated with OXBRYTA.

COVID-19 product revenues are now expected to be $10.5 billion, $5 billion for COMIRNATY, and $5.5 billion for Paxlovid. Our guidance for adjusted SI&A, adjusted R&D, and our effective tax rate on adjusted income remains unchanged. And lastly, we expect adjusted diluted earnings per share of $2.75 to $2.95, primarily reflecting the top-line increase and absorbing the OXBRYTA impact. As a reminder, our EPS guidance includes an anticipated $0.40 of earnings dilution from the Seagen acquisition, largely due to financing costs.

Now as we begin to look towards next year, I want to touch on a few modeling considerations. As we've previously discussed, there are several non-recurring items included in our 2024 results. First, during 2024, Paxlovid revenue included a US government revenue credit true-up and the fulfillment of our obligation to the US national strategic stockpile.

Second, given our ownership of Haleon is now below 20%, we will no longer record equity income from that investment in our adjusted earnings beginning in 2025. And finally, our 2024 tax rate on adjusted income was favorably impacted by timing with respect to the impact of Pillar 2, and to a lesser extent, audit settlements. All in, these items are expected to have a favorable impact on full-year 2024 adjusted diluted earnings per share of approximately $0.30.

In closing, I'm extremely pleased with our third-quarter 2024 results and our overall performance this year. Our team remains dedicated to strong operational execution, and we believe our cost-saving programs will drive enhanced operating leverage over time that will enable us to consistently deliver on our financial commitments to our shareholders. We are committed to driving long-term value creation through scientific leadership, portfolio strength, and productivity across all aspects of our business.

And with that, I'll now turn it back over to Albert.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Thanks, Dave. It's time for the Q&A, but before we take our first question, I want to briefly address a topic that I know is in the minds of many. We

seek to be attentive to our shareholders and are always open to hearing their perspective.

We had a meeting with Starboard Value two weeks ago. I was there with our Lead Director and our Head of Investor Relations. The meeting was constructive and cordial. They presented the same deck they made public last week. And given the proximity to our quarterly earnings day, we were mainly in listening mode.

While we agree with some of the points they raised, we have vastly different views on many others. For example, they expressed dissatisfaction with our total shareholder return. We are not satisfied either, though we believe we are executing on the best path forward to increase shareholder value.

On the other hand, they challenged our capital deployment for business development. We believe that our deals will produce significant shareholder returns, and some of them, like Seagen or BioNTech, have been transformational for Pfizer. The important thing is what we do to improve shareholders.

In January, we presented a five-point plan aiming to create shareholder value that has guided our decision-making all year long. We remain focused on executing this plan and on delivering for our commitments, including driving long-term shareholder value. We will engage productively with our shareholders, including Starboard, and will consider all good ideas that are offered.

And with that, operator, please assemble the queue to discuss our third-quarter performance and pipeline.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Chris Shibutani, Goldman Sachs.

Chris Shibutani - The Goldman Sachs Group, Inc. - Analyst

Good morning and thank you very much. I wanted to ask questions about the pipeline, in particular with regard to obesity, where we appreciate the additional insights into what you have in the clinic. Albert, you previously said that you believe that Pfizer could be the number-two company on the market with an oral. That would imply that danuglipron is the lead asset there.

However, you do have two additional assets that we find intriguing, a GLP-1 oral that is in 1Phase I that is once a day but would clearly be behind, and then now an oral GIPR antagonist, which I think is a source of debate. Can you frame what your strategy is, how important it is to be second to market versus perhaps having a differentiated approach with these two assets? Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer

Look, I will ask Mikael to comment because there is a lot of activities going on right now. But my general comment is that, as I have said, if danu moves fast, based on what we know right now, we should be the second oral into the market, provided that the first one will be successful and the other ones will not come before us.

But so far, this is what the situation looks like. The market is very, very large, and there is a significant need for oral solution. We know that. So there is no doubt that if successful, we will have our decent market share over there. But the important thing is that the obesity market is developing, let's say nicely also in terms of science, and we are exploring several other opportunities right now. The two that we have mentioned in the clinic, Mikael can speak a little bit more, both about the danu and the other two. Mikael?

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

Thank you, Albert. Yes, as you heard in Albert's remarks before the meeting, we continue to execute on our danuglipron plan, which includes a once-a-day profile with a modified release type of system, and we do believe that once a day with modified release could have some really special features. And bringing that as a second oral would help really to have a strong foot into this market.

In the same way, we have seen the injectable being split between two different products. I don't expect that the various oral will in the end differ that much in the GLP-1 class. So that's why we were keen also to move a GIPR, which could add better probability and more efficacy. And we're right now initiating Phase II studies on the backbone of GLP agents. And these are our two more advanced bets. Plus, we always like to bring in this huge segment in drugs and have more options as we advance. And you have heard there are so many applications for GLP-1s, and that's why we have a second once-a-day agent.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Mikael. Next question, please.

Operator

Srikripa Devarakonda, Truist.

Srikripa Devarakonda - Truist Securities, Inc - Analyst

Hey, guys. Thank you so much for taking my question. I have actually a question on your recent data from ponsegromab program in cachexia. You reported positive filter data. And just broadly speaking, this program has been previously highlighted as well. For the registrational trials, would a trial that replicates your Phase 2 in a larger group of patients be

sufficient? Or would you need to show outcomes like survival? And also, as we await details of the registration trials, can you help us understand how big of an opportunity you see for this drug? Thank you so much.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Let's start with Mikael a little bit on the science, and then maybe Andrew can speak about the potential market size of the cachexia.

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

I think, in general, for cancer agents, and this is more in the supportive care, we're addressing segments of unmet patient needs which relates to be able to regain performance status with better body weight, have higher physical activity, and be able to go through more treatment cycles, which should often translate to better long-term survival.

