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PRESENTATION

Operator

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

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

Thank you, Chelsea. Good morning, everyone. Welcome to Pfizer's first quarter earnings call. I'm joined today by Dr. Albert Bourla, our Chairman and CEO; Dave Denton, our CFO; and Dr. Mikael Dolsten, President of Worldwide Research and Development and Medical.

Joining for the Q&A session, we will also have Angela Hwang, Chief Commercial Officer and President, Global Biopharmaceuticals business; Aamir Malik, our Chief Business Innovation Officer; Dr. William Pao, our Chief Development Officer; and Doug Lankler, our General Counsel.

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

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

Thank you, Chris. Hello, everyone, and thank you for joining us today. Q1 was a solid, foundational quarter in what we expect to be an exciting year for Pfizer and patients. Our financial results were as we anticipated. Our non-COVID revenues grew 5% operationally compared with the year-ago quarter, while overall revenues declined 26% operationally primarily due to a previously communicated and expected decline in Comirnaty revenues. Even with Comirnaty's decline, our COVID franchises remained significant contributor to the business with a combined $7.1 billion in revenues during the quarter. This growth was driven primarily by recently acquired products,

Nurtec for migraine and Oxbryta for sickle cell disease, our anti-infective Sulperazon, Eliquis, in the non-valvular atrial fibrillation indication in the U.S., and our Vyndaqel family of products for the treatment of transthyretin amyloid cardiomyopathy.

We also continue to be proud of our patient impact. During the first quarter, more than 250 million patients were treated with our medicines and vaccines. With this solid start to the year, we remain on track to grow our non-COVID revenues by 7-9% operationally in 2023. That's because the majority of our potential near-term product launches as you can see mapped out on this slide, are expected to occur in the second half of the year, following regulatory approvals where not yet secured. As such, we expect our non-COVID revenues to grow at a faster rate in the second half of the year than in the first.

Overall, we are in the midst of an 18-month period in which we expect to launch up to 19 potential new products and indications. Over the first four months of the year, we have made excellent progress toward this goal with the approval of Zavzpret, an expanded indication for Cibinqo to include adolescents, and last week's approval of Prevnar 20 for pediatric use all in the U.S. We also have secured regulatory filing acceptances for elranatamab, for Braftovi and Mektovi for non-small cell lung cancer, and for our RSV maternal vaccine candidate, which if approved would be the first vaccine for administration to pregnant individuals to help protect against the complications of RSV disease in infants from birth through six months.

In addition, the U.S. Food & Drug Administration has granted priority review and the European Medicines Agency has accepted our MAA filing for review of Talzenna for use in combination with Xtandi for patients with newly diagnosed metastatic castration-resistant prostate cancer, based on the TALAPRO-2 results.

Regarding our COVID-19 franchise, we continue to expect 2023 to be a transitional year as the virus continues to mutate and to remove from advanced purchases under government contracts to more transitional supply arrangements in the commercial model for both Comirnaty and Paxlovid in the U.S. As previously discussed, in 2023 and 2024, we expect vaccine utilization to decline compared with 2022. Then starting in 2025 and continuing in 2026 and beyond, we expect to see an increase in COVID-19 vaccination rates assuming the successful development and approval of various COVID combination vaccines. Outside the U.S., we expect these general trends to be similar with some variations from country to country.

Regarding Paxlovid, we continue to expect the government inventory that was built around the world last year to be absorbed by the end of this year. We then expect that in years '24 and beyond, the courses sold and courses used were more closely align. With its robust efficacy, consistent safety profile and potential to help mitigate the burden of COVID-19 on patients and their families, health system and society, Paxlovid is proving to be an important and durable complementary tool to vaccination strategies for the estimated 40% of the global adult population at high risk for progressing to severe disease.

Now let's take a look at Pfizer's next potential moonshot, the battle against cancer. Oncology remains a core therapeutic area for Pfizer, and we believe the proposed acquisition of Seagen will enhance our position in this important space. Integration planning is already underway and we continue to expect the deal to close in late 2023 or early 2024, subject to the satisfaction of customary closing conditions. By combining Seagen's category-leading antibody-drug conjugate technology with Pfizer's scale, expertise and capabilities, we believe we can accelerate potential breakthroughs in cancer medicines and introduce new solutions to patients around the world. The potential combined commercial infrastructure for Pfizer and Seagen will be 3x the size of that of Seagen alone in the U.S. and 4, 5x larger globally. As a result, we believe acquiring Seagen could contribute more than $10 billion in 2030 risk-adjusted revenue with potential significant growth beyond 2030.

Even with the Seagen deal, given the strength of our balance sheet and cash flows, we continue to have the flexibility to take additional actions to create shareholder value. Dave will provide more details on this during this presentation.

One of the key areas of focus for Pfizer in 2023 is continuing to build trust, which is a key asset for every biopharmaceutical company. Since the beginning of the year, we have received 2 accolades that demonstrate we are doing just that. In February, Pfizer was named to the top 10 of Fortune's Most Admired Companies List for the second year in a row. And in March, Ethisphere recognized Pfizer as one of the world's most ethical companies, also for the second year in a row.

At Pfizer, trust is everything. It gives us our license to operate, allows us to attract the best talent and enables us to deliver breakthroughs that change patients' lives.

With that, I will turn it over to Dave. After Dave, Mikael will provide an update on R&D pipeline. Dave?

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

Thank you, Albert, and good morning, everyone. I want to begin with Pfizer's capital allocation strategy before we dive into additional commentary about our quarterly performance and importantly, our outlook for the remainder of 2023. As you know, our strategy includes 3 main pillars: reinvesting in our business, growing and paying dividends and repurchasing our shares. In the first 3 months of 2023, we have invested $2.5 billion in internal R&D and returned $2.3 billion to shareholders via our quarterly dividend. And importantly, allocated approximately $43 billion for the proposed Seagen acquisition. Over the last few years, we have reinvested heavily into our business to drive long-term growth and enhance long-term shareholder value. We have invested in Pfizer's own science while acquiring the best external science to supplement our pipeline.

Since 2022, we have invested approximately $70 billion, including Seagen in business development. In addition, we have continued to grow our dividend. For the past 14 years, we have raised our dividend annually. Since 2010, our quarterly cash dividend grew from $0.16 a share to $0.41 a share in 2023.

Looking ahead, as we exit this unprecedented period of anticipated launches, we would expect to achieve operating margin improvement over time. As we began to de-lever our capital structure after the closing of the Seagen transaction, we expect to return to a more balanced capital allocation mix between our 3 pillars. While we will continue to invest in our business, we do expect more balance between that priority and returning value to our shareholders via increased dividends and value-enhancing share repurchases. Our capital allocation strategy is squarely focused on driving shareholder value, while at the same time, remaining committed to a high investment-grade Tier 1 commercial paper rating. Now turning to the quarter.

