

Amgen Inc. NasdaqGS:AMGN

FQ3 2024 Earnings Call Transcripts

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S&P Global Market Intelligence Estimates

	-FQ3 2024-			-FQ4 2024-	-FY 2024-	-FY 2025-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	5.11	5.58	▲9.20	5.43	19.51	20.61
Revenue (mm)	8498.64	8503.00	▲0.05	8869.03	33200.27	34212.00

Currency: USD

Consensus as of Oct-25-2024 3:14 AM GMT

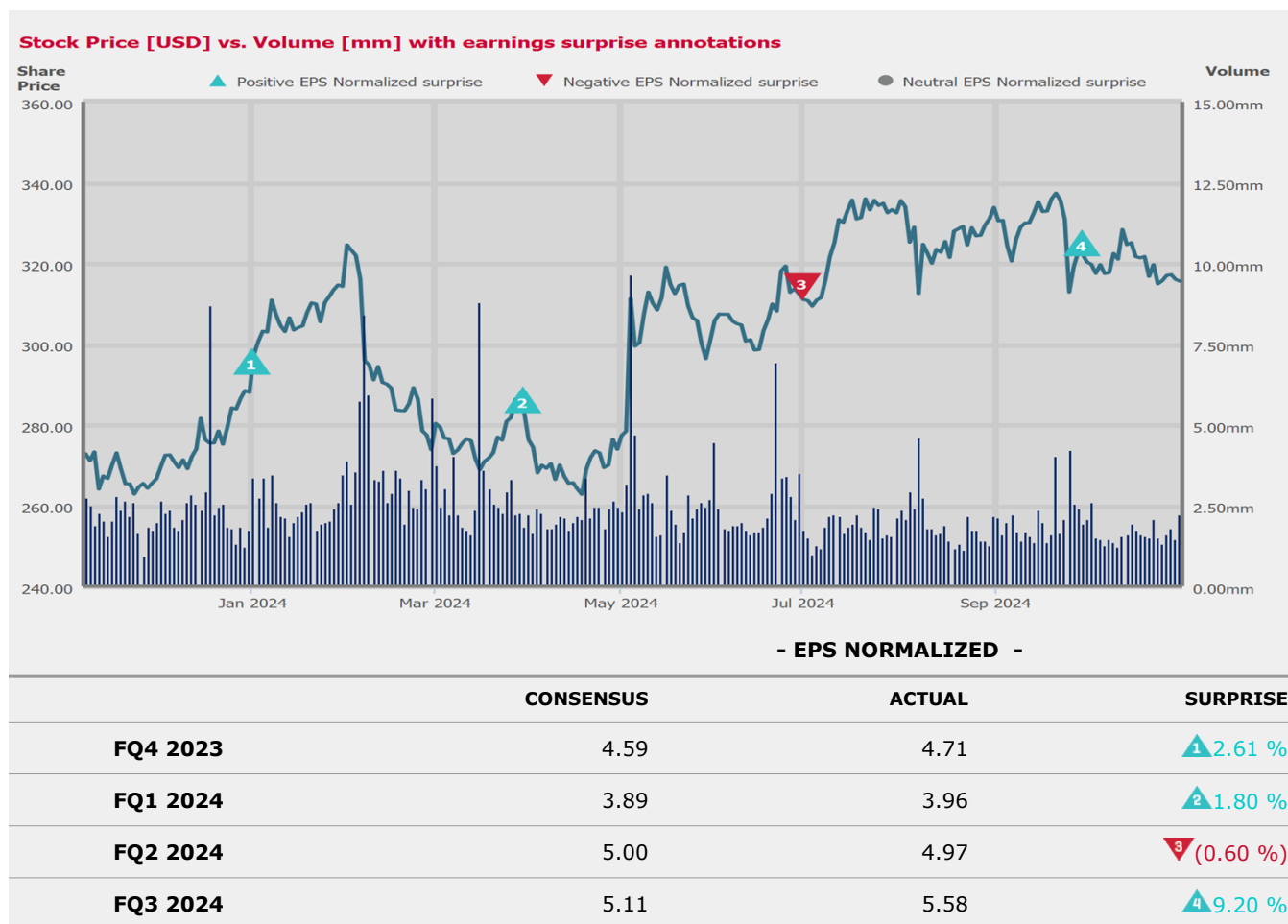


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Call Participants

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Presentation

Operator

My name is Julianne, and I will be your conference facilitator today for Amgen's Third Quarter 2024 Financial Results Conference Call. [Operator Instructions] I would now like to introduce Justin Claeys, Vice President of Investor Relations. Mr. Claeys, you may now begin.