As you know, that is always dependent on how patients cross over to different trials. So I do think initial registration will come from a similar endpoint as in our Phase 2 studies, but we clearly aim to translate that better patient performance to other outcomes that are more harder endpoints, going through more treatment cycles and treatments that correlate with better cancer outcomes over time.

And this will be shown in multiple cancer types, so we do think, similar to other products that earlier have been heavily used in supportive cancer care, this could be very a large opportunity. And in addition to that, we are running heart failure studies and looking at a third opportunity, also large chronic disease.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer And with that, Andrew, some comments on the potential of this molecule?

Andrew Baum - Pfizer Inc - Chief Strategy and Innovation Officer, EVP
Yes. Hello, Kripa. I'm building on Mikael's comments. Look, cachexia is a massive unmet medical need. It's 50% to 80% of patients with oncology

suffer from it, particularly, as within pancreatic and non-small cell lung cancer. It's probably about 20% to 30% in heart failure and COPD.

The size of the market really depends on whether it's viewed as a supportive care therapy. But also, obviously, as Mikael mentioned, whether you have outcome benefit. And obviously, depending on the outcome of those trials, we're going to be looking at different price points. So the size of the market, or particularly the size of this drug, is going to be very much informed by the data that we deliver in the pending Phase 2 and Phase 3 trials.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you. Next question, please.

Operator

Umer Raffat, Evercore ISI.

Umer Raffat - Evercore ISI - Analyst
Hi, guys. Thanks for taking my question. I feel like it's still very early in your engagement with some of your shareholders and the new shareholders,

so perhaps it might be too premature to ask much further on that. So instead, maybe I'll focus on pipeline briefly.

I know you mentioned, Mikael, that the oral GIPR antagonist adds better tolerability and more efficacy. It sounded like you were implying it's more incremental to what an oral GLP could do as a standalone. Could you just lay that into context? For example, in the four-week Phase 1 study you ran, did it hit 4% to 5% weight loss? And secondly, the more than 30-valent pneumococcal vaccine that you guys disclosed this morning, does it have more than one carrier protein? Thank you very much.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Mikael?

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

Yes, I think the ability of GIPR to act in concert with GLP-1 has been well documented in a few different peptide settings, so we aim to be the first to document this with an oral approach, and that could offer a really nice differentiation for patients that need more and faster achieving of their treatment objectives. That's what we want to reveal right now.

Under our new platform for PCV generation four and five, we include a number of technical improvements. We don't want to disclose those today, but we're open to mention that our PCV fourth generation, which covers 25 serotypes, have as an example an improved serotype 3 based on new technology that moves it far beyond what we believe any other technology has been able to accomplish.

And why is that important? Well, serotype 3 covers somewhere between 15% to 30% of disease in different countries. And improving on that can have a bigger impact than adding a number of rather infrequent serotypes. As we go to the more than 30 valent, it will be a combination of such improvement and many more serotypes.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Mikael. Next question, please.

Operator

Trung Huynh, UBS.

Trung Huynh - UBS Securities LLC - Analyst

Hi, guys. Sorry, I was on mute there. Trung Huynh from UBS. Thanks for taking my questions. I have two. So thanks very much for the comments on the activist investor. You said you disagreed with the thoughts over capital deployment and then you cited significant shareholder returns for Seagen and BioNTech. What's the difference between what you're thinking and perhaps what the Street's thinking here on BD? And then how do you intend to restore that investor confidence back into the company so that bridge between your expectations and the Street can be aligned?

And then just on your commitment to delevering, thanks for the comments on the prepared remarks here. Is there an appetite to delever even quicker and sell the hospital business and fully divest the Haleon stake earlier? You do have products going off with LOE soon. That could give you a little bit more flexibility on the balance sheet. So yes, just thoughts here.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Why don't we start with this one, and then I'll take a little bit of the activist question.

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP
Yes. So first on the delevering point, yes, our objective is to delever as rapidly as possible, and I think the company's been laser focused on doing

that, given the fact that we've taken out about $4.4 billion in debt year to date, and we'll continue to do that.

Secondly, without speaking directly around any potential BD opportunities here, is we're always looking to evaluate the infrastructure that we have and the assets that we currently maintain and understand if there's availability to, I'll say, monetize some of those assets over time to further support our delevering activities. So I would say all options are on the table, and we'll continue to evaluate on what makes the most sense for us strategically long term.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer

As regards to the -- our projections compared to the Street projections in the business development, first of all, let's start by saying that by far, the two biggest, it is Seagen and BioNTech in terms of revenues, right? And in both of that, I think the Street moved on Seagen way up compared to when we made the deal. And on COMIRNATY, we are very, very stable.

The other ones that also, if you add to that the Biohaven with NURTEC, which we are on our plans and we just exceeded for the second quarter, straight expectations, it is covering 80% of the investment that we have made and probably way

more in terms of revenues. And the most important thing is that those Seagen, for example, or the BioNTech with our development of mRNA infrastructure around the world, and the Seagen acquisition with our taking over the ADC technology of it, which was a unique, unique asset, is transformational for Pfizer.

It's not the revenue growth that we are seeing right now and will continue seeing all the way towards the end of the decade. But it is two ADCs, one already in Phase 3, the other is about to start Phase 3, that we got from Seagen, one the SV and the other the PDL-1 ADC. Those are mega blockbusters if there are technical successes. Mega blockbusters. And we are moving to Phase3I because we have seen very positive earlier data.

The same issue we are starting with in Disitamab vedotin in genitourinary cancer, another ADC. So I would say that I think we truly think that this was well invested capital and will demonstrate significant value for shareholders. But I want also to make a final comment for any discussion with activists. But no matter if we agree or disagree on what has happened, I think the most important thing, it is what we are doing going forward.