As Albert said, our results were in line with our expectations, albeit slightly better than consensus. As expected, overall revenues declined 26% operationally, primarily driven by the anticipated decline in commodity, which was partially offset by strong Paxlovid sales. I want to point out that our COVID-19 products produced $7.1 billion in revenues in the first quarter alone. Our non-COVID operational revenue growth was solid at 5% year-over-year. Primarily driving this growth was the inclusion of Nurtec ODT and Oxbryta and an increase in Sulperazon revenues in China. Revenues for Eliquis in the U.S. and the Vyndaqel family globally also contributed to this growth.

Now I want to remind you of the seasonality of some of our products. In the first quarter, Nurtec ODT and Oxbryta typically have lower sales quarter-on-quarter due to annual copay reset dynamics with higher sales anticipated in the latter quarters. Most importantly, both products continue to experience strong growth in demand. Sulperazon revenues increased more than $100 million year-over-year due to higher demand in China during the quarter, which we do not expect to be sustained going forward. The demand was due to increased bacterial infection from patients being hospitalized for COVID. To help ensure the success of the expected launches of a large number of new and acquired products and indications, we've increased our investments in SI&A. These investments are squarely focused on Pfizer's 2025 to 2030 growth aspirations.

Now moving to the bottom line. Reported diluted earnings per share this quarter declined by 29% to $0.97 a share, while Adjusted diluted earnings per share of $1.23 declined 20% on an operational basis during the quarter. Once again, this quarter, foreign exchange movements significantly impacted our results, reducing first quarter revenues by $730 million or 3% and Adjusted diluted earnings per share by $0.07 or 4% compared to LY.

Now turning to the full year financial outlook for the company. Our full year 2023 guidance remains unchanged. On a total company basis, we continue to expect revenues of $67 billion to $71 billion, reflecting an operational decline of 31% at the midpoint, with 5% operational growth in our non-COVID revenues this quarter, we are on track to achieve our non-COVID revenue guidance of 7% to 9% operational growth for the full year. Given that a large number of launches are expected to incur in the third and fourth quarter of '23, we anticipate our quarterly revenues will not be linear this year and that our non-COVID revenues will grow more quickly in the back half of

this year versus the first half of '23.

In terms of our COVID products, Comirnaty and Paxlovid, we expect sales to trend more seasonally this year. Given these dynamics, we expect significantly lower sales contributions from our COVID products in the second quarter versus the first quarter. In fact, given the anticipated timing of approvals for a fall vaccine with strain change, we would expect more substantial vaccine deliveries to start in September, which is late in the U.S. third quarter and the beginning of our international fourth quarter. With respect to Paxlovid, we continue to expect '23 to be a transitional year as we anticipate shifting to a commercial market in the second half of this year. We are reaffirming our Adjusted diluted earnings per share guidance range of $3.25 to $3.45 per share. On a full year basis, we expect that foreign exchange will have an unfavorable impact compared with full year 2022 of approximately $0.13 on Adjusted diluted earnings per share. We are also reaffirming the remaining components of our full year 2023 guidance which you can find in the appendix of the Q1 '23 earnings presentation.

So in closing, this is an exciting period for Pfizer as we continue to invest to drive long-term growth and, importantly, enhance long-term shareholder value.

With that, now let me turn it over to Mikael.

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

Thank you, Dave. Today I would like to start off with one of the four pillars of our oncology portfolio, which are breast, urogenital, blood cancers and precision medicine.

Within urogenital, prostate cancer is an area in which we have strong momentum. Recent positive study results further strengthen our franchise, building upon the global standard of care set by XTANDI, and underscoring our long-standing commitment to the pursuit of breakthroughs that define new standards of care in prostate cancer.

I will highlight data from two Phase 3 studies, EMBARK and TALAPRO-2, as well as early, but promising signals from our EZH2 inhibitor, each of which has the potential to reach broader patient populations across the treatment continuum in prostate cancer. Final analysis from TALAPRO-2, evaluating our potential blockbuster PARP inhibitor TALZENNA, in combination with XTANDI were presented at ASCO GU. Results showed significant and clinically meaningful improvement across the all-comers population in radiographic progression-free survival or rPFS, in men with metastatic castration-resistant prostate cancer with or without homologous recombination repair or HRR gene mutation. There was a 37% reduction in risk of disease progression.

Median rPFS in patients treated with TALZENNA and XTANDI was not reached at the time of analysis versus 21.9 months for placebo plus XTANDI. A trend in overall survival favoring TALZENNA plus XTANDI was also observed, though these data are immature. The final OS data will be reported once the predefined number of survival events has been reached. Treatment with TALZENNA and XTANDI resulted in statistically significant improvement in overall response rates, which suggests a potential cooperative effect between the two treatments.

The U.S. FDA has granted Priority Review for our sNDA for TALZENNA in combo with XTANDI for metastatic castration-resistant prostate cancer with a decision expected in '23. The ongoing TALAPRO-3 study, if successful, may further expand the reach of this potential blockbuster into the HRR-deficient metastatic castration sensitive population. We recently presented data from our Phase 3 EMBARK study, evaluating XTANDI plus leuprolide in men with non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence at the American Urological Association's '23 Annual Meeting. The study met its primary endpoint with statistically significant and clinically meaningful improvement in metastasis-free survival with a 58% reduction in risk for radiographic progression or death. Key secondary endpoints were met, including time to PSA progression. These results suggest XTANDI, the only novel hormone therapy approved for 3 disease states of prostate cancer in the U.S., has the potential if approved to expand to patients in the hormone-sensitive or castration-sensitive setting for the first time.

Next, I'd like to share early data from one of our next wave candidate, a potential first-in-class and best-in-class EZH2 inhibitor, which we shorthand as 1497. EZH2 is an epigenetic transcriptional repressor that frequently over-expressed in prostate cancer. We believe that

inhibition of EZH2 may provide synergistic effects in combination with XTANDI with a potential to address unmet needs of patients with androgen-sensitive and resistant disease. Here, our data from our ongoing Phase 1/2 study evaluating 1497 in second-line mCRPC patients with prior abiraterone and/or XTANDI and up to one line of chemo.

On the left are updated data from a Phase 1 dose escalation study shared at ESMO last year. These encouraging results show durable antitumor activity in both XTANDI-naive and experienced patients, with all XTANDI-naive patients having received prior abiraterone. Importantly, this suggests that the addition of our EZH2 inhibitor has the potential to sensitize XTANDI-resistant tumors, which is an increasing clinical unmet need. The early rPFS data also highly encouraging, reaching 8.7 months in XTANDI-experienced and 17.1 months in XTANDI-naive, both of which are notably longer than historical controls. For example, in the control arm of the CARD study, rPFS for XTANDI alone was only 4.8 months in XTANDI-naive patients.

And although cross-trial comparison cannot be made these results in combination with emerging objective response rate and PSA50 response are supportive of the contribution of our EZH2 inhibitor candidate in driving these responses. From a safety perspective, the combination was generally well tolerated with mostly Grade 1 and 2 events. The randomized Phase 2 study in second-line mCRPC is ongoing with data expected early '24.

