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Pfizer Inc.

Pfizer Inc. - Q3 2025 Earnings Call

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Event Participants

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Operator Operator

Good day, everyone, and welcome to Pfizer's Third Quarter 2025 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 Executive

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 2025 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. Before we get started, I want to remind you that we will be making forward-looking statements and discussing certain non-GAAP financial measures.

I encourage you to read the disclaimers in our slide presentation, the press release we issued this morning and the disclosures in our SEC filings, which are all available on the IR website on pfizer.com. Forward-looking statements on the call are subject to substantial risks and uncertainties, speak only as of the call's original date, and we undertake no obligation to update or revise any of the statements. With that, I will turn the call over to Albert.

Albert Bourla Executive

Thank you, Francesca. Good morning, everyone, and thank you for joining our call. The past few months have been pivotal for Pfizer. We are really excited about our future and confident that we

are in a strong position to continue delivering value for patients and our shareholders. Our third quarter performance shows how we continue to execute with discipline and focus even while taking on major strategic efforts.

I will discuss highlights, including our agreement with the U.S. government, which has provided greater clarity of our strategic investment in future innovation and growth. Additionally, with our proposed acquisition of Metsera and the progress we have made since closing our licensing agreement with 3SBio and key upcoming catalysts, the strength of our R&D pipeline continues to grow. Our landmark agreement with the U.S. government was an important milestone because it removed uncertainty on 2 critical policy fronts.

We successfully addressed the administration's call to lower prescription drug costs and align prices with those in other developed countries, and we will have a 3-year grace period from certain U.S. tariffs with our commitment to further invest in manufacturing in the U.S. Now I want to address our proposed acquisition of Metsera. We believe that Novo Nordisk offer is illusory and cannot constitute superior proposal under the terms of our merger agreement with Metsera because it violates antitrust law and there is a high risk it will never be consummated. We are encouraged by the U.S.

Federal Trade Commission's decision to grant early termination of the HSR waiting period, which is unprecedented during a government shutdown and clears the path to completing this transaction following the Metsera shareholder vote on November 13. With the pending legal action we have taken to enforce and preserve Pfizer's rights under the merger agreement, you understand that we will be limited in the details we can address further during today's call. What I can say is that our belief in the promise of the Pfizer and Metsera combination is strong and unwavering. We are confident it will create substantial value for shareholders and advance innovation to bring important medicines to patients in the high-growth therapeutic area of obesity. Plus, we believe Pfizer will have distinct advantages in developing and delivering new potential treatments because of our proven scientific and commercial strength.

Our R&D infrastructure has global reach and extensive experience running clinical trials in large population. Our commercial teams have well-established capabilities in bringing primary care therapies to patients. We have proven we can drive leading clinical commercial and strategic momentum with key cardiovascular brands such as Eliquis, Lipitor, Norvasc and the Vyndaqel family, and we plan to execute in a similar way with Metsera as we reinvigorate Pfizer's cardiometabolic presence. The licensing agreement with 3SBio is another way we have strategically enhanced our pipeline. Encouraging Phase II first-line metastatic colorectal cancer efficacy and safety data for SSGJ-707, the PD-1 x VEGF bispecific was shared last month at the European Society For Medical Oncology meeting.

Looking ahead, we are excited to present additional clinical data at the upcoming Society for Immunotherapy of Cancer Meeting. We are also encouraged by our discussions with regulators about our plans to unlock the potential of 707 with a robust clinical development program. As we look forward to executing with 707, Pfizer has distinct advantages. We have deep experience in the development of multi-specific antibody therapeutics and the ability to leverage unique combination regimens that make this promising cancer immunotherapy candidate a strong complement to our oncology portfolio. We've also made progress in advancing other key programs in our late-stage R&D pipeline.

This was reinforced by our presence at ESMO last month with over 45 abstracts, 5 late-breaking presentations and recognition in Presidential Symposium. Starting with the Presidential

Symposium, new Phase III data demonstrated that Padcev in combination with pembrolizumab reduced the risk of recurrence and death by at least half for patients with cisplatin ineligible muscle invasive cancer when given before and after surgery. This is the first and only regimen to improve survival when used before and after standard of care in this patient population. With this unprecedented data in hand, we see the potential to substantially increase the U.S. addressable population with approximately 18,000 patients under the current label in metastatic urothelial cancer.

And if there are further positive data and it's approved, up to approximately 22,500 additional patients across both cis-eligible and cis-ineligible muscle invasive bladder cancer. We also presented follow-up results from the PHAROS single-arm Phase II clinical trial supporting Braftovi and Mektovi as a standard of care for patients with metastatic non-small cell lung cancer harboring a BRAF V600A mutation -- V600E mutation. This updated analysis showed a substantial median overall survival benefit of 70 -- of 47.6 months in treatment-naive patients with metastatic non-small cell lung cancer with a BRAF V600E mutation. We are pleased with the continued strong year-over-year growth of Braftovi and Mektovi with a 30 percentage point increase in new patient starts since the October '23 launch. We believe the results from the PHAROS trial could establish a new benchmark with targeted combination therapies for its population of patients.