Starboard has not presented any specific actions, but they suggested something needs to change. From that point, in the beginning of the year, already a year ago, we are already starting changing a lot of things. Over the past 10 months, we have implemented changes like we changed our commercial model to separate the US and international business and appointed new leaders who have now delivered three consecutive quarters of revenue and earnings.

We integrated Seagen and created an end-to-end oncology research organization to ensure a successful integration of the company, of the Seagen pipeline, and we have retained the vast majority of the legacy Seagen colleagues, and we have delivered multiple, multiple successful readouts from that.

We announced a plan to reduce OpEx by $4 billion, which we are executing successfully without negatively affecting the top line. We announced an additional plan to reduce manufacturing costs by $1.5 billion, which so far is delivering satisfactory results. We brought in Andrew Baum, who is a knowledgeable research analyst to help prioritize our R&D pipeline and future business development.

We are advancing now the process of selecting a new Scientific Officer. And we have enhanced our Board with two terrific new Directors who have deep expertise in corporate governance and stakeholder value creation. So what we believe is that all these changes are the result of an intentional five-point plan that we rolled out already in January of last year.

So as I said in my personal, let's say, remarks, we plan to engage with shareholders, including Starboard. and consider any good ideas that create long-term shareholder value. But I don't think that the statement something needs to change is really pragmatic because it's coming 15 months later. Next question, please.

Operator

Louise Chen, Cantor. Your line is open.

Louise Chen - Cantor Fitzgerald & Co. Inc. - Analyst

Hi, thanks for taking my questions. So I just had two here. First one I wanted to ask you is how we should think about the big pushes and pulls for sales and EPS in 2025. And when you might give guidance, could it be as early as this year? And then second one, just on Seagen, just wondering how the integration is coming along and if you have any updates to some of the metrics that you gave like sales in 2030 and what have you for the Seagen deal. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Okay, Dave, let's start with the first question.

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP

Yes, so thank you. Regarding 2025 is really topical because we're in the middle, as you can imagine, building our 2025 financial plan here across all of our business lines. To your point, there's going to be a lot of pushes and pulls as we think about growth into next year on both our core business as well as our COVID business.

It is our expectation that we will provide guidance for 2025, most likely by the end of this year. So stay tuned, more to come. We will lay out all the pushes and pulls when we give guidance for 2025, so you can get a very clear understanding of our business and the opportunities to enhance shareholder value longer term.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Chris, can you give us an update on the Seagen integration? Both, speak a little bit about the commercial, but also focus on the research, which is

a significant value.

Chris Boshoff - Pfizer Inc - Chief Oncology Officer, EVP

Thank you very much for the question. Overall, we're very pleased with the integration to date. We've retained the vast majority of colleagues at legacy Seagen, and we now have over 1,500 colleagues working in our facilities in Bothell, just outside Seattle. As you saw, the global revenue in Q3, we printed $854 million from legacy Segen, and of that, PADCEV printed over $400 million in Q3.

Seagen, year to date, delivered for us $2.3 billion, which is 38% year over year on a pro forma basis. We continue to execute very well on the portfolio, on the pipeline. We started Phase 3 studies with Disitamab vedotin in urothelial cancer, that's HER2 low, which is up to 40% of bladder cancer; with

Sigvotatug vedotin, the differentiated B6A, started the first Phase III study in non-squamous, non-small cell lung cancer. That's where we saw the most significant data.

And we're also planning to start a combination of Sigvotatug vedotin plus pembrolizumab in the first line setting of non-small cell lung cancer and recently discussed and aligned with the FDA on the trial design and on the dosing. We're also progressing and should start a Phase 3 program with the PD-L1V, vedotin and disi in combination with pembrolizumab early next year. So overall, great commercial performance so far. We haven't missed a beat, and we continue to execute on the pipeline.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Chris. Next question, please.

Operator

Geoff Meacham, Citi.

Geoff Meacham - Citigroup Inc. - Analyst

Good morning, everyone. Thanks so much for the question. Just had a couple of quick ones. Mikael, another one on obesity, and I know you've added assets outside of danuglipron and I appreciate that it's early. I want to ask you, what does success look like on efficacy, just given the bar today? And then strategically, how does Pfizer view orals versus longer-acting injectables when you think about the investments Pfizer is making in this category?

And then real quick, Albert, on the IRA, obviously, it seems here to stay. But when you think about the potential for a new administration, what would Pfizer like to see, obviously, beyond closing the gap between orals and biologics on exclusivity? Thank you.

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

For orals, to keep it very general, I think you have a number of things that could be advantageous. One is, of course, they combine so well with all other drugs that are involved in cardiometabolic disease to give long outcomes. And what you're looking for, I would say, is 10% to 20% all the way, the lower range for the first GLP.

The upper range is where you can see oral-oral combinations edge towards. And that's very much similar to what you can see with a peptide. I kept it very broad with a lower and an aspirational range, the lower for more single agents that will edge above that and combo agents that can aspire to go above 15 and an edge above that.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer

Thank you, Mikael. Now Geoff, on IRA, clearly, IRA overall is negative for innovation and does not promote a spirit that people could provide investments. But there are also some good things about it. So clearly, I wouldn't like to see that the out-of-pocket limit that next year would be $167 per month for all your medicines for seniors, that's what we want to be maintained.

But this forced price setting is not a negotiation, and also the penalty bill are things that need to change. And it's not only on IRA. I would mention that 340B right now, it is one of the biggest issues, and it is unethical, and it is the way that it is evolving, and it is creating significant transfer of funds from where it needs to be used, the poorer people, to boost the profit lines of some business. So 340B reform is something that myself and the entire pharma is setting as a priority. So thank you for your question. Next question, please.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - Morgan Stanley & Co. LLC - Analyst
Great. Thanks so much. Appreciate the questions. Two for me. I guess first one is on the RSV opportunity. Just wondering what you see as the most

likely outcome here for revaccination frequency and the potential impact on the longer-term market opportunity.