Now we turn to the potential for near-term growth across our respiratory vaccine franchise. Prevnar 20 or our 20-valent pneumococcal conjugate vaccine is now approved for children aged 6 weeks through 17 years. We are confident in our ability to maintain leadership in the pneumococcal vaccine space with Prevnar 20, which offers the broadest serotype coverage of any pediatric pneumococcal conjugate vaccine helping to protect against the 20 serotypes in the vaccine. We have strong momentum with our RSV vaccine candidate, having received a positive VRBPAC committee vote, supporting potential approval to help combat RSV in older adults and PDUFA dates for our older adults and maternal indications in quick succession in the coming months. And just last month, New England Journal of Medicine published results from the 2 positive Phase 3 studies.

Emerging data from the middle of the second RSV season in the Northern Hemisphere in the Phase 3 older adult study support meaningful durable vaccine efficacy. We will share the data once completed. In the coming months, we plan to start the Phase 3 study of the RSV vaccine candidate in 18- to 60-year-olds at high-risk for RSV and in immunocompromised adults 18 and over and a Phase 1 study in 2 to 18 year old at high risk.

With the potential to expand broadly the reach of our vaccine candidate, both to those age 18 to 60 with high-risk condition as well as to pediatrics and adolescents.

Our RSV-flu coadministration study met its primary endpoint, demonstrating non-inferiority for all four flu strains and the RSV A and B strains. This suggest the RSV vaccine candidate, if approved, could be co-administered with flu vaccination and add an important component of seasonal protection against respiratory pathogens.

Finally, the FDA recently updated the EUA for our Omicron BA.4/5 bivalent COVID-19 vaccine to enable those at high risk of severe COVID-19 illness, including the elderly and immunocompromised to partner with the health care providers to be proactive in helping them to protect themselves against COVID-19. We anticipate another update from FDA in June that will provide guidance on COVID-19 vaccine strains and vaccination timing for the 2023 fall and winter season. Beyond vaccines, antivirals are an important component of our strategy in respiratory viruses. Here, we share data for the first time from our second gen oral COVID-19 antiviral candidate, a potent and selective SARS-CoV-2 Mpro inhibitor that is currently in Phase 1. We designed this candidate to achieve clinical exposure that would have similar antiviral activity to PAXLOVID, but without the need for ritonavir boosting and with the potential for reduced drug interactions.

Early results from Phase 1 dose escalation are encouraging with no dose-limiting safety tolerability findings. Dosing achieve concentration manyfold over in vitro EC90 and is, therefore, expected to have similar antiviral activity to PAXLOVID. On the right of preliminary results from our Phase 1 pharmacokinetic study of midazolam drug interaction, which is a well-known standard for indicating CYP3A4-mediated drug-drug interaction.

These data show there is a lack of such drug-drug interactions, suggesting there may be no related restrictions of co-dosing with drugs metabolized by CYP enzymes.

Based on these encouraging data, we are planning to advance to Phase 2 dose-ranging study in the first half of this year.

In addition to the assets I spoke about today, we continue to make progress on the pipeline with more than 25 milestones recently achieved or anticipated through the first half of '24. As examples, in inflammation and immunology, the FDA has approved our sNDA for CIBINQO, enabling a label expansion for adolescents with moderate-to-severe dermatitis. In internal medicine, ZAVZPRET, the migraine nasal spray has received FDA approval expanding our migraine portfolio. Recently, the FDA Advisory Committee voted in support of PAXLOVID's favorable benefit-risk profile with a soon PDUFA date in May.

In closing, we are very excited about the potentially transformative catalyst expressed across the entire pipeline as we work with continued urgency to bring breakthroughs to patients. Thank you.

Let me turn it over to Chris to start Q&A.

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

Thank you, Mikael. All right. Chelsea, please queue up us for Q&A. We have at least 30 minutes for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question will come from Umer Raffat with Evercore ISI.

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

I have 2 here, if I may. First, your expectations on the cisplatin eligibles in the EV-302 trial especially because it's so significant to the acquisition you're going down the track on? And then secondly, based on my...

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

Umer, can you repeat the question, I'm not sure, we understood it.

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

Sure. On the Seagen trial on PADCEV, EV-302, I know there's been a huge emphasis on cohort K, which is a cisplatin ineligible. My question is, this ongoing trial also has cisplatin-eligibles, which is 2/3 of the target population. What's your expectation there? Because it was -- I felt like it was not a coincidence, Seagen never showed any data disclosure from the eligibles Part A. And secondly, for the guidance for the full year, I noticed there's perhaps $1 billion-or-so worth of contribution from new launches. And I'm just trying to make sense of that in light of the fact that these are going to be launches sort of in the fall of this year? I realize it's important like RSV, elranatamab, but is it reasonable to expect $1 billion-or-so, so early into the launch from those?

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

Yes. Thank you very much. Angela, why don't you take the second question about the guidance, about $1 billion estimated sales in the last quarter.

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

Sure. So from a launch perspective, I think the 2 big ones to look out for this year are Prevnar 20 peds and RSV adult. And as you know, it goes through the typical ACIP process for recommendation and then launches can really only happen or commercialization after the publication of MMWR. So if you consider all of that, that puts us into fourth quarter, which is when Prevnar 20 peds as well as when RSV older adult will actually be commercialized and revenue being generated. And so yes, we are anticipating that there's going to be a big bolus of revenue because, first of all, if you think about Prevnar 20 peds, that is going to be a conversion from Prevnar 13 peds and Prevnar 13 today has a significant market share, right, in pediatric pneumococcal is 80% market share.

So we're going to be converting those accounts, the physicians, the inventory, all of that from 13 over to 20. And so if you look at, I guess, a good analogue for that would be our Prevnar 20 adult launch, which was the conversion of the Prevnar 13 adult launch. And there, it went really well. Today, we have, what, over 95% market share. And then, of course, the second one is the RSV adult. And there, it plugs into an already established commercial infrastructure that we've built around COVID, around the Prevnar franchise, the adult franchise. It comes at a great time during the fall and the winter when vaccinations for respiratory vaccines actually increases. So there's a lot of reasons to believe why that fourth quarter is going to be a really big quarter for both Prevnar peds as well as RSV adult.

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

Thank you, Angela. On the question about the Seagen asset, although we should be very careful because we can't comment on that. But maybe you can make William quick comments, generally speaking.

William Pao ***Pfizer Inc. - Chief Development Officer & Executive VP***

Yes, sure. I would say we're just very excited about the recent approval in the first-line cisplatin ineligible population, which Seagen just got, which is about 8,000 to 9,000 patients in the U.S. And we're excited to see additional data coming in the first-line cisplatin eligible EV-302 study, which, as you know, is Padcev plus pembro versus platinum gemcitabine. We can't comment any further at that Seagen study. And if that is positive that would increase the eligible population by another 10,000 to 12,000.