These results fortify the strength of our growing lung cancer portfolio that includes small molecules, ADCs and our 707 bispecific. We are confident in our potential to deliver treatments across the lung cancer spectrum, a large and growing market expected to reach approximately $70 billion by year 2030. We also presented final overall survival results from the Phase III EMBARK trial evaluating Xtandi in combination with leuprolide and as a monotherapy in non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence. As the first and only ARI-based regimen to demonstrate overall survival benefit in this population, these results highlight the potential benefit of Xtandi in this earlier line treatment setting. This strengthens our position for a product that is experiencing strong demand growth in hormone-sensitive prostate cancer and rapid uptake in the approximate 16,000 U.S.

patient population with non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence. I want to mention another update about our program in sickle cell disease. We are very pleased that last month, the FDA concluded that Pfizer may resume enrollment of osivelotor studies outside of Sub-Saharan Africa and in individuals who have not relocated from Sub-Saharan Africa. We are still engaging with regulatory authorities to determine possible next steps for Oxbryta. We will look forward to sharing more details in the months ahead about our key pipeline catalysts for 2026 and the coming years.

With disciplined execution and our continued focus on key products, both in the U.S. and key international markets, we continue to build on our leadership position within our commercial portfolio. Our Vyndaqel family of products achieved 7% year-over-year global operational growth in the quarter. Strong demand reinforced that this is the foundation of treatment for patients with a heart condition of ATTR cardiomyopathy, helping them live longer and avoid hospitalization. We are encouraged by our continued strong market leadership.

In international, we achieved 40% growth in the quarter in total patients on treatment. In the U.S., our continued double-digit demand growth reflects strong diagnostic efforts, broad access and favorable affordability dynamics. Nurtec continues to lead with the oral -- to lead the oral CGRP class in primary care penetration in the U.S. In international, we achieved growth with continued

strong uptake in key markets. Globally, we achieved 22% year-over-year operational growth in the quarter.

We are pleased that our new consumer campaigns continue to perform well, and our team has been effective in sharing new compelling clinical data with health care professionals. Padcev, another market leader in our portfolio, achieved 13% year-over-year global operational growth in the quarter. Padcev in combination with pembro continues to expand utilization and has been established as a standard of care first-line treatment for patients with locally advanced metastatic urothelial cancer. Our vaccine portfolio is a key area of focus in international markets. We are pleased with the strong performance of the Prevnar family, driven by share gains and launches in several key markets.

We achieved 17% year-over-year international operational growth in the quarter. Pfizer is the pediatric pneumococcal vaccination leader with public funding secured in about 140 national immunization programs around the world. After launching in the majority of key international markets, Prevnar Adult is the established leader among adult pneumococcal conjugate vaccines. In the U.S., where we did experience a year-over-year decline in the quarter, we are pleased with the overall performance of Prevnar 20. For adults, Prevnar held a market-leading position and grew with the expanded recommendation for adults over 50.

In the pediatric market, accounting for about 60% of Prevnar revenues in the U.S., we experienced a delayed timing of government bulk order, which we have seen from time to time. So it's a question of time. I want to provide an update about the next-generation PCV programs. While we previously guided to a Phase III start of our adult 25-valent program in 2025, we are planning to start the study next year if the FDA aligns with our approach. For our pediatric program, we expect fourth dose data from our ongoing Phase I/II study early next year.

And pending positive data and regulatory feedback, we have the potential to start both Phase III programs in 2026, streamlining our development approach and aligning with our strategy to provide a single vaccine across age groups. We are committed to maintaining leadership in the PCV space. And as a reminder, our 25-valent vaccine candidate has the potential for improved immunogenicity for serotype 3, which is one of the largest remaining contributors of pneumococcal disease. Serotype 3 alone is estimated to cause approximately 20% of invasive disease in the 65-plus population in the U.S. and EU.

Abrysvo also achieved significant international momentum with 75% year-over-year operational growth in the quarter due to expanded access in key markets. In the U.S., we are experiencing the headwind of a more difficult to activate population as we enter the third season of RSV. Still, we are continuing to strengthen our position with a 59% market share in the U.S. in shipped-dose volume in this quarter. From the significant strategic milestones we have achieved in recent months to our solid financial performance during this quarter, we are demonstrating how we are building for long-term value with near-term execution of our 2025 strategic priorities.

By committing to focus simplification and leveraging technology across our business, we are accelerating progress and improving productivity. In the quarter, we achieved another strong gross margin performance. Additionally, we were able to deliver adjusted diluted EPS that was ahead of expectations significantly, even with lower infection rates contributing to a revenue decline in our COVID-19 portfolio. Our business is performing well, and we are raising the range of our adjusted diluted EPS guidance for full year 2025, while also remaining committed to our dividend. And with that, I'll turn it over to Dave.

David Denton Executive

Thank you, Albert, and good morning, everyone. To begin this morning, I'd like to highlight that our solid financial performance directly reflects our continued disciplined execution of our key strategic priorities. We continue to prioritize enhanced patient outcomes as well as the achievement of our financial objectives. Furthermore, our recent agreement with the U.S. government demonstrates our ability to navigate in a complex external environment.