And then the second question is more of a clarification on your CDK4 inhibitor. You got it to starting a first-line Phase III study early next year. Just wondering if you can share any more detail there on the design, if that would be a head-to-head versus IBRANCE, and if it would be in combo with [VEFDAG], or if that's a monotherapy-type design. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer All right. Aamir, would you like to speak a little bit about the RSV?

Aamir Malik - Pfizer Inc - Chief US Commercial Officer, EVP

Yes, just maybe, Terence, to directly answer your question -- so how the market evolves, it's going to be a function of how ACIP recommendations for RSV evolve, and that includes revaccination timeframe, as you mentioned, but also eligible populations. I don't think it's really productive for us to predict how ACIP is going to evolve these recommendations. But we do feel confident in the ABRYSVO profile. And importantly, what I would like to highlight is we feel very confident in our ability to pull that profile through.

You heard Albert describe our momentum in the US market, particularly in light of dramatic improvements in our market share versus last year. And we continue to be ready to advance in vaccinations in the fourth quarter as well. And the last thing I would say is the FDA's recent approval of the 18- to 59-year-old at-risk population makes ABRYSVO the only RSV vaccine that's indicated to protect patients as young as 18 years of age. And it further strengthens this perspective on the viability of ABRYSVO.

Last thing I'll say is on maternal, we have also had really good momentum on our principal maternal indication. We see very strong signals in uptake for the month of September. We had a 20% uptake, which is a full doubling of where we ended the last season, and we continue to see uptake amongst OBGYNs and health systems. So in the first four weeks of this season, the units that we shipped into those systems are up 56% from the first four weeks of last season. So we see momentum on ABRYSVO, and we look forward to future ACIP updates.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
And Alexandre, you want to add something on the international because that's also an important market for us?

Alexandre de Germay - Pfizer Inc - Chief International Commercial Officer, EVP

Yes, absolutely. Even though it's still not material yet, we are actually making very good progress. So on the adult front, we actually got [VTC] recommendations since the beginning of the year in large markets like UK, Germany, in France, in Canada, in Australia, in Saudi Arabia, and a lot of other mid-sized markets. Lots of positive VTC recommendations. Now we're moving into funding. And on the second quarter, we said that we won the exclusive UK tender. That's what we did. We also won the Canadian tender.

Now in terms of reimbursement, we just got actually regional reimbursement in Germany, and we are launching at least in October in Germany. Now, all the others, the large market and the mid-sized market that I've talked about, are in phase of negotiation. On the adult side, the last thing I want to say is actually we are working toward our immuno-bridging study in 2025 in China so that we can do an NDA filing, which is also an important market for us.

On the pediatric side, also, we are making good progress. We also got VTC recommendation in large market like the UK, in France, in Australia, in several other mid-sized markets. And actually, yesterday, we just got also the Pan American Health Organization that covered 40 markets in the Americas that actually listed agreeable in their RSVC recommendation.

So we're getting also reimbursements in France, and we have actually just launched in France recently. There again, on pediatrics, once we got all those positive recommendations, we are moving into reimbursements. So we see great potential. It's going to take a bit of time because we go through all those different steps, but we see good potential there. Absolutely.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Thank you. And then why don't we go to Chris for the question on the design of the Phase 3?

Chris Boshoff - Pfizer Inc - Chief Oncology Officer, EVP

Thank you very much for the question. On atirmociclib, our highly selective CDK4 inhibitor, this was another small molecule that was conceptualized and discovered in our laboratories in La Jolla. And it's currently in a Phase 3 program for second-line plus hormone receptor-positive breast cancer. And this is potentially not only a first-in-class but best-in-class highly selective CDK4 inhibitor.

And as you know, CDK6 leads to some of the vulnerabilities including the bone marrow toxicity, and that's why we're focusing on CDK4, which drive breast cancer proliferation. So we believe with the current data, including the safety and tolerability, the early clinical data support the potential for more complete and continuous dosing with CDK4.

And as you've seen, we've got no Grade 4 neutropenia, no Grade 3 or 4 diarrhea, and no Grade 4 treatment-related AEs was observed. We've aligned with the FDA on the first-line hormone receptor-positive breast cancer study, which will start in the coming months, and it will be against physicians' choice of CDK4/6 inhibitor. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you. Next question, please.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - BMO Capital Markets - Analyst

Hi there. thank you for taking my question. So I have one for Andrew in honor of what I believe is his first call on the other side. In your first four months or so, can you help us better understand your findings regarding the portfolio? And more broadly, how do you hope to shape and focus the wide variety of assets that Pfizer has to drive sustainable growth?

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer So now that you're in the dark side, what is your opinion, my friend?

Andrew Baum - Pfizer Inc - Chief Strategy and Innovation Officer, EVP

Well, I think, a, Evan, thank you for the question; b, I think in response to Albert's question, I think coming from finance, I guess pharma is stepping to the light side rather than the dark side. But in terms of the question, look, I've always regarded Pfizer's R&D engine highly, just because when you look at the stream of molecules that have been internally discovered at Pfizer over the years, first ALK inhibitor, first CDK4/6 inhibitor, numerous JAKs, ABRYSVO, there's clearly a very, very strong record of discovery and execution.

And it's not just small molecules I hasten to add. You see that in vaccines and oligos and cell therapies and bispecifics. And for me, when I made the move, this was absolutely key in terms of a company that had this. Because if you don't have this, then life is very, very difficult.

Now in answer to where I hope to add value coming forward, I think as Albert alluded to earlier, historically, perhaps we may have pursued areas where that R&D investment hasn't translated into the type of revenues you want. The point is that this is a much easier challenge to solve. It's a matter of taking this incredibly powerful machine and pointing it in the right direction so that we are targeting those areas that translate into revenues. If there's one thing that I think the COVID experience shows you is once Pfizer focuses, execution is something you should feel very comfortable about.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Andrew and Evan, for the question. Next question, please.