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

Doubling the population that excites us. But of course, we can't comment on Seagen's progress.

Operator

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

Keith Tapper ***BMO Capital Markets - Senior Equity Research Associate***

This is Keith on for Evan. Maybe just shifting to M&A execution. Thinking about your recent acquisitions with Nurtec and Oxbryta. You've done a great job describing the plans to add value, drive commercial and clinical synergies. We're seeing the outcomes on our end. Could you comment on how this is going from year-end? And then could you talk about specifics for operationalizing the same for Seagen integration, and how this would differ from recent examples, that would be great.

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

Again, Angela, back to you.

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

Sure. So we are incredibly proud of the work that we've done with -- on Nurtec since the acquisition. As you know, in July of 2022, we had already begun a co-promote with Biohaven to ensure that we were co-promoting the product early. And I think that has really paid off. If you really look at what has happened from a just leading indicators as well as actuals. Today, Nurtec is the leading product in the oral CGRP class with over 47.5% market share. It is also the leading product when it comes to new-to-brand prescription share at a high of 46%. It also has the highest number of prescribers at over 110,000 prescribers and 80% of new CGRP prescribers choose Nurtec.

So I think we've demonstrated in the time that we've had it, that we are able to drive performance and drive excellent education and awareness of the product. And we're seeing consistent great metrics as it pertains to Nurtec. And of course, the opportunity is huge, right? Because we have zavegepant launching later this year. We also know that as a whole, there are over 1 billion migraine sufferers and only 18% of them are using CGRPs today. So we have a great opportunity to expand the class of CGRPs, but specifically Nurtec.

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

Thank you, Angela. Next question, please.

Operator

Our next question will come from Mohit Bansal with Wells Fargo.

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

If I may ask 2 questions here. So on European negotiation, just because there was some news this week. Just how much can you comment on that? And the real question there is that, I know you when you provided guidance in the beginning of the year, you anticipated some of that. But so far as the negotiation see any risk to the guidance as the negotiations get finalized in that? And the other question I have is more about the -- your demand chart for PAXLOVID in vaccinations board. It seems like you are assuming both PAXLOVID and vaccination utilization going up into 2024 plus timeframe. Would it be both demand -- demands going up, or do you think it will be either or as vaccinations come down, probably the demand for PAXLOVID would go up. How should we think about that?

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

Maybe I can answer those questions. So on the Seagen negotiations, they are still ongoing. So we can't comment on that. Yes, we have included part of -- included our estimation of how these negotiations will end up in our guidance. And still, we are not closing. So I can't make any comments on that. It wouldn't be appropriate as the discussions are still ongoing. As regards to the demand for PAXLOVID or for vaccines. As we had said, we expect that the demand for vaccines will go down. We gave estimations that will go down to approximately 24% of people in the U.S. and relevant numbers, different country by country as underlying demand for boosters. And things -- I think our progress towards that goal, we will have to see as most of this will happen in the last after summer when it is the traditional period that flu vaccinations are also happening. Demand for PAXLOVID right now is following very, very accurately the infection rates. So when we monitor it on a weekly basis. And really, it is going when we have almost equal percentage of infections is equal percentage of the case for PAXLOVID. And so we expect that will continue going like that. Because we have less compliance with the vaccination recommendations across the world as people are tired with COVID, and we expect that fewer people, as I said, this year will get a vaccine compared to last year. And so this means that the immune protection of the operation will go down. As a result, we expect that we have more infections and that will drive more use of PAXLOVID. But of course, that's what our epidemiological models are telling us, we'll have to see what eventually will happen in real life.

Operator

Next, we have Robyn Karnauskas with Truist Securities.

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

Just 2 big picture ones. Just first on for your vaccine franchise, we think about the competitive landscape, a couple of things. What do you think is going to be the most important differentiation for you versus the competition that will drive the most uptake as people have different options. And have you developed any new LNP technology that might reduce the biggest pushback with the vaccines as people feel sick still when they get them for some of your products. And then lastly...

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

We couldn't hear, which product you spoke about?

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

Oh, I was just talking about the (inaudible) vaccine franchise for RSV and flu and COVID, thinking big picture, how you are differentiated? And what do you think is going to be key because you're all competing to make -- to determine who's going to be the winner. And the second question is, there's big proposal out of Europe for new legislation for drugs. And since you're launching all the new products in Europe. I just want to get your thoughts on whether or not you think that legislation may hold? Or what kind of impact that might have?

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

And maybe I can give you a very general answer, and then if Angela wants to chime in, please. On the COVID, we are the winners right now, all right? We have the big markets there. And we plan to maintain that. So I think we are there. When it comes to RSV, we are the only ones that we have both or we have positive data on both on adults and on maternal, and we have already approval for the adults and then we are expecting approval for the maternal so that the strength of our data with efficacy and safety profile that we think is differentiated, will provide us with what we hope also to be the winners in that one. And the flu on mRNA technology still the jury is out.

[In response to a question, the Pfizer spokesperson was referencing the positive vote received in February 2023 from the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) for the RSV bivalent vaccine adults 60 years of age and older, when the

spokesperson indicated that Pfizer had received approval. As noted in the earnings materials as of May 2, 2023, the above mentioned vaccine has not to date received FDA approval.] (added by company after the call)

We are very optimistic with the totality of the data that we are having from our flu vaccine, and we will wait to see, of course, how that will continue. And then, of course, the winners will be also those that they will be able to build a combination from all of that. So the fact that we have all 3 of them, or we have a good chance to have all 3 of them if the studies are successful and if the products are approved, of course, also provides a good differentiation. In addition to all of that, I think the trust for the Pfizer brand name, which has been very, very strong, I think, also plays a key differentiator.

Now as regards to the EU legislation that we have just seen in the recent days, we are noticing the positive things of EU trying to be more competitive in attracting reserves and creating a regulatory framework for more rapid approvals. Clearly, we are also concerned at the same time with provisions that would like to reduce exclusivity of data and other provisions. So we hope that there will be an open dialogue with the EU so that we can create a framework that really will enhance innovation. Angela, anything that you want to add to all of that?

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

Maybe just to add to your question specifically about the adult portfolio, I really do believe that this plays into our sweet spot. You know through the last several years, both from the Prevnar franchise and for vaccination, vaccinating adults through our work in COVID, we've learned that the clinical profile is one thing that you really need reliable supply, you need a commercial infrastructure. You need a great ability to educate, raise awareness and drive people to vaccination. And I think on all of those counts, Pfizer is a winner. And so we look forward to having a growing and a very robust respiratory portfolio that really leverages off of this incredible commercial machinery.

Operator

Next, we have Louise Chen with Cantor.

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

So I want to ask you about margin improvement. You talked about that in your opening remarks. I'm curious when we might start to see that? And does that include the Seagen acquisition in your comments. And second question I have for you is, what are some of the key steps that you've taken already to transition Comirnaty and PAXLOVID in the commercial market? And when will you know how the Seagen will shape up?