Our cost improvement measures have driven greater operational efficiency and streamlined decision-making, which is evident in the solid operating margins for this quarter. Year-to-date, margins expanded despite the unfavorable impact of the acquired in-process R&D from the 3SBio transaction. Going forward, we expect to improve our cash flow and increase flexibility across our 3 capital allocation pillars. Our focus remains on creating long-term shareholder value. We will continue to invest in our business for the long term, evidenced by our recent business development activity while prudently returning capital to our shareholders.

Now with that, let me start with our third quarter results, then I'll touch on our cost improvement initiatives as well as our capital allocation priorities. I'll finish with a few comments on our 2025 guidance, which continues to improve as we move throughout this year. For the third quarter of 2025, we recorded revenues of $16.7 billion, a decrease of 7% operationally versus the same period of last year. That's largely driven by a decline in our COVID products. The decline was primarily due to Paxlovid, which experienced reduced demand from lower levels of disease incidents as well as last year's onetime Paxlovid government stockpiling recorded in Q3 of '24 and to a lesser extent, Comirnaty.

With that said, our non-COVID products performance was solid, growing 4% operationally versus the same period of LY. On the bottom line, third quarter 2025 reported diluted earnings per share was $0.62 and adjusted diluted earnings per share was $0.87, ahead of our expectations due to our overall gross margin and cost management performance. I'll point out that this profit performance includes a headwind of approximately $0.20 of acquired in-process R&D from the 3SBio transaction. Our results demonstrate the effectiveness of our refined commercial strategy. We remain committed to prioritizing key products and markets, optimizing the global allocation of our commercial field resources and concentrating our market efforts on high priority areas.

We saw solid contribution across our product portfolios, primarily driven by Eliquis, the Vyndaqel family and Nurtec, but it was more than offset by declines in Paxlovid and Comirnaty. Through the first 9 months of '25, Pfizer's recently launched and acquired products delivered $7.3 billion in revenue while growing approximately 9% operationally versus last year. This lower growth rate in the third quarter as compared to Q2 was primarily driven by the timing of pediatric CDC shipments of Prevnar and a onetime favorable impact in Q2 for Seagen products transitioning to a wholesale distribution model in the U.S. We plan to continue to invest behind these 2 product groups to drive the future performance and help enable the company to largely offset our LOEs over the next several years. Adjusted gross margin for the third quarter was approximately 76%, primarily reflecting the product mix in the quarter and continued strong cost management within our manufacturing footprint.

As a reminder, over the past 2 years, our adjusted gross margins have generally remained in the mid- to upper 70s, excluding Comirnaty, which has a 50-50 profit split with our partner, BioNTech. We expect $1.5 billion in savings from Phase 1 of the manufacturing optimization program by the end of '27 to support our long-term operating margin expansion goal. Going

forward, cost management across our manufacturing network remains a top priority. Total adjusted operating expense were $7 billion for the third quarter of '25, an increase of 21% operationally versus LY, driven in large part by the acquired in-process R&D expense for 3SBio. Excluding the 3SBio deal, adjusted operating expenses contracted by approximately $150 million versus last year.

And looking at the components, adjusted SI&A expenses decreased 3% operationally, primarily driven by focused investments and ongoing productivity improvements that drove a decrease in marketing and promotional spend for various products. Adjusted R&D expense decreased 3% operationally as well, driven by a net decrease in spending due to pipeline focus and optimization, including the expansion of our digital capabilities. And finally, acquired in-process R&D expenses increased $1.4 billion, largely resulting from the 3SBio deal. As our adjusted SI&A and R&D expenses demonstrate, we continue to be disciplined with our operational expense management. Q3 reported diluted earnings per share was $0.62 and our adjusted diluted earnings per share was $0.87, which benefited from our efficient operating structure.

Additionally, EPS was aided by our effective tax rate, primarily driven by favorable changes in jurisdictional mix of earnings and tax benefits related to global income tax resolutions in multiple jurisdictions spanning multiple years, partially offset by the aforementioned 3SBio acquired in-process R&D charge. We continue to be disciplined with [indiscernible] expense management, progressing multiple cost improvement programs as we remained focused on driving operating margin expansion over the coming years. Phase 1 of the manufacturing optimization program contributed savings in the third quarter. In addition, we remain on track to deliver on our goal of at least $4.5 billion in cumulative net cost savings from our ongoing cost realignment program by the end of this year. As a reminder, in total for these programs, we expect approximately $7.7 billion in savings by the end of '27 to drive operational efficiencies, strengthening our business with the potential of contributing significantly to our bottom line over this period.

Of these savings, approximately $500 million identified in R&D will be reinvested in the pipeline, which we expect by the end of 2026. With that, now let me quickly touch upon our capital allocation, which is designed to enhance long-term shareholder value. Our strategy consists of maintaining and growing our dividend over time, reinvesting in our business at the appropriate level of financial returns and making value-enhancing share repurchases. In the first 9 months of this year, we returned $7.3 billion to shareholders via our quarterly dividend, invested $7.2 billion in internal R&D and invested approximately $1.6 billion in business development transactions, primarily reflecting the 3SBio licensing deal. As a reminder, our business development capacity after the 3SBio deal is approximately $13 billion.