Operator

(Operator Instructions) Courtney Breen, Bernstein.

Courtney Breen - AllianceBernstein Holding L.P. - Analyst

Hi, everyone. Thanks so much for the time today. This is Courtney Breen from Bernstein. Perhaps building on the last question, looking at slide 28 in the presentation today, it suggested that in the last three months from the end of July to today that there has been no meaningful advancement of the pipeline, albeit there are a number of pipeline actions kind of suggested to be initiating soon.

We're suggesting this is likely as a response to the reset and cost cutting that's going on. My first part to this question is how will you ensure that this isn't repeated in further quarters, and how are you balancing the need to kind of take stock and cut while ensuring that high potential opportunities are getting appropriately accelerated through the pipeline?

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Then maybe I will ask the two R&D heads to comment on that. Please, let's start with Chris.

Chris Boshoff - Pfizer Inc - Chief Oncology Officer, EVP
Yes, thank you for the question. So just a reminder, this year, we've already started eight new first-in-patient studies in oncology, which I believe

makes us the number-one and company in terms of Phase 1 clinical trials started. In the coming months, we expect potential Phase 3 readouts for

BREAKWATER, which is a very important indication for us in BRAF mutated colorectal cancer, which is up to 10% of colorectal cancer. That will be in the first-line setting, a big unmet need, because there's particularly poor prognosis in patients presenting with BRAF mutated colorectal cancer.

We also expect readouts for VERITAC-2, our ER PROTAC we're co-developing with Arvinas for ER-positive second-line plus metastatic breast cancer and potentially for CREST, which is sasanlimab, a differentiated subcut PD-1 in combination with BCP in non-muscle invasive bladder cancer. We will also present in the coming months Phase 2 randomized data for mevrometostat.

This is randomized Phase 2 data in patients with prostate cancer. We've seen the data, and that provided us the confidence to initiate the two Phase 3 programs. In the coming months, we'll also start additional Phase 3 studies, as I

mentioned, CDK4, in first-line ER-positive breast cancer, Sigvotatug vedotin in combination with pembrolizumab, in PD-L1 high, first-line non-small cell lung cancer, and CAT6 in ER-positive breast cancer.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer So quite impressive from the oncology side. Mikael, what about the rest?

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

Yes, we thought we'd help you to focus by this quarter displaying some nice movement at the most valuable part of this chart, the right hand. When you look over the next 18 months and including oncology and non-oncology, we will have up to 40 different opportunities to fill the left side that I hear you are eager to see progress on. And the right turn, it will include -- the 40 will be divided between potential approvals, projected pivotal readouts, and potential proof of concept. And that did not even include early signals in clinical development. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Courtney, for the question. Next, the question, please.

Operator

Steve Scala, TD Cowen.

Steve Scala - TD Cowen - Analyst

Thank you very much. Pfizer has previously stated it anticipated having visibility on long-term COVID product sales based on 2024 trends. Since we are now nearing the end of 2024, I'm wondering what that long-term number is. And then secondly, does Pfizer have the Phase 3 booster data for the RS vaccine in adults in-house? And if yes, does the data show a similar step down in booster immunogenicity as did the GSK vaccine? Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
All right. So on the stability, let's maybe -- Aamir, do you want to make a comment? I could also comment, but why don't you?

Aamir Malik - Pfizer Inc - Chief US Commercial Officer, EVP

Let me just comment on performance. I think -- Steve, I think both on Paxlovid and COMIRNATY, I think with our performance to date, as well as the quarter, which show us is that these are both entering into a category where we understand what the volumes are likely to be and we believe these are going to be durable businesses going forward.

So just as an example on Paxlovid, even if you take the one-time items that Dave alluded to aside for a moment, we've seen significant Paxlovid treatment course utilization, right? Even just in the summer wave that happened over the course of the third quarter, we saw an average of about 100,000 courses of treatment at the start of July, growing to about 225,000 treatment courses in mid-August before that wave declined.

And we've built a very durable commercial engine to support that with increasing treatment rates, with very viable reimbursement both on the government side as well as on the commercial side, and a way to activate HCPs and consumers who need treatment. And similarly, on the vaccine, our goal this year with COMIRNATY, and we had the benefit of being able to start three weeks before last year, was to start the season with plenty of vaccine in fridges, both in the retail setting as well as in the health system setting.

And again, we've demonstrated an ability to do that quite well. When you look at where vaccination is this year versus last year, it's a little bit higher, actually, but a big part of that is just a function of the calendar and the three weeks earlier. We expect to see vaccinations continue in October through December. And the shape of that curve will continue to evolve, but all of this makes us confident that we're seeing a durable business, both on vaccines and Pax.

Alexandre de Germay - Pfizer Inc - Chief International Commercial Officer, EVP

And for international, this is Alexandre, thanks for the question too, same principles we see in during business. In COMIRNATY, I just want to remind everyone that in the international division, we close our third quarter at the end of August. So basically, you don't see any sales of community simply because most markets are starting their vaccination campaign in September.

Having said that, we're progressing very nicely in our key regions. So in Europe, we got the approval of the Gen 1 adapted vaccine in July, and we got the [KP2] adapted vaccine in September. Since basically end of August, we started to work with our healthcare authorities partner in Europe, where we have an existing contract, to implement the multi-year contract that is in place.

Same thing in the UK and Canada, we've also worked with the other authority to actually execute our contract. In Japan, we also got the general adapted vaccine approved in mid-September, and COMIRNATY is actually the only PFS vaccine never frozen, which could be a competitive advantage considering the distribution model in Japan. So again, we see this as an enduring business and we see us, as I said, executing our existing contract in our key location.