Justin G. Claeys

Vice President of Investor Relations

Thank you, Julianne. Good afternoon, everyone, and welcome to our third quarter 2024 earnings call. Bob Bradway will lead the call and be followed by a broader review of our performance by Murdo Gordon, Vikram Karnani, Jay Bradner and Peter Griffith.

Through the course of our discussion today, we will use non-GAAP financial measures to describe our performance and have provided appropriate reconciliations within the materials that accompany this call. We will also make some forward-looking statements, which are qualified by our safe harbor statement, and please note that actual results can vary materially.

Over to you, Bob.

Robert A. Bradway

Chairman, CEO & President

Thank you for joining us today. Our performance this quarter reflects the strength of our business across our core therapeutic areas and geographies. Our in-market medicines performed well in the quarter with third quarter revenues up 23% to \$8.5 billion and 10 of our products delivering double-digit or better sales growth. We're also rapidly advancing our pipeline with a significant number of potentially first-in-class or best-in-class medicines, positioning us for long-term growth.

Let me address MariTide directly. Our ongoing Phase II study is progressing well, and we look forward to sharing results later this year. We're well advanced in preparing to launch a broad Phase III program for MariTide, including obesity, obesity-related conditions and type 2 diabetes. You may have noted that we recently initiated a Phase II study in patients with type 2 diabetes. As we shared after the interim analysis, we're confident that MariTide's differentiated profile will address important unmet medical needs across a number of diseases, including type 2 diabetes.

Beyond obesity, we have momentum across each of our therapeutic areas, and I'll start with oncology. In the third quarter, we saw strong in-market performance with 17% sales growth across the innovative oncology portfolio and several products experienced double-digit growth, including BLINCYTO, which, of course, is our first bispecific T cell engager or BiTE, which is now established as the standard of care in B-cell acute lymphoblastic leukemia. The launch of our BiTE IMDELLTRA is also progressing well with strong clinical conviction and 3 Phase III studies underway in small cell lung cancer. And further demonstrating the strength and promise of this platform in solid tumors, we're pleased to announce today that we will advance xaluritamig into Phase III clinical development in advanced prostate cancer in the fourth quarter.

Let me remind you to also keep an eye out for Phase III bemarituzumab data in gastric cancer, which we should have in the next few months. Our rare disease portfolio delivered \$1.2 billion of sales in the quarter, growing 21% year-over-year, driven by TEPEZZA, KRSTEXXA, UPLIZNA and TAVNEOS. These medicines are highly innovative, are still in the early stages of their life cycles and have significant upside potential, including expansion into new indications and geographies. For example, TEPEZZA was recently approved in Japan. Also in rare disease, UPLIZNA demonstrated compelling data in generalized myasthenia gravis and was granted breakthrough therapy designation in IgG4-related diseases. We're excited about the promise of inebilizumab in these settings and potentially in other B cell-mediated autoimmune diseases.

In inflammation, TEZSPIRE continues its strong trajectory with 67% growth year-over-year in the quarter. We're further encouraged by the potential of TEZSPIRE in COPD and additional indications that we're also actively exploring. And finally, in General Medicine, Repatha and EVENITY are each delivering strong volume growth again this quarter. These products are pivotal as we continue to serve more patients and meet the growing demand for therapies that address some of the most serious health challenges worldwide like heart disease and osteoporosis. Looking ahead, we remain confident that Amgen is well positioned to deliver long-term growth and innovation across each of our therapeutic areas. Our balanced portfolio, combined with the strength of our pipeline, we think will continue to drive our business forward.

As always, I'd like to thank my colleagues across Amgen for their unwavering commitment to patients. And I want to now turn the call over to Murdo.