In the third quarter, we announced the planned acquisition of Metsera for approximately $4.9 billion with additional contingent value rights tied to the successful pipeline progression. The transaction is expected to be funded through a mix of available cash as well as debt. We expect the deal to be dilutive through 2030 as we continue to invest to enable further promising late-stage pipeline assets. Specifically, we currently expect the Metsera transaction to be approximately $0.16 dilutive to 2026 adjusted EPS. Additionally, we expect another $0.05 of dilution in '26 from the 3SBio deal, which closed in the third quarter.

With that said, we believe the 2 deals set up a strong potential revenue growth trajectory in 2030 and beyond. And lastly, through the first 9 months of '25, operating cash flow was approximately $6.4 billion, which includes the $1.35 billion upfront payment for the 3SBio transaction. Our gross leverage at the end of the third quarter was approximately 2.7x. That said, upon the close of the Metsera transaction, our leverage is expected to be above the 2.7x target. We expect to

bring our leverage back down to the target levels over time to continue to support a balanced allocation of capital between reinvestments and direct return to shareholders.

Now let me turn to our full year 2025 guidance. As Albert noted in September, we reached a new voluntary agreement with the U.S. government that will help ensure U.S. patients pay lower prices for prescription medications while providing the clarity we need to focus on our business and our investments in future innovation. The agreement has no impact on our 2025 guidance, but we expect a dilutive impact to our 2026 financial outlook.

We continue to expect full year 2025 revenues to be in the range of $61 billion to $64 billion. Non-COVID products continue to perform very well operationally and ahead of our plan. However, we note there is softness in our COVID products due to lower vaccination rates and COVID infection rates. In addition, our guidance assumes a favorable impact to revenues from foreign exchange rates. Furthermore, we now expect adjusted R&D to be in the range of $10 billion to $11 billion and our effective tax rate to be approximately 11%.

Additionally, adjusted SI&A remains unchanged. Now given our strong performance to date and our fourth quarter outlook, including our more efficient cost structure, we are raising and narrowing our full year 2025 adjusted diluted earnings per share guidance by approximately $0.08 at the midpoint to $3 a share to $3.15 a share. I'd like to emphasize our adjusted diluted earnings per share guidance substantially derisked the current lower-than-anticipated COVID trends. In closing, we remain committed to enhancing the value of our product portfolio and advancing innovation to further strengthen our pipeline. With a stronger balance sheet, we plan to continue deploying capital effectively.

We aim to boost R&D productivity with digital tools, including AI, prioritize investments in key R&D programs and to deliver new growth through business development. Furthermore, our performance continues to exceed expectations and deliver strong results even as the incidence of COVID remains low. This consistent performance highlights our resilience and commitment to excellence. Regardless of the challenging external environment, our efforts to enhance cost efficiency and generate improvements in operating margins by driving productivity and optimizing processes. Lastly, with the recent agreement with the U.S.

government, we can now focus on executing our strategy and our strategic priorities across our business to deliver new medicines for patients and enhance long-term shareholder value. I'd like to just close by noting that it is our expectation that we'll provide guidance for 2026, most likely by the end of this year. So with that, I'll turn it back over to Albert, and we'll begin our question-and-answer session.

Albert Bourla Executive

Thank you, Dave. So operator, please assemble the queue.

Operator Operator

[Operator Instructions] Our first question comes from Vamil Divan with Guggenheim Securities.

Vamil Divan Analyst

I'm going to have to defer the Metsera questions to other analysts, but curious to hear what you say there. I'll just ask a couple more on the commercial side. So one, Vyndamax, obviously you're facing more competition there. Surprised to see the performance there was a little bit of

sequential decline. So maybe you can just comment on the pricing and sort of market share dynamics you're seeing in that space, obviously, with the new competitors.

And then similar question on Padcev. Obviously, great data that you shared at ESMO. The commercial uptake for the quarter at least was a little bit less than we thought. So maybe just how you expect the muscle invasive indication, assuming you get that here soon to impact uptake of that program and kind of drive upside to where the numbers are right now?

Albert Bourla Executive

Thank you, Vamil. Aamir?

Aamir Malik Executive

Sure. Vamil, thanks for the question. So let me start with your question on Vynda. And I'll just -- I want to level set a couple of things about Vynda, and then I'll talk about the performance in the quarter. So there's obviously new competition in the category, and it's important to note that Vynda is still the only ATTR-CM product that has statistically significant reductions in both mortality and CV-related hospitalizations together and as a stand-alone.

And it's also the only product where there is a once-daily capsule, placebo-like safety and near-complete TTR stabilization. And we've got 90% access for Vyndamax across the U.S. Now with regards to the quarter, there are a couple of different dynamics that are happening. First of all, we saw very strong demand growth, and that's reinforced by our continued market share leadership, both on a TRx basis, clearly, but also in terms of first-line share. Now that volume growth was offset by 2 gross to net headwinds.

One is the IRA manufacturer rebates, which we've talked about before. And the second is what we alluded to last quarter, which is payer contracting that took place in the third quarter. So Vyndamax is performing exactly where we thought it would and consistent with what we guided and performance continues to reflect strong diagnosis, broad access, improving affordability dynamics and that's going to continue to grow our volume. We are seeing competition. Attruby is taking some first-line share from treatment-naive patients and Amvuttra has driven minimal switching to date.