From a Paxlovid standpoint, Q3 was a good Q3 for us, and it's actually very good because it satisfies our perception that Paxlovid is a sustainable business with sustainable demand, which coincides with the COVID waves. And we had quite a strong spring wave in Europe and Asia, and that translated into immediate demand.

Just to close, I want to say that 47 countries outside of the US have transitioned from advanced purchasing into commercial. So as we see in the US, it is enduring, and now the sales that we see quarter after quarter reflect the absolute demand and reflect the waves as they hit the different regions of the world.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer

And Steve, also, I can't resist also making some comments. In the 5.5 years as CEO, I had 23 earnings releases, of which 22 we beat EPS of Bloomberg and one we missed. And I don't like the one that we missed, and that was in Q3 last year, and we missed it because of COVID. We severely miscalculated. Yes, there are excuses that the last pandemic was 100 years ago, so we didn't have, let's say, a benchmark.

And also, we had to reduce it significantly. We had $56 billion of COVID revenue in 2022, and we had a guidance of 22. So we reduced it at 40% on what it used to be. However, life proved that we got it wrong, and us, and Moderna, and everybody else. And the reality was that it was not 22, but 12. So we are very careful now when we speak about COVID because we don't want to miss it again.

But I would like to say that when I see the trends of the COVID business, Paxlovid, which for us is even more important because of the higher level of profitability, it is basically identical to the utilization of last year compared to this year. So far, we had 4.9 million patients treated until Q3 with Paxlovid in the US, compared to 5.2 million people last year, the same period.

The treatment rates have improved from 50% last year to 57%, and the fulfillment rates went a little bit down because now there is co-paying. From 88%, it went to 81%, but it's very, very stable. The same is with the COVID vaccination. When you see the trends of COVID vaccinations, the utilizations are basically the same like last year, more or less. And still, it's early in the season, so there could be fluctuations over there.

So I think your statement that shall we consider COVID as normal business now, it's absolutely true. And this is how we regard it. And we will stop separating our business to COVID/non-COVID because it's Pfizer business. And with that, I will ask Mikael to make a comment on the RSV.

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

Thank you for your question. We have started to accumulate data on both durability and the impact of revaccination for RSV. On the majority of patients that we expected to go to pharmacy for revaccination, the titers remain robust after one and even two years, which is -- punctuate the quality of our vaccine. But they, of course, decline gradually. And we can have some meaningful improvement in those titers with a booster.

But I believe that likely in three years, around three years, we will see a drop in the titer that makes the boost really improve meaningfully the protection for a substantial fraction of the patients. And that's what we are going to monitor now, whether the three years is a good interval. But otherwise, it's performing exactly as expected for a high-quality vaccine.

Now there could be patient groups that go to physician offices that are more immunocompromised, moderate to severe patients that may benefit from a once-a-year, and that would be more a physician directive. So I hope that will give you a bit of an understanding how this will evolve.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Mikael. Next question please.

Operator

Rajesh Kumar, HSBC.

Rajesh Kumar - HSBC Bank PLC - Analyst
Hi there. My apologies, I was on mute. So two questions, if I may. What is the impact of Part D and IRA on your business next year? Are there any

numbers you're calling out which might help us with the modeling? That would be very helpful to understand if there are any impacts.

And the second one is, I appreciate the color on the Seagen pipeline and how you're progressing and how the market underappreciates the size of the opportunity. The sell-side estimates clearly do not reflect your optimism. When is it that you'll feel a bit more confident or what do you need to see to increase your longer-term guidance on Seagen?

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you. Dave, can you take the IRA impact next?

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP

Yes, I'll just hit on it very briefly. Obviously, the IRA in that, the redesign has pluses and pushes and pulls to us as we cycle into next year. When we provide guidance by the end of this year, we will give you a view on the net impact of that as we think about our business. So more to come, hold tight on that.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
And there are puts and takes, so positive things and negative things, right? So we need to assess it as we are building now these calculations, as

we are building our budgets for next year. Seagen pipeline. Chris?

Chris Boshoff - Pfizer Inc - Chief Oncology Officer, EVP

Yes, thank you for the question. So I think last year at this time, we didn't expect we're going to have PADCEV approved in first-line bladder, and everyone forecasted that approval for the first half of this year. And obviously, the approval happened very early because of the unprecedented data. So I think the performance commercially is really as we expected or exceeded what we expected in 2024.

If you look at the rest of the pipeline now, the new molecules like Sigvotatug vedotin and desitamab, PD-L1V, as well as next-generation, CD30 ADC called 35C for (inaudible), we will present next year at conferences more updated data on these, including in combination with pembrolizumab for Sigvotatug vedotin for DB and for PD-L1B, as well as really highly encouraging data for 35C, the next-generation CD30. So I think by showing and releasing more data next year will help all of you to build confidence in the pipeline.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Chris. And thank you for the question, Rajesh. Next question, please.

Operator

Akash Tewari, Jefferies.

Akash Tewari - Jefferies Financial Group Inc. - Analyst

Hey, thanks so much. So looking at some of your IP around 25-valent PREVNAR, it looks like you'll have to step up versus your previous 20-valent vaccine. But it does look like effective serotype coverage could lag meaningfully versus Merck and Vaxcyte approaches by 10% or more in older adults. How confident are you that this fourth-gen vaccine could stave off a preferential wreck from some of your peers down the line in adults?

And then number two, can you talk about what special properties your once-daily modified-release danuglipron could have outside of improved half-life that investors might be underappreciating? I think those earlier comments stood out to us. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Mikael?

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

Yes. The 25-valent that you asked about, the fourth generation, we aspire to be the one that first hits the pediatric market, which is where the bulk of use of doses -- but we also think because of this unique improvement of serotype 3 that is far more important than several of the other tiny serotypes will bring an overall value to the adult segment, that will be very meaningful.