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

Thank you very much, Louise. Dave, you want to take the margin improvements and then Angela, the Comirnaty and PAXLOVID.

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

Yes. Thank you for your question. It is our expectation that as we integrate Seagen in either late '23 or '24. Early '24, we will begin to see margin improvement, and that will happen as we continue to improve our performance from a top line perspective. At the same time, we're going to be very efficient and really work to minimize our SI&A investments going forward. So I think you should start to see that post the integration and the closing of the Seagen transaction.

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

Thank you, David. And Angela, how are we preparing to transition commercial commitment?

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

So Louise, as you know, both of these products, both Comirnaty and PAXLOVID are products are very familiar to us. They fit very well in the existing portfolio of products that we have. So the ability for us to move from an EUA into a full launch or into, it is business as usual for us, right? So the typical things that we would always do, which is awareness building with physicians and with patients that has begun and is well underway. The things that you would do as a regard your discussions with payers to demonstrate value and to create your value argument for reimbursement and access, that has begun.

We have done a tremendous amount of work as it pertains to retailers and making sure that we have our distribution and our supply chain well-oiled and the ability to be able to supply and to vaccinate to administer these products at both -- at a physical side like a retailer or even in the case of PAXLOVID getting telehealth and sort of remote health capability set up. So all of these capabilities in many of them, in fact, have been underway throughout the entire time of the pandemic. So I think we're in a very, very good position to seamlessly transition into commercialization.

Operator

Our next question will come from Akash Tewari with Jefferies.

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

Can you talk about your next-gen CDK4 program? You'll have first-in-human data at ASCO. Why does your team believe just hitting CDK4 allows you to improve on IBRANCE's efficacy. And are there any plans to combine that drug with the Arvinas SERD, given the DDI that's been shown up with IBRANCE. And then on your next-gen PAXLOVID program, can you confirm that it can achieve multiple fold over the EC90 when adjusted for plasma protein binding? And is that -- for time-lines on that product, is the earliest possible commercial entry 2026? Or is there a path for expedited approval?

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

Thank you very much. Mikael, I think both questions can go to you.

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

Thank you. We are very excited about the next-gen CDK4 inhibitor. It's looking really good in 2 aspects. You can dose and get activity after patients paying CDK4/6 because it deals with higher inhibition of this mechanism. And you have a better tolerability with no -- with much less neutropenia, less risk for infections. We expect midyear to report out, and we have an aspirational target to start Phase 3 late this year, possibly early. At the same time, as you asked, we are now running combination studies CDK4 with KAT6. Another inhibitor that has a nice single agent activity and seem to combine well. We have a second combination with CDK2. And we think this would allow us next year to pick 1 or 2 combinations to advance up the lines with more potent treatment what's available today. Similarly, we're looking at combination with 471, as you alluded to, in order to benefit from the Arvinas collaboration. Next Gen PAXLOVID, yes, as I alluded to in my introductory remarks, we have many fold above EC90. And as you know, for PAXLOVID, what's unique with that drug that the manifold exposure above EC90 as this fall led to no detectable meaningful emergence of mutations, which is always what you fear in antiviral single-agent therapy, and this has been unique for PAXLOVID versus other agents that have been used so far, whether antibodies or antivirals, and this is exactly the profile for the next-gen, but without DDIs that allow us to improve and also to move into other supplementary segments. We're planning soon to start a Phase 2 and pending data possibly move quickly to Phase 3. And of course, we would like to see that agent introduced as soon as possible. I think we can hope to move swiftly pending event rates of COVID that will happen in the fall and further on that influence enrollment. So I think you said '26, and I would certainly hope we'll be ahead of that.

Operator

Next, we have Terence Flynn with Morgan Stanley.

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

Maybe 2 for me because I'm not sure you'll be able to answer one of them. I guess any -- would love your latest thoughts on your seasonal flu mRNA vaccine just in light of some of the Moderna data on the B-antigen side. Just how should we think about your profile there? And then there's been some focus on this ADCETRIS versus OPDIVO first-line Hodgkin's lymphoma data that's going to be presented at ASCO. Just wondering if you can offer your high-level perspective on how you see that frontline landscape evolving?

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

Mikael, why don't you take the flu question and then the oncology question will go to William.

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

We are very pleased what we see so far, the totality date of our flu mRNA. As you know, we have reported out very high antibody type A, similar or possibly lower to the B antigen versus standard flu vaccines. But in contrast to standard flu vaccines, we have very nice T cell

activity. And I think we are the only mRNA platform that has dosed CD4 and CD8 T cells of significance. We do think that could offer a unique profile for flu and the tolerability with our dose is very encouraging. So the trial is -- in the last leg for a readout. Hopefully, we'll be able later before to share an update. And we are very encouraged, and we are in parallel at risk investing in combination opportunities with recent COVID and RSV in various combination, as Albert earlier alluded to.

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

Thank you, Mikael. And William, on the oncology front, how do you feel about?

William Pao ***Pfizer Inc. - Chief Development Officer & Executive VP***

Yes, sure. So again, this is a molecule for Seagen ADCETRIS, which is the CD30 ADC. It's already been approved in Hodgkin's lymphoma post-transplant and then in previously untreated Hodgkin's lymphoma now with chemotherapy, doxorubicin, vinblastine and dacarbazine. And it's already -- we anticipate actually later this year that the label will be updated for overall survival. Now the data you're talking about is from the SWOG S1826 study with nivo AVD versus ADCETRIS AVD, and I believe they'll be presenting PFS data, but this is a curable disease. And we believe that the OS update with the ADCETRIS label will show that ADCETRIS is the favorite product at this time.

Operator

Our next question will come from Colin Bristow with UBS.

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

Maybe first on danuglipron on the upcoming data. Could you just walk us through what the key efficacy and safety thresholds you're looking to meet to move this forward. And sort of with regards to those thresholds, how you think about them in light of that, this is BID dosing? And how does that potentially impact the sort of commercial opportunity. And then just second, a quick one on your DMD Phase 3 CIFFREO trial. You previously guided to completion of recruitment in April of this year. Just could you give us a quick update here, and then how you view the opportunity and positioning in light of the fact that there's a potential competitor approval at the end of this month?

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

Mikael?

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

Yes. We are very excited about our 2 oral GLPs, the 1532 and danuglipron, 1532 called lotiglipron, and we are looking for a differentiated profile that will be a combination of rapid onset, high control of HbA1c, bringing it down and body weight loss at various doses to be very competitive and a more easily titrable drug that can optimize a preferred profile versus injectable when it comes to nausea and other well-known effects. So we look forward very much to data, maybe later this year or possibly early next year and cherry-pick the winner here. You also asked about DMD. Well, if there is an approval, it is based just on the surrogate markers. And in this area, I think it's very important to report out data when it comes to real patient benefit. And we expect possibly already late this year, alternatively next year to have data from the first randomized study that if positive could show favorable benefit for patients doing better according to the North Star scale. So we feel really positive about our own DMD program, and I think the entry will be competitive with the real data that patients need.