And as we kind of look forward on Vynda, we'll see some of these dynamics continue into Q4 as well, where we expect continued volume growth, but the 2 GTN drivers that I described will certainly impact our net sales, but Vynda is performing in the way that we expected. On your question with regards to Padcev, we're, again, very encouraged by how Padcev is doing. For us, we look at this through 2 lenses. First is the la/mUC population, where we currently have about 55% share among cisplatin-ineligible patients and 45% to 50% share among cisplatin-eligible patients. So there is headroom for us to continue to focus on that segment of the market.

I think your question with regards to how Padcev performed on consensus is related to the comment that Dave made, which is as part of integrating the Seagen products into the Pfizer portfolio in Q2, we moved from a drop ship model to a wholesaler model. So that resulted in a onetime growth in our Q2 sales. So you have to grow products off of that adjusted for 2 to 3 weeks of inventory. So as we cycle into Q4, we expect the whole Seagen portfolio, including Padcev to return to growth. And then finally, on MIBC, we're excited about the possibility as a result of both the 303 and also 304 trials that are ongoing, and that will open up a patient population of close to 22,000 patients to help with the next rise in Padcev growth.

Operator Operator

We'll go next to Dave Risinger with Leerink Partners.

David Risinger Analyst

Congrats on the performance in the quarter. So my question is on Metsera. Could you just comment on the legal process ahead? I know that Pfizer is arguing that Novo's acquisition of Metsera would be anticompetitive. And even if the FTC doesn't allow it, it could be anticompetitive.

So could you just talk us through the clock and the process for courts to hear Pfizer's arguments?

Albert Bourla Executive

Thank you, Dave. As I said in my opening comments, it is very difficult for us to start commenting when we have all these legal issues pending, right, as we speak. But I will repeat what I did say, which is kind of an answer to your question, not on the timing, but we don't see how Novo's deal can be superior. It is an illegal attempt by a foreign company to do an end run around antitrust laws, taking advantage of the government shutdown, what they want to achieve, not to get the products, to destroy them. What they want is to catch and kill an emerging competitor, which is a significant antitrust concern given Novo's dominant market position.

So all I can say is that we are continuing to pursue all legal resources. Thank you.

Operator Operator

We'll go next to Asad Haider with Goldman Sachs.

Asad Haider Analyst

I guess just for Albert and Dave, just a quick high-level question on BD. What's the plan if Metsera doesn't work out for some reason? And then second, on 2026, any early framing on guidance pushes and pulls, specifically on how we should think about OpEx with and without Metsera? And then any additional color on how to think about the dilution you mentioned from your recent MFN deal with the administration?

Albert Bourla Executive

I will send the question to Dave because there are a lot of financial also elements. And then if Andrew wants to add something on the BD.

David Denton Executive

Yes. So maybe we'll start with business development. Obviously, the company has still significant resources to understand and how to deploy successfully transactions to bring science in-house, and we will continue to work aggressively to do so across all of our 4 therapeutic areas, and we continue to work across the globe to identify potential candidates for acquisition to help bring new and innovative medicines to patients. So that's still a very ongoing focused activity for the company. I think it's probably a little early to talk exactly about 2026.

You heard me give a little color in the sense that clearly, we're making investments today and those investments carry over into '26 and beyond with either Metsera or 3SBio to bring these innovative medicines to market. Those will have a slightly dilutive effect to our operating

performance next year. We will then wrap all that together with the puts and takes of '26 when we give guidance by the end of this year.

Albert Bourla Executive

Anything to add on BD, Andrew?

Andrew Baum Executive

Yes. I mean I'd echo what Dave said. We are very active in all geographies, especially in China. You saw the 3SBio, which has a foundational asset to become the backbone across multiple indications. And the same is true in China and beyond across all the main therapeutic areas.

We've increased the size of our team in China, in particular, and we have very active efforts. And when we have something to inform you, you'll certainly be the first to know.

Operator Operator

We'll go next to Geoff Meacham with Citibank.

Geoffrey Meacham Analyst

I guess one for Albert or Dave. When you look at the manufacturing investments you're making as part of the MFN agreement relative to the operational cost efficiencies, how would you rank those as priorities? I guess, both seem to have 3-year time frames. I'm just trying to get a sense of the incremental dollar and the strategy there.

Albert Bourla Executive

Dave?

David Denton Executive

Yes. Clearly, there are important elements of our strategy. We're going to clearly invest in the U.S. from a production perspective. We're working now to work through our plans with the new agreement with the U.S.

government on how to effectively deploy our capacity here in the U.S. and further build it out. So more to come. We will also provide some color to that when we give guidance for 2026. But we will be able to improve our operating -- manufacturing operating infrastructure and at the same time, invest in manufacturing here in the U.S.

And those 2 are not necessarily completely in conflict with one another. We'll be able to do both.

Operator Operator

We'll go next to Courtney Breen with Bernstein.