And as you have heard, we are working on a fifth generation that will include both improved performance such as serotype 3 and go far beyond any of those serotypes that you are talking about in numbers. We use 30 plus just to keep a bit of detail for the future.

For the QD, I think, in general, you saw of course with injectable when you went from once a day to once a week and you got a smoother profile and reduced the number of peaks, that many patients perform better on them. So that's a hypothesis we are keeping our eyes on: that with a modified release, you will have a more smooth profile. You avoid certainly additional high peaks that immediate release has, and that's something we've seen in other formulation of other drugs. And that's why I think we are trying to be attentive in order to have our eyes on details that can help to make this product a really nice oral product with some differentiation.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Mikael. Next question.

Operator

Vamil Divan, Guggenheim Securities.

Vamil Divan - Guggenheim Securities LLC - Analyst

Great. Thanks for taking my question. So I have a few, but I'll keep it to two. So one, just on the guidance for the full year, you increased the total sales guidance by $1.5 billion. You increased the COVID products by $2 billion. So I guess you're lowering the non-COVID by about 500 million. I guess some of that looks bright up. But I'm wondering if there's anything else you might call out, where you're sort of trimming your expectations for the full year.

And then second one, sort of tied to the OXBRYTA news from a few weeks ago, we noticed the GBT-601, Osivelotor. So that seems to be progressing still in your pipeline. I'm just curious if you're contemplating or have you made any changes to that approach? And the mechanism is obviously similar to OXBRYTA. So I'm just wondering if any of you have learned from the OXBRYTA situation. Should we think about carrying over to this one? Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Vamil. Dave?

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP

Yes, on the guidance from a revenue perspective, you're absolutely correct. We increased our overall guidance by $1.5 billion. We increased Paxlovid by $2 billion, which implies a $500 million compression someplace else in the business. Think about that as largely OXBRYTA. We're absorbing the OXBRYTA headwind and maintaining our 9% to 11% growth rate in our non-COVID business, which actually implies that our baseline business is actually performing quite well.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
And I want to remind that the non-COVID business was 14% growth this quarter. Then, Mikael?

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

Yes, on one end, with Osivelotor, which was previously called 601, yes, I am encouraged about that opportunity. And of course, we try here to incorporate learnings, how OXBRYTA was developed to our advantage. As you know, that drive was already approved 2019 when we did acquisition a bit later and with several programs already up and running.

601 by itself is at a tenfold lower dose. It has more potency and brings more improvement for hemolytic anemia as one example. So this part has performed very well in our Phase 2 and looked really nice in tolerability, so I'm optimistic about that one. When I speak about trial learnings, OXBRYTA was performed in the more recent studies in a part of the world where it's really difficult to do the type of high-quality consistent three clinical trials.

And as we investigate in some of those learnings with OXBRYTA, we are, as a countermeasure, focused on Osivelotor entirely on high-performance sites that have a history of delivering great drug development. And this will obviously also support a profile. So I'm optimistic. And as a final end here, please remember that when we did the GBT deal, our eyes were really on Osivelotor, where maybe up to 80% of the value of the deal. But OXBRYTA allowed early entrance into the market, and we'll continue to investigate OXBRYTA and keep you updated with what we learn.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Thank you, Mikael. Next question, please.

Operator

Dave Risinger, Leerink Partners.

Dave Risinger - Leerink Partners - Analyst

Yes, thanks very much, and thanks for taking all these questions today. So my first question relates to cost cutting ahead. Obviously, the company is already engaged in significant SG&A and R&D efficiency initiatives, but I'm curious about whether management sees opportunities for further SG&A and R&D reductions. And then with respect to the over 30-valent pneumococcal conjugate vaccine candidate in pre-clinical development, given management's prior statements about its R&D initiatives, I'm assuming that that will be adjuvanted, and I just wanted to confirm that. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer
Let me take quickly, although that's David's domain, the SG&A and R&D. Look, we did significant reductions, and we were very careful to make

them in a way that will not affect our pipeline and will not affect our business. So we are very happy with what has happened.

Now are we going to not continue being efficient? Of course we will. I think I see tremendous opportunities ahead of us that we can reduce some of the less ROI-driven investments that we are doing, both in R&D and SG&A. And part of that will be, of course, reinvested in more productive -- with a trend to be able to control the cost and absorb our cost inflation. So you should see a constant, very cost-focused, very cost-conscious culture as we move on.

Now, Mikael, on the 30-valent?

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

Yes, Dave, thank you for a timely question. And I think we really have been breaking new ground in our PCV technology platforms. And we were obviously very pleased to get some of our new technologies validated with the serotype 3 that you heard about in the fourth generation, the 25-valent. The components that allows us to go far beyond 30 includes a very sophisticated new type of chemistry that on certain types of serotypes can give several-fold improvement in titer.

There are minor or more substantial formulation changes that can give some to quite significant fold increase, and that may or may not include adjuvants and also experience that we're gaining on the use of carriers that we haven't been working on in PCV before that can add to this toolbox.

So we are right now bringing all of these data together. And while we feel we have learned a lot with the adjuvants as seen in our CDP program that allow us to go from three to two and we have a toolbox of new adjuvants, whether it really will be necessary or not, it's too early to tell. But I acknowledge your good skills in the vaccine technology, and we'll keep you updated as we get closer to selecting candidates.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Okay, next question, please.

Operator

Chris Schott, JPMorgan.

Chris Schott - JPMorgan Chase & Co. - Analyst
Great. Thanks very much. Just two quick ones here. Just first on margin structure and following up on the prior question, is a mid to high 30%

adjusted kind of operating margin adjusted for COMIRNATY still fair for Pfizer, and what's a rough timeline to get there?

And then my second question was just on the vepdegestrant max franchise. Obviously, very strong year this year. But switching out to next year, we've got the Part D redesign, we've got incremental competition. Is there still enough volume opportunity here to think about this as a franchise that's going to be generating healthy growth, or should we think about growth slowing significantly going forward? Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Dave, you start.