Operator

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

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

Just have 2. The first, Angela, on the I&I landscape, can you just talk about your expectations for category growth, just looking this year and next, just in light of the Humira and Stelara biosimilar to come. I'm asking just in the context for the etrasimod launch as well as Cibinqo. And then Albert, I know this question has been asked, but a different way though. I know you expect this year for COVID to be a down year, but when you think about your scorecard outside the U.S. with payers, as you've transitioned to commercial, what's been the initial feedback from a -- sort of from a price and volume perspective. Obviously, that's a key to your assumptions in 2024 and beyond.

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

Let me answer the COVID question, and then Angela will answer the I&I landscape. We expect to have commercialization in the U.S., I think, likely the U.S. government will stop purchasing outside the normal (inaudible) products. We do not expect that to be the case in most of the countries international. We think that most of the countries will continue having governmental practices. And most of them, we have already long-term contract. So I don't think there will be much fluctuation over there in the price given the longevity of the product. When the products -- the contracts expire, of course, prices also will be adjusted. Now let's move to the question about I&I and Angela, please.

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

Sure. Well, I think to answer that question, you really have to look at each product and the specific disease that they're in. So let's start with etrasimod, which is UC. There, we believe that we have an advantage from a clinical profile perspective. We believe that we have the best-in-class S1B inhibitor, but there are also other great benefits such as the fact that it can be used steroid free, that we have convenient dosing. We also offer an oral option in a world that is very prevalent with injectables. And even with all of the assets out there, we still have 50% of people that have not achieved remission. So I think that the unmet need in UC is clear.

And for us, in particular, given the profile of etrasimod, what we think is the greatest opportunity for us is in earlier lines of treatment, where there has not been as much advancement, right? There's a lot of anti-TNF. There's a lot of biosimilars, there's JAKs, there's other mechanisms. But in earlier lines of treatment, there really is not enough. And so that's where we think we have an opportunity to meet an underserved need today, and that's where we're going to be -- that's where we're going to be positioning etrasimod. Ritlecitinib is a different story. When you look at that particular indication for alopecia that is really an underdeveloped market.

There's 3 million people today, there are no great options for adults. And there are absolutely no options for adolescents and children. And so the profile that we have with ritlecitinib is a -- it's the best-in-class JAK. It's the best JAK. And I think that we're going to compete well in addition to the fact that we're going to be the only JAK compared to ritlecitinib that has an indication for adolescents. So I think in this regard, because it's a new disease or a highly undeserved disease, I think education and awareness, education at the level of the prescriber, the patient but also with the payers is going to be key to our ability to access this market.

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

Thank you. And of course, considering these all the time.

Operator

Our next question comes from Trung Huynh with Crédit Suisse.

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

Trung Huynh from Crédit Suisse. I have 2, if I can. So first one, a few days ago, you saw the FDA Advisory Committee vote on Lynparza's PROpel trial. In that, the committee voted against the approval in all comers. So for TALZENNA and TALAPRO-2, what's your expectations for your label here given the strength of your data. And could that affect your $1 billion peak sales number that you gave in December. And then for the RSV flu co-administration study, what flu vaccine did you test that with, is at the high dose or the low dose? And if it's the low dose, could you be approved for use with the high dose, which is more relevant today.

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

Thank you very much. William, would you like to take the TALAPRO part question?

William Pao ***Pfizer Inc. - Chief Development Officer & Executive VP***

Yes, sure. So thanks for the question. So as Mikael said, the study showed with enzalutamide plus TALAPRO -- TALZENNA versus enza, we showed a 37% reduction in the radiographic progression-free survival. Notably, in the same presentation, we also showed a hazard ratio in the HR deficient population of 0.48, a significant p-value. And then in the HRR non-deficient unknown population, HR of 0.7 with the p-value of 0.004. So we remain confident about our data in the all-comer population. Obviously, we can't compare to PROpel. Notably, in TALAPRO-2, we had prospective testing for HRR deficiencies, including BRCA1 and 2. I also want to point out that our control arm of XTANDI reaffirms XTANDI is best-in-class NHT for the indication with a radiographic PFS of 22 months. And in the treatment on

the TALA, our PFS was not reached. So we expect that the HR population, which is 25% will be compelling with the data. And we'll also continue to present additional data in the HR subpopulation at ASCO in 2023. And notably, we did get priority review, and we're currently in registration.

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

Thank you, William. And Mikael, about RSV and flu.

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

Yes. We are extremely excited about the RSV vaccine, and we'll provide data on co-administration of that vaccine with adjuvanted flu. We expect it to be available and generalized to all flu vaccines. And then when it comes to longer term, we also are already in combination study with our RSV and using our internal portfolio of COVID and mRNA flu. So we see this as a developing a very strong portfolio this year with core administration opportunities next year, possibly our own flu vaccine and then combination thereof. So stay tuned.

Operator

Next question will come from Andrew Baum with Citi.

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

Just coming back to the -- your oral GLP-1 portfolio. Lilly has called out an anticipated weight loss at 32 weeks from memory of around 14%, 15%. And they hesitate to give baseline. Given the competitive nature of the field, you're late to market and the cost of running CVOT trials in this setting. Where does the relative weight loss need to be from your Phase 2 for you to advance given the benchmark that Lilly seems to be setting?

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

That's a good question for Mikael. Mikael?

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

Yes. No, we agree completely with you that we should have an ambitious profile, and we have certainly seen in patients up to 15% weight loss depending on different dose regimens. So for obesity, that's a really good ambition to have up to 15%. And for diabetes patients, of course, it's about having a very strong HbA1c lowering, maybe 2% or even more, so we think it's feasible with orals, and we think that will open up a very large place, and we think that pending data readout that we may have a differentiated profile for our full agonists.

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

Thank you, Mikael. So we are waiting to see the data that I will speak.

Operator

Next, we have Chris Schott with JPMorgan.

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

Just 2 questions for me. Maybe first on the capital allocation comments. I guess the more balanced capital allocation post the SGEN de-levering. Just on that front, where do we need to see leverage go to before we can think about that balanced allocation? And in the meantime, what is the capacity and appetite for further deals? So can we think about kind of Biohaven size deals while you're de-levering from Seagen, or is it really smaller transactions? And then my second question was just one on RSV market development. Just how quickly do you see this market developing? I guess I'm just trying to get my hands around how much education this requires, and do you worry at all about vaccine fatigue, I guess, just given all the boosters that this population, I guess, received during the pandemic, does that slow at all the uptake versus kind of a normalized environment?

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

Good questions, Chris. Dave, capital allocation.

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

Yes. So thank you, Chris, for the question. Obviously, we have invested heavily back into our business here's all with the focus of growing our business from -- both from a top line perspective, but importantly, from a bottom line perspective. And I think now as we begin to cycle into I'll say, post the peak of this reinvestment in the business, we should begin to harvest, if you will, some of the cash flows coming out of the investments that we made and capitalize, if you will, on the returns that we expect out of these investments.