Courtney Breen Analyst

I really wanted to understand and perhaps another question on Metsera, but from a different angle. I wanted to understand, in your mind, what factors supported Pfizer in garnering that unprecedented early termination of the waiting period from the U.S. Federal Trade Commission. That would be really helpful.

Albert Bourla Executive

I'm not sure I understood the question.

Francesca DeMartino Executive

The FTC clearance.

Albert Bourla Executive

Why the FTC clearance?

Francesca DeMartino Executive

If there are any factors that drove the early...

Albert Bourla Executive

If there are any -- no, I think the FTC made their own decision. Of course, they were aware of this question. So I don't want to speak for them, but they decided that it is appropriate in the middle of a foreign attempt to supervening to just release our deal, which is now clear. So that's all.

David Denton Executive

I think it does further demonstrate the strength of our deal and the pathway to clearance and the pathway for us to be able to further develop these products and take them to the marketplace in a very rapid fashion. This is helpful to patients long term, is helpful to prices long term under our management and our direction with these assets.

Albert Bourla Executive

Yes, and should not be surprised, right, because we all understand that's the epitome of antitrust conflict. The entire pipeline of Metsera, it is the entire pipeline of Novo plus they have a dominant position with the current products that they have. Of course, FTC would worry about that. I don't want to speak for themselves, but it is something that it is -- everybody understands.

Operator Operator

We'll go next to Terence Flynn with Morgan Stanley.

Terence Flynn Analyst

Maybe 2 for me. You've previously talked about Elrexfio being a key driver for you over the long term. We noticed that MagnetisMM-5 trial was pushed out data into 2026. We know J&J had a similar trial in a similar patient population that just read out. So maybe you could just remind us of any potential differences here in terms of your trial versus their trial and why there might be a difference in timing given they started around the same time?

And the second question is just a clarification on Paxlovid dynamics for the quarter. It looks like by our math, price per script went up over last quarter. So just wondering if there's any onetime items that we need to think about here as we think about the trends in the fourth quarter.

Albert Bourla Executive

All right. Chris?

Chris Boshoff Executive

Yes, thanks for the question. So MagnetisMM-5, as you know, double class exposed. Possibly later this year, beginning next year, it's an event-driven study. So timing could shift due to events not happening, which we cannot speculate. But as you can imagine, that's often positive if events are not happening in the study.

So we'll just continue to follow the events and hopefully report early next year.

David Denton Executive

Yes. And on the Paxlovid question, I don't think there's any material change in price. We have -- maybe there's different channels mix and things of that nature, but nothing significant from that standpoint.

Albert Bourla Executive

Thank you for clarifying, Dave.

Operator Operator

We'll go next to Akash Tewari with Jefferies.

Akash Tewari Analyst

I had a question on your upcoming Phase III EZH2 readout in CRPC. I'm surprised the study isn't more prominently flagged given the potential to extend the Xtandi franchise. What drives your confidence that you're getting adequate target exposure after examining some of your food effect studies? And also, what's your expectations around overall survival? Could we see a 20% to 30% benefit here?

Albert Bourla Executive

Chris, that's for you.

Chris Boshoff Executive

Thank you very much for the question. This is another first-in-class internally discovered program, EZH2 program. We've previously shared randomized data, which showed significant PFS benefit in all comers in late-line metastatic castration-resistant prostate cancer. And we now have three Phase III studies ongoing. The first one will read out, to your point, is post abiraterone metastatic hormone-resistant prostate cancer, and that we expect in the coming months.

We recently also presented data at ASCO, randomized data on the food effect to your question, which was 875 milligrams twice a day with food and show that the data are comparable with the dose we now use in Phase III with reduced GI AE. So we are confident in the dose that was selected.

Operator Operator

We'll go next to Kerry Holford with Berenberg.

Kerry Holford Analyst

Just on the guidance for this year, you've clearly reiterated the total revenue range of $61 to $64, but when you first set that guidance, you spoke of total COVID-19 sales of around $9 billion for the year, seeing that you booked only around just over $4 billion year-to-date, just interested

in your comments on whether that $9 billion is still achievable for the full year? And if not, what other assets would you call out as likely to fill that gap and give you confidence to reiterate the total sales guidance?

Albert Bourla Executive

Thank you. Dave, please?

David Denton Executive

Yes. On the -- you're absolutely right, Kerry, as you pointed out, I would say that to the low end of our guidance range from a revenue perspective would assume that the COVID franchise continues a very modest uptake for the balance of this year, particularly in the U.S. However, as you know, the COVID franchise is subject to peaks and valleys. If there happens to be a wave of COVID in the next several months, you can see utilization spike up. So that's why the range is so large.

I'll just point out that what we have done with an earnings per share guidance range is we've derisked the COVID franchise with the guidance that we provided, given that if the trends continue, we'll be closer to the low end of that range, and we will still be able to deliver on our earnings commitment.

Albert Bourla Executive

Thank you, very clear, Dave.

Operator Operator

We'll go next to Mohit Bansal with Wells Fargo.

Mohit Bansal Analyst

Just wanted to understand the thought process around the pricing of the GLP-1 and this class of medicines given that -- I mean, even today, there's a news article out there suggesting the price could be $150 or so. So it seems like the price is only going in one direction. In that case, I mean, how do you justify the price that you're paying to Metsera and, in general, the obesity landscape over time, how do you think about that with this pricing decline for the class?