Murdo Gordon

Executive Vice President of Global Commercial Operations

Thanks, Bob. Execution was strong across our core therapeutic areas in the third quarter, driving 24% year-over-year product sales growth. Each of our regions delivered double-digit volume growth. And sales of 10 products grew by double digits or better, including Repatha, TEZSPIRE, BLINCYTO, EVENITY and TAVNEOS, all brands that are important to our future growth trajectory.

Starting with our general medicine portfolio, sales of Repatha, EVENITY and Prolia collectively grew 18% year-over-year in the third quarter, driven by volume growth. We serve large patient populations with these therapies. For example, we expect Repatha and Prolia alone will help over 11 million patients in 2024. Repatha sales increased 40% year-over-year to \$567 million for the third quarter, now annualizing at over \$2 billion in sales. In the quarter, we saw year-over-year volume growth of 41% and favorable changes to estimated sales deductions of 8%, partially offset by lower net selling price of 10%.

In the U.S., our expanded primary care field force efforts drove a 50% year-over-year increase in primary care physician prescribers. U.S. volume growth was enabled by broad reimbursement and removal of prior authorization requirements by several payers. Outside the U.S., Repatha retains category leadership and continues to grow across major markets despite increased competition in the segment. EVENITY sales increased 30% year-over-year to almost \$400 million for the third quarter. In the U.S., EVENITY continues to be the segment leader with 61% of the bone builder market. Strong U.S. volume growth was supported by an increase in prescription volume from both established and new EVENITY prescribers with a 34% quarter-over-quarter increase in new provider accounts ordering EVENITY.

In Japan, EVENITY continues to hold a leading position with 47% of the bone builder segment. Since launching in Japan in 2019, EVENITY has been prescribed to approximately 600,000 patients. EVENITY sales are now annualizing at approximately \$1.5 billion. We're encouraged by the growth momentum we are driving and have conviction in the potential for EVENITY to help the many more women globally who remain at risk of a fracture due to their post-menopausal osteoporosis.

Prolia sales increased 6% year-over-year to \$1 billion for the third quarter, driven by 9% volume growth. In the U.S., we see broad prescribing base with more than 13,000 provider accounts using Prolia so far this year.

In inflammation, TEZSPIRE continues its strong trajectory with \$269 million in sales in the third quarter. Sales increased 67% year-over-year, supported by TEZSPIRE's uniquely differentiated profile and increased adoption by pulmonologists. We're encouraged by the growth of TEZSPIRE to date and its potential to treat the 2.5 million patients worldwide with severe uncontrolled asthma.

Otezla sales decreased 1% year-over-year for the third quarter with 5% volume growth. This volume growth was offset by 7% lower net selling price. Otezla remains the only approved oral systemic therapy with a broad indication and is well positioned to help the more than 1.5 million systemic treatment-naive U.S. patients with milder psoriasis who cannot be optimally addressed by a topical treatment.

Enbrel sales decreased 20% year-over-year for the third quarter, primarily driven by 13% unfavorable changes to estimated sales deductions and 12% lower net selling price. Volumes grew 4% in the quarter.

Going forward, we expect continued declining net selling price, relatively stable volume, providing strong cash flow for our business.

Sales of our biosimilar products increased 9% year-over-year in the third quarter. We have fully deployed our team in support of the recent U.S. launch of PAVBLU, a biosimilar to EYLEA. Our teams moved quickly to engage retina specialists, and we're encouraged by the enthusiastic feedback from customers. Our teams are also ready for the upcoming U.S. launches of WEZLANA, a biosimilar to STELARA and BEKEMV, a biosimilar to Solaris, expected in the first and second quarters of 2025, respectively. Overall, our biosimilars portfolio continues to deliver attractive returns driven by our efficient business model.

In oncology, sales of our 7 innovative products, BLINCYTO, LUMAKRAS, Vectibix, KYPROLIS, Nplate, XGEVA and IMDELLTRA grew 17% year-over-year for the third quarter, driven by volume growth and higher net selling price. In total, these products contributed over \$2 billion of sales in the third quarter. BLINCYTO sales grew 49% year-over-year to \$327 million for the third quarter. Growth was supported by the recent expansion of the BLINCYTO label, now approved by the U.S. Food and Drug Administration for use in patients with Philadelphia chromosome-negative B-cell ALL in the consolidation phase regardless of measurable residual disease status.