So having said that, we expect, because of that, we should get ourselves back more balanced into the 3 pillars, again, reinvesting back in our business, growing our dividend and doing value-enhancing share repurchases. From a leverage perspective, obviously, we want to maintain our high investment-grade rating in access to Tier 1 commercial paper, that would say that we would probably be in the low 3x levered ZIP code from that perspective. And then from an M&A perspective, we're still active in the M&A market. Obviously, first and foremost, on our objective now is to close and begin to integrate Seagen, so that's priority #1. Having said that, we will still look at the M&A marketplace, understand if there's assets that meet our criteria to supplement our business and we could theoretically execute against that given our capital structure. Having said that, in the near term, those will probably be smaller, little tuck-in type deals given our leverage ratio in the very near term.

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

Thank you, Dave. Angela, what about RSV and the educational efforts that the market would mean.

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

Well, with all launches, education is really important. And that's why we've already begun our unbranded disease education with physicians, laying the groundwork for the importance of vaccinating with or vaccinating for RSV. But of course, with all launches and with all new diseases and education is important to consumers, it's important to caregivers, to payers. And so on all of those fronts, those discussions have either begun or are beginning, and we plan to obviously implement a robust market development plan like we do for all of our vaccines. However, I think that the biggest advantage here is in the synergies of RSV together with our other adult vaccines, right? We have not 20 adults. We've had COVID. We -- all of these vaccines follow a very similar pattern in terms of the commercial needs that they have.

And I think that we have the opportunity to quickly and seamlessly bring RSV on into our portfolio and use the very same approaches and mechanisms and the same conversations that whether it's with a retailer, whether it's a payer, whether it's with our point of vaccinations to bring RSV on. So actually, I think that this is a very exciting time, and we feel very confident about the ability to seamlessly introduce RSV as another vaccine in our respiratory portfolio.

Operator

Our next question comes from David Risinger with SVB Securities.

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

First, could you discuss the PAXLOVID private market sales potential in China after March 31 that isn't included in your PAXLOVID guidance for the year? And also, could you comment on the late-stage competitive threats from Sanofi's 21-valent pneumococcal conjugate vaccine in adults and infants and Merck's 21-valent in adults.

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

Thank you. Angela, PAXLOVID equity in private market in China?

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

Sure. So after April, we are -- we continue to have PAXLOVID available, and -- but it will be accessed through an out-of-pocket payment mechanism. So if you're a private patient, you can get it, if you're a public patient, you can get it, you just need to be able to pay out of pocket for it. And we intend to continue to work with the public and with the Chinese government to ensure its access.

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

We can't give now guidance for a particular product in a particular country. So but -- Angela explained the dynamics. Mikael, very quickly on the competition of pneumococcal.

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

Yes, I mean, we are extremely excited about the PCV20 recent pediatric approval with a stellar labor, reflecting the strength of our data. We monitor carefully competitor activity, as you alluded to and are planning ourselves to enter next year, further expanded PCV vaccines, followed by additional expansion a few years later, including optimization of the conjugation procedures, including different carriers and possibly for the adult also adjuvants that we think could be useful. So this is a market where we have been the leaders. We have a unique platform. And we monitor and feel very confident that we are going to have a bright future, although you mentioned competitor which is a nature of markets that are becoming, of course, more saturated like the adult market. But there, we also hope to benefit from our broader portfolio of respiratory vaccines from COVID flu RSV that cannot be matched by others at the moment.

Operator

Our next question will come from Steve Scala with Cowen.

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

I have 2 follow-ups. First, on pneumococcal vaccine. So Pfizer just started a study of a vaccine, including a new ingredient. Is the new ingredient an adjuvant? Is it more valent, or is it something else? And then a follow-up on the OPDIVO versus ADCETRIS study. Can you say whether you are aware of the data at the time of announcing the Seagen acquisition? And why should we not view this as a significant risk.

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

Thank you. Mikael, what is the secret ingredient?

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

The secret sauce in this particular trial is a new adjuvant that we think could play a potential nice role in the PCV adult market as you go to increasing valency in this space. As I said before, in parallel, we are working on -- looking at different carriers, different chemistries and we'll shortly reveal for next year a start of a broader expanded PCV vaccine that will incorporate all these learnings. So stay tuned.

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

And William, on the -- again, on the OPDIVO study.

William Pao ***Pfizer Inc. - Chief Development Officer & Executive VP***

Yes, sure. So again, on the OPDIVO study, that SWOG study has been ongoing for a while. We were not aware of the data that's going to be presented at ASCO. I would reiterate again, it's early PFS data from what we can see and the most important measure of activity in Hodgkin's lymphoma would be overall survival. And again, we expect Seagen to get an updated label showing overall survival benefit in first-line Hodgkin's lymphoma.

Operator

Our next question will come from Kerry Holford with Berenberg.

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

Two questions on the RSV vaccine, please. Firstly, on the older adult vaccine. On Slide 22, you note emerging mid-second season data supporting durable efficacy. I wonder if you can elaborate a little more here on patent you have in hand today, and you want to act to get that second-season data in front of the FDA approval. And assuming you do see protection into that second season, how might that imply your pricing in the U.S.? And then secondly, on the maternal vaccine, you have had launch schedule in Q4 on Slide 6 and it implies that, that may not happen until the first quarter of next year. So could you just provide more clarity on when you could launch a maternal vaccine.

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

Yes. Mikael, what about the RSV vaccine?

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

Yes. We were very pleased to get our first data chunk from second season, mid-season data for older adults, and it clearly shows that robust data that we shared, for example, we shared high 80% reduction in lower respiratory tract infections with 3 symptoms. We see also on this and similar on other end point a very robust, very meaningful protection also in the second season. Now as you know, at the same time, we are preparing for the future combination vaccines, and we think, in general, that you will see an evolution in the adult market with simplified vaccination schedule, annual revaccination of COVID flu RSV. For those that, for some reason, miss a vaccination, we think, the second season data will be very good. On the maternal, we are preparing for an advisory committee, we think we have great data. We are the only one that have been able to conclude a maternal vaccination. We're the only one that we're able to construct an RSV vaccine without using an adjuvant, and we think it's a differentiated product. And I assume it will be soon after a potential approval, ACIP, and opportunity for Angela to launch to a very eagerly awaiting community of increasingly attentive pregnant women and maternal clinics to protect the newborn.

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

Thank you, Mikael. As we said -- as we have in our slide, we expect to be approved in this year in the last quarter. So it will launch. We expect the publication of the MMWR likely to happen at the beginning of the next year. So that plays also a key role in the uptake of the vaccine. But keep in mind, the launch of vaccine starts before the approval, right? We have done a lot of educational efforts and there are a lot of investments that we are doing in that field. So in that aspect, the launch already has started from our side at least.

Operator

Next question will come from Carter Gould with Barclays.