Albert Bourla Executive

Yes. Thank you. This is also competition brings prices down. And of course, they try not to restrict competition. But anyway, the -- yes, we -- in our calculations, we have taken into consideration that the prices of GLP-1s probably will start going down.

So I don't know what will be announced now. But in our calculations, we took already that into consideration. Thank you, Mohit.

Operator Operator

We'll go next to Alex Hammond with Wolfe Research.

Alexandria Hammond Analyst

Can you elaborate more on the reason for the delay to the initiation of the pivotal trial for the adult 25-valent pneumococcal program? You had mentioned the caveat of if the FDA aligns with

your approach. So if the tenor of the dialogue change with the FDA, is there a chance that surrogate endpoints may no longer be approvable?

Albert Bourla Executive

Thank you very much. Chris?

Chris Boshoff Executive

Yes. Thank you for the question. Across all our vaccine programs, we're obviously working very closely with the FDA and other regulators on the designs of the study and also the endpoint. PCV25, pending positive data and FDA feedback, we -- as mentioned, we intend to start that study as well as the pediatric 25-valent program next year. So it means we will align the pediatric and the adult study.

We expect the fourth dose data from the pediatric study early next year. So that helps us to coordinate the 2 studies. So it will just make it easier. The 25 vaccine candidate covers 25 serotypes, particularly I need to point out serotype 3, which we did before because the vaccine is designed with significantly enhanced immunogenicity against serotype 3, which currently constitutes up to 20% of infections in the U.S. and the EU.

And to continue our leadership, we also continue to study our fifth generation with 30-plus serotypes, which we'll update you on more in 2026.

Albert Bourla Executive

Thank you, Chris.

Operator Operator

We'll go next to Chris Schott with JPMorgan.

Christopher Schott Analyst

Just maybe 2 MFN questions. First one is kind of bigger picture. As you think about MFN on new launches over time, what do you think about this suggesting for international revenues? Is this, I guess, I could read this as a net positive that you can get higher price? I can read as net negative because reimbursement hurdle is going to be tougher at these higher prices, it could be neutral.

Just how you kind of envisioned what plays out with international as you signed that deal? And then the second one is just trying to get a little bit more color on the MFN impact for 2026. I think you mentioned some dilution there, but just any more quantitative metrics you could provide of just like how much of a headwind is that for next year?

Albert Bourla Executive

Yes. I'm sorry if I ask Dave to tell you, which he will tell you, we will provide guidance at the end of the year, and that will incorporate everything, including that and the other things that he was talking. So I don't think you will get more words out of our mouth no matter how much you talk to us. But on the new launches in international, of course, we are waiting to see how things may play. The price differential is not sustainable.

We are speaking about the smaller basket of countries in international that are affected by that. And with these countries, we are hoping that they will understand that they need to change the way that they price their products going forward. Of course, a little bit help from the U.S.

government and USTR through trade negotiations also can make that happen. And my assessment is that Howard Lutnick and the U.S.

trade representatives are highly, highly committed to make this go away. So we will see how that plays. But in theoretical, if the prices over there are -- they are not -- we are not agreeing a decent way of pricing our products, clearly, we will not get reimbursement there, and we will price them to the price that will not affect the U.S. price. Thank you.

Operator Operator

We'll go next to Umer Raffat with Evercore ISI.

Umer Raffat Analyst

First, on Metsera, I realize this is perhaps in the hands of your M&A lawyers and antitrust lawyers. But from an R&D perspective, can we make sure you'll be evaluating all the new data that's imminent, for example, the monthly transition and how the GI tolerability holds as well as even more importantly, the amylin plus GLP early combo data? And then separately, I was very intrigued by a Phase IIb trial you guys initiated on an oral drug in atopic derm. Could you confirm if it's a STAT6 inhibitor? And were you able to gauge the magnitude of STAT6 inhibition Phase I?

Albert Bourla Executive

Look, on the Metsera, it's easy if they provide us data or if they publicize data, of course, we will -- we are eager to see them. And we believe it will be positive. On the second question, I will ask Chris to comment.

Chris Boshoff Executive

Thank you, Umer, to ask a question regarding our I&I portfolio. I just want to check, are you referring to [PF9820]?

Albert Bourla Executive

I don't think he can come back in...

Chris Boshoff Executive

It is, okay. So you are correct. That is a STAT inhibitor. I want to point out that we currently have a very differentiated I&I portfolio with at least 5 molecules in-house discovered and developed, most of these at a significantly accelerated speed, including obviously p40/TL1a, which we co-developed or which is being co-developed with Roche, which covers IL-12 and IL-23 by p40. Our 2 tri-specifics covering IL-4, IL-13, TSLP or IL-33, both of those now entering Phase II for atopic dermatitis and for other Th2-related diseases.

LITFULO with the ongoing and Phase III trial in nonsegmental vitiligo, which is a JAK3/TEC inhibitor, also differentiated in-house. And then the STAT6 early, just entering Phase II could be potentially first-in-class oral. We're currently further optimizing dose and formulation and hope to update you on that program in 2026.