Our U.S. launch of IMDELLTRA is progressing well, generating \$36 million of sales in the third quarter. There's strong clinical conviction in both academic and community settings, driven by IMDELLTRA's breakthrough efficacy. We have a strong sense of urgency to bring IMDELLTRA to patients living with this aggressive disease.

LUMAKRAS sales increased 88% year-over-year to \$98 million for the third quarter. Vectibix sales increased 12% year-over-year to \$282 million for the third quarter, now annualizing at over \$1 billion. And KYPROLIS grew 8% year-over-year to \$378 million in the quarter. Nplate sales increased 9% to \$456 million for the third quarter. If we exclude government sales, Nplate sales grew 18% year-over-year for the third quarter, driven by 14% volume growth and higher net selling price. We've made significant progress in this quarter, driving execution and accelerating performance of our most important growth brands.

And with that, I'll turn it over to Vikram, who will cover our rare disease portfolio.

Vikram Karnani

Executive VP and President of Global Commercial Operations & Medical Affairs (Rare Disease)

Thank you, Murdo. I am pleased to provide an update on rare disease, which delivered product sales of \$1.2 billion in Q3. Beginning with TEPEZZA for the treatment of thyroid eye disease, third quarter sales were \$488 million, reflecting growth of 8% year-over-year when compared to results from the legacy Horizon business. Recall, there are roughly 100,000 TED patients in the U.S. and penetration is currently only in the single digits. We are excited about the growth opportunity presented by the roughly 80% of TED patients who have a lower clinical activity score, or CAS.

As we have discussed previously, to more effectively reach these patients, we have recently reorganized and expanded our field force into 2 separate and dedicated teams, one focused on comprehensive ophthalmologists and ocular specialists and the other focused on endocrinologists. This approach reflects an optimized footprint to continue to serve patients with high CAS disease while expanding our reach to those patients with low CAS disease who can benefit from TEPEZZA. We made this change in the third quarter. And over the last few weeks, these teams have been actively focused on establishing new relationships with potential new prescribers. We expect this optimized focus to gain traction over the next few quarters as physicians become more experienced identifying the right patients for treatment and navigating the reimbursement process to enable access to TEPEZZA.

Following our 8% year-over-year growth this quarter, we remain confident in the long-term potential for TEPEZZA in the U.S. as we expand our reach to patients with low CAS disease and continue to work closely with payers to expand access. International expansion remains a key growth opportunity with regulatory filings completed or in progress across multiple regions. TEPEZZA's approval in Japan in September marked a key milestone ahead of its launch, which is expected by early 2025. We also initiated

a Phase III subcutaneous study and see this as an opportunity to increase adoption and improve the patient experience with an alternative option to our current IV formulation. KRYSTEXXA for patients with chronic refractory gout delivered \$310 million in sales in Q3, representing 23% year-over-year growth driven by volume growth from strong commercial execution. KRYSTEXXA with immunomodulation has established a new standard of care for chronic refractory gout.

UPLIZNA for patients with neuromyelitis optica spectrum disorder, or NMOSD, delivered \$106 million in sales in Q3, representing 58% year-over-year growth. International expansion of UPLIZNA is also underway with launches in multiple markets, including Canada, which launched earlier this year. Additionally, we're excited by the growth potential of UPLIZNA driven by the striking data in both IgG4-related disease, which affects over 20,000 patients in the U.S. and generalized myasthenia gravis or gMG, which affects nearly 80,000 to 100,000 patients in the U.S.

Sales of TAVNEOS were \$80 million for the third quarter. Sales increased 116% year-over-year, driven by volume growth. In the U.S., more than 4,300 patients with ANCA-associated vasculitis have been treated with TAVNEOS. Over 2,600 health care professionals have now prescribed TAVNEOS, a roughly 53% increase in the prescriber base so far this year. As we reflect on the past year, it's clear how far we've come in the integration and how well we're progressing.

I want to take this opportunity to express my sincere gratitude to all the team members that are working tirelessly to serve the needs of patients suffering from rare diseases. Looking ahead, we're excited about the opportunities and confident in what we'll achieve in our rare disease business and beyond. Now I'll hand it over to Jay for our R&D update.