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP

So first, obviously, mid to high 30s is very much within the realm of our business model. We're very focused against that. We continue to march and make progress against that over time. So we don't have a specific date for you at this point in time, but as we continue to progress both this year and we give guidance for next year, you should see us progress on that front.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer And I think COMIRNATY was also a little bit the question.

Dave Denton - Pfizer Inc - Chief Financial Officer, EVP

Yes, well, I think COMIRNATY is a down draft to that. So obviously, adjusted for the size of that business will be important. But having said that, we continue to make investments in our business such that we're more productive top to bottom, therefore expanding our operating margin profile of the company.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer

And we don't want to speak for specific products, the markets, right? Because it's a little bit misleading. It depends on multiple things. We did it because of the extraordinary circumstances in '22. But in general, you all know that from our two products, Paxlovid is very, very high margin and COMIRNATY is on the low. VYNDAQEL, why don't we start international this time and then we end up with Aamir on party redesign?

Alexandre de Germay - Pfizer Inc - Chief International Commercial Officer, EVP

Okay, so on the international, we had a very strong year, and we continue to grow very strongly this quarter at 31%. Actually, our total patients on treatment have increased by 14% in the third quarter versus the second quarter. So this illustrates the fact that we are growing, and we continue to add new patients on treatment. This is essentially the result of three things: one, the establishment of VYNDAQEL as a standard of care pretty much in all the countries where we operate; two, the establishment of a robust infrastructure of care, which will enable a faster diagnosis and treatment of this complex disease.

So this is a complex disease and finding those patients takes time, and now we have a robust infrastructure. And the third element is also, of course, the increased access. Today, we have 45 countries where we have reimbursements. And we just recently had in this quarter two countries, the UK and Australia, so two significant countries that have started to reimburse VYNDAQEL.

So moving forward, we really see that those three elements will continue to deliver and drive growth in the key international markets. And if you look at the treatment rates in our major international market, we still see some potential to increase that diagnosis. So that will be the drivers of growth in the next few quarters.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Aamir?

Aamir Malik - Pfizer Inc - Chief US Commercial Officer, EVP

So Chris, in the US, I'll give you a little bit of color. Obviously, VYNDA's had very strong growth this year. And I think a big part of that has been just a direct result of the commercial effort and attention that we've put on it, where we've seen real growth in diagnosis rate and new patient starts. So new patient starts are up about 61% versus last year, and they're up about 3% quarter over quarter as well. And we're also improving compliance rates significantly with existing patients.

For the market, there's a lot of patients, nearly half, that remain undiagnosed, so there's significant opportunity there. We will have tailwinds as we go forward, so we continue to put attention on this, and that's going to be largely increased diagnosis education, the prescriber rate that we're growing, as well as affordability conditions, and we've turned the page into 2025.

But we do think that the volume growth will be at meaningfully lower levels than what we've seen year to date. And a big part of that is obviously headwinds we're going to see from the changing market landscape where we will have new competitive entrants that will impact new patient starts as well as potential switching of existing patients onto some of these options. So those are some of the puts and takes on VYNDA. IRA will be a piece of that as well, as Dave mentioned, and we'll have more to share about 25-specifics when we get guidance.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Okay. And the last question?

Operator

Mohit Bansal, Wells Fargo.

Mohit Bansal - Wells Fargo Securities LLC - Analyst

Great. Thank you very much for squeezing me in. And first of all, congrats on phenomenal hire in Andrew Baum. So maybe, taking a step back, can you comment something about ABRYSVO, if there was any stocking in this quarter? This particular market is a lot like stocking driven in fourth and first quarter, so how you are thinking about that? It looks like from the IQVIA trends, price implied, price jumped a lot. So if you could help us understand what is going on there and how should we think about this particular product in coming quarters. Thank you.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer Which product it is, Mohit?

Mohit Bansal - Wells Fargo Securities LLC - Analyst ABRYSVO.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer ABRYSVO. Thank you. All right.

Aamir Malik - Pfizer Inc - Chief US Commercial Officer, EVP

So a few comments on ABRYSVO. So we wanted to, as I mentioned before, really start this vaccination season with ABRYSVO in fridges, in retailers, predominantly where the volume is, as well as with health systems. So we worked with our customers and our channel partners to make sure that we were appropriately stocked, and that's reflected in our Q3 numbers.

Now what we have also seen over the course of Q3 is that administration volumes, and for ABRYSVO, that began in August, over the course of the quarter have continued to steadily rise. Now they are at lower volumes than from a market perspective where they were last year. Lots of reasons for that, including timing of the COVID vaccines, as well as the change in the ACE recommendation. But we anticipate that there will be volumes that continue into the fourth quarter.

And then finally, our results are also a function of what Albert mentioned is our significant improvement in market share. So we've doubled our market share and customers from wholesalers, and our market share of actual shots in arms, of administrations in the retail setting in the middle of October was at 43%. So those are all the dynamics that are going into play for ABRYSVO performance in Q3 and heading into Q4.

Albert Bourla - Pfizer Inc - Chairman of the Board, Chief Executive Officer

Thank you, Aamir. And thank you, everyone, for your attention. It was another good quarter for Pfizer. I think we are continuing to execute the five-points plan that we have presented at the beginning of the year. There is an underlying operational health of our business. There is stabilization of the COVID business tool. Now we feel comfortable to forecast it. And we have seen strong growth from the remaining part of the business.

We have seen strong performance from new products. Most of them, they have beaten analysts' expectations this quarter, which shows that they are doing better at least than what was perceived they would do. And we are looking forward to continuing this path of executing and creating shareholder value. Thank you for your interest in Pfizer and you have a wonderful week.

Operator

That concludes today's call. You may disconnect at any time.