Albert Bourla Executive

Thank you very much.

Operator Operator

We'll go next to Steve Scala with TD Cowen.

Steve Scala Analyst

Two questions. What does the drug pricing deal with Trump allow Pfizer to do that other companies will not be able to do other than, of course, AstraZeneca? And secondly, on Metsera, so the data looks more similar than different than competitors and Metsera disclosures haven't been completely transparent, raising serious questions. Many other big cap pharmas have passed over Metsera when pursuing other products, validating the me-too point. Nothing in all this justifies a bidding war or even a protracted legal battle.

Is Pfizer's determination to persist underpinned by substantial confidentiality data -- confidential data or simply the desire to be a player in obesity? Or does Pfizer agree with the points that I just said and could it just walk away?

Albert Bourla Executive

Thank you, Steve. On the first one on the drug prices and what we have that other companies may not have, I can't answer because I don't know what the other companies are having. As you know, the discussions are between the administration and individual companies, which also ensure that there is no antitrust issues. And also, of course, if they are confidential because that's also what the administration and the agreements portray that we should keep confidentiality of those assets. So I know what we are getting.

Some of that has been public and some of that is part of the overall very lengthy deal, but I don't know what others I will take. On the Metsera, look, we have seen the data. We did extensive due diligence, and we priced -- the asset into a price that we thought offers tremendous value to the shareholders of Metsera and to shareholders of Pfizer because those assets that we like in our hands, of course, will provide significant competitive edge. What you see now, it is, I repeat, an effort to catch and kill this emerging competitor, which is Pfizer, and to do that by evading the antitrust scrutiny and virtually get control, de facto control of the company as they will become the major shareholder and the major creditor without any regulatory scrutiny. So that's all I have to say.

And I'm -- we will see how things go.

Operator Operator

Our next question comes from Evan Seigerman with BMO.

Evan Seigerman Analyst

Assuming Metsera closes, what near-term factors must you consider to continue growing the dividend and then delevering, Dave, as you had said, when do you think you may be able to also start to repurchase shares? Or is that less of a priority with all this BD?

Albert Bourla Executive

Dave?

David Denton Executive

Evan, very good question. Obviously, you've seen us over the last 1.5 years or 2 years really lean into productivity across our platform. That productivity has allowed us to delever from roughly 4x to 2.7x. That's given us increased flexibility to do both business development as well as

maintain and grow our dividend over time. That cycle of improvement in productivity is something that we've now embedded in the company.

We will continue to do that. We will continue to do that across the enterprise. We will continue to prioritize ourselves from an R&D perspective. Clearly, we have several assets that we think are key to the growth of this company by the end of the decade. We are going to invest behind those assets from a pipeline perspective, and we're going to invest behind the categories of products that we've either acquired and/or recently launched because those will ultimately allow us to offset the LOEs over the next several years.

So we'll be able to do all of that. Share repurchases is an important lever for us. In the near term, it's not a tool that we're going to use. We have to get the balance sheet back to where we need to be. And we -- again, we have business priorities that come in the forefront of that at this point.

Great question. Thank you.

Albert Bourla Executive

Okay. So now I think let's get the last question.

Operator Operator

Our last question comes from Rajesh Kumar with HSBC.

Rajesh Kumar Analyst

Two questions, if I may. I appreciate you cannot say a lot about Metsera at this junction. Just from a modeling perspective, if we are thinking of additional balance sheet capacity for dealmaking, how much capacity would you assume -- assuming that you are keeping some capacity away from Metsera at the moment in 2026 on your own internal budgeting, that would be really helpful. And just on the 3SBio, I appreciate the deal has just closed and some of the trials have just started. When can we expect to see data news flow come out of that deal?

Is it more a 2027 event? Or do we have any interim readouts or updates in '26?

Albert Bourla Executive

Thank you. I think Dave can answer the Metsera modeling?

David Denton Executive

Yes. So as you think about BD capacity, as I said in my prepared remarks, we have approximately $13 billion of capacity as we enter here into the third quarter, so with that...

Albert Bourla Executive

Chris, let's understand the 3SBio.

Chris Boshoff Executive

Yes, the data flow. So just a reminder, at ASCO 2025, we shared Phase II monotherapy or -- [indiscernible] Phase II monotherapy data in first-line non-small cell lung cancer showing the overall response -- objective response of 65%. At ESMO, Phase II combo data plus chemotherapy XELOX or modified FOLFOX6 was shown for first-line metastatic castration -- sorry, metastatic colorectal cancer, and that was showing a response rate of close to 60%. At SITC, we'll provide additional data, combination data in lung cancer and you've just seen we

posted two Phase III programs starting now this year in first-line non-small cell lung cancer and in first-line colorectal cancer. And in the coming weeks, we'll also provide the full development plan to you at event, and that will be -- show the broad -- the breadth and the depth of our clinical development program for 707.

Albert Bourla Executive

Thank you, Chris. So thank you very much all for your attention. We have been successful in achieving a series of significant strategic milestones. We delivered a solid performance during the quarter, and we are confident in our business, and that's why we are raising the rates of our