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

I guess first on the decision to establish a new operating segment and specifically launched this Pfizer Ignite offering. Can you talk about what drove that? And if there's sort of like an aspirational target and how meaningful of a driver that could be? And then secondly, sort of on the decision to divest BAVENCIO. Did that reflect sort of a signal you got from FTC or a proactive move in your mind? Or are there other factors we should think about and the fact that we haven't seen other divestments to that, should that reinforce our confidence that you think that the deal can go through without other issues?

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

Thank you very much. On the Bavencio question, the discussions to return the rights for royalties -- in exchange for royalties had started well before Seagen, so it has nothing to do with the acquisition of Seagen. It was something that was ongoing between us and Merck Serono for the benefit of the product and for (inaudible), just was completed after we announced the deal shortly after, but it had started way, way before. Aamir, would you like also to explain the Ignite business?

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

Yes, Carter, thanks for the question. I think you've seen us collaborate with the biotech ecosystem in lots of different ways, and Pfizer Ignite is another way in which we can effectively do that. Frankly, there's a lot of interest and demand on the part of particularly biotechs for working with us to access some of our distinctive research and clinical development capabilities, and we think Ignite gives us a platform to do that, to work with these companies, get closer to the science, which over time also then improves our ability to access that science and make determinations about what we would like to bring in-house. So we think this is an excellent way for us to continue to collaborate with the biotech ecosystem and add to our growing and compelling pipeline overtime.

Operator

Our next question will come from Chris Shibutani with Goldman Sachs.

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

On PAXLOVID, the U.S. commercial opportunity, can you update us on any framing of what you're thinking in terms of pricing and when we will know that. And in particular, with the commercial availability, are you anticipating much in the way of sort of payer engagements in terms of thinking about how that process will unfold utilization management wise. And then on the business development front, if we go to the $30 billion that you had outlined for a while now and think about what is remaining from that unadjusted target in terms of 2030 revenues let's say, approximately $5 billion is left. As we're thinking about how you guys are contemplating what areas to go into in terms of verticals or therapeutic areas or modalities, would it be fair to expect that at this stage, a consideration might be to minimize the extent that you would have to rebuild or sort of refurbish on the SI&A front, given your margin objectives longer term?

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

Angela, on PAXLOVID commercialization.

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

Sure. So Chris, yes, we're preparing for launch now. But as we've said, we've shared before, the date of launch and exactly how that's going to happen is still very much subject to our discussions with the U.S. government. So we're going to align with guidance from them in terms of how that's going to happen. Of course, in the meantime, we are preparing for the commercialization of PAXLOVID and payer discussions around the world is critical. So those have begun. Obviously, it's too early for me to share the price of PAXLOVID. But suffice to say that the price ranges that we have brought to our payers together with the value argument that we have been able to develop through robust real-world evidence from the number of hospitalizations, the number of deaths that we've been able to avert through the treatment with PAXLOVID is very much supportive of the pricing ranges that we're talking about. So I think very soon, we'll be able to share more.

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

And Aamir, about -- what is the profile of future BD activities?

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

Yes, Chris, as you mentioned, we have a goal of $25 billion in risk-adjusted revenue by 2030. And I should remind everyone that is a 2030 goal. We -- with the deals that we've done, have a remaining balance of less than $5 billion against that goal. And I think our strategy to pursue that is going to be consistent with what we have employed to date. First and foremost, it's going to be about compelling science that we can add value to. That's also going to contribute growth in the 25 to 30 period and take lots of things into consideration, including the impact on the P&L profile. So that will continue to be our focus, and we'll continue to be disciplined in the opportunities that we look for. And as Dave mentioned earlier, our priority right now is ensuring that we close out and successfully integrate the Seagen transaction as well as drive value from the other deals that we've done, and we'll continue to actively look for opportunities.

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

Thank you, and we are a bit out of time, so last question, please.

Operator

Our last question will come from Tim Anderson with Wolfe Research.

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

A couple of questions. The first is, how much of your future COVID vaccine revenue forecast are tied to the ability to have the combination product if something like mRNA flu ends up not being viable and knocked out of flu COVID combo, would that impact your anticipated uptake in 2025 and beyond? Or can you get to those longer-term guidance levels, regardless of whether you have any combos or not. And then last question, Albert, I'm guessing there's some frustration among management with what the stock has been doing a tough 2023, 2022 wasn't a great year. This is despite Pfizer helping lead the world out of the pandemic, which was a remarkable accomplishment, even today, beat consensus, stock is down a little bit. So as you talk to analysts and investors, what are you hearing are the biggest concerns that you think could explain this? And what do you think analysts, investors are missing or misunderstanding?

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

Thank you, Tim. Let me start with the first one. We do expect that if there are successful combinations with flu, that will drive utilization of the COVID vaccine much higher. As you know, we now in our estimation should we expect, for example, in the U.S. around 24%, 25% in the next few years of, COVID, the vaccine. The flu right now utilization around 50%. So there is a big gap. So that's why we believe that the combination between flu and COVID will arise also to the COVID and eventually potentially we can call the way up to the same utilization like flu, particularly given that there are no copays approved and recommended vaccines. Now as regards to the frustration, for the 2023, clearly, I believe that the stock price right now does not reflect the value that Pfizer has.

The fact that we are so proud because of our contribution in saving the world, I don't think, that we expect the stock price increases because of that. We did it because it was the right thing to do. And I think we are very, very proud of that. But we expect to see stock price increases as we are executing our plan, which is to create sustainable top line revenue growth that will allow us to leverage the bottom line, that will grow faster than the top line. And I think we articulated the plan about that and that plan was to invest in acquiring good scientific substrate that will allow us to launch products that will give us $25 billion revenues by year 2030, and we have done tremendous progress on that by having already according to our calculations of $20 billion.

We are also invested in R&D in the last -- in the past few years, and we have now an unprecedented launch of new products. And I think the Street is expecting to see how those launches will evolve. Clearly, I think there is over hand -- over the COVID revenues. There is uncertainty if the COVID revenues will materialize. We don't have any precedents to show that we know how to predict it well. So our predictions are based on epidemiological science. And based on trends that we are testing with market people. So I think that from my perspective, what I said, we are very committed to creating value for the shareholders. We know that everything we do, we do it with their money. It's not our money. And we want to be very good stewards of that. So it's not enough to save the world, I think also, we need to increase the stock price. We are highly committed to do that. We are explaining, better the strategy more importantly, executing on it.

So with that, I think it gave me also seem a good segue to close. In summary, we believe that, that was a solid quarter. We delivered on our commitments. We exceeded actual expectations from the Street. And we will continue doing so with the compass, but we will create serious value for patients. And that we are certainly will translate into value for shareholders. We are executing our plan, and we will remain very committed to doing that.

Thank you very much to all, and have a nice day.

Operator

Thank you, ladies and gentlemen. This does conclude today's teleconference, and we appreciate your participation. You may disconnect at any time, and have a wonderful day.