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Thank you, Vikram, and good afternoon, everyone. In the third quarter, we made significant progress advancing our broad clinical pipeline, which includes a number of potentially first-in-class or best-in-class therapies. Since our last update, we have initiated a Phase II study of MariTide in type 2 diabetes and delivered positive potentially practice-changing Phase III data with UPLIZNA in generalized myasthenia gravis.

Additionally, the FDA granted Breakthrough Therapy designation for UPLIZNA in IgG4-related diseases underscoring the important potential impact of this medicine. We also showcased promising data from several oncology programs at major medical conferences, including IMDELLTRA, xaluritamig and AMG 193, while reporting positive results from the first of 8 Phase III studies evaluating rocatinlimab in atopic dermatitis.

Let's begin with general medicine. As previously mentioned, based upon the interim analysis of the ongoing Phase II study of MariTide in chronic weight management, we are seeing a differentiated profile and are confident MariTide will address important unmet medical needs in obesity, obesity-related conditions in type 2 diabetes. We remain on track and look forward to top line 52-week data from the MariTide Phase II study in late 2024. We are actively planning and expect to initiate a broad Phase III program in obesity, obesity-related conditions and type 2 diabetes.

This quarter, we initiated a dedicated Phase II trial investigating MariTide in patients with type 2 diabetes, living with and without obesity. MariTide has the potential to be the first therapy in this setting with monthly or even less frequent dosing. Beyond MariTide, our Phase I trial of AMG 513 is actively enrolling patients. We also continue to advance our preclinical obesity programs, which include both oral and injectable approaches comprising both incretin and non-incretin mechanisms.

Also in general medicine is olpasiran, our potentially best-in-class LP(a) targeting small interfering RNA medicine. The fully enrolled Phase III cardiovascular outcomes trial of olpasiran continues to progress. In oncology, IMDELLTRA, a first-in-class bispecific T cell engager or BiTE molecule, targeting DLL3 for small cell lung cancer is rapidly advancing into earlier lines of therapy with 3 Phase III studies underway in both extensive stage and limited stage disease.

To further enhance the patient experience, we are evaluating reduced monitoring protocols as part of the Phase III program, and we have initiated a Phase Ib study evaluating subcutaneous tarlatamab in patients with second line or later extensive-stage small cell lung cancer. In September, we presented impressive follow-up data from our DeLLphi 301 Phase II study of IMDELLTRA in patients with extensive stage small cell lung cancer, demonstrating sustained anticancer activity and a manageable safety profile.

We also presented data from DeLLphi 303, the Phase Ib study of IMDELLTRA combined with a PD-L1 inhibitor as maintenance therapy following 4 cycles of chemotherapy and first-line extensive-stage small cell lung cancer. This design is similar to our ongoing Phase III study, DeLLphi 305, which test the efficacy of IMDELLTRA and PD-L1 inhibition versus PD-L1 inhibition alone, in first-line extensive-stage small cell lung cancer, following platinum-based chemotherapy.

With a median follow-up of 10 months, IMDELLTRA has demonstrated a manageable safety profile, median duration of disease control of 9.3 months, median progression-free survival of 5.6 months and a 9-month estimated overall survival of 89%.

Moving to our first-in-class STEAP1 CD3 bispecific molecule, xaluritamig, we are pleased to announce that following consultation with regulatory authorities, we will initiate a Phase III study in post-taxane metastatic castrate-resistant prostate cancer, or mCRPC, this quarter. The promise of xaluritamig was recently evidenced by data presented in September from a Phase I dose exploration cohort evaluating monotherapy in patients with mCRPC.

With a median follow-up of 27.9 months, the median overall survival was 17.7 months across all cohorts, a potential improvement upon the historical median survival of 12 to 15 months in this patient population. Additional data from a Phase I randomized dose expansion and optimization cohort has identified the recommended dose and schedule for Phase III clinical investigation. Additionally, we are studying xaluritamig in earlier lines of therapy in combination and in earlier stages of prostate cancer.

Our Phase I study of xaluritamig in combination with enzalutamide and abiraterone, is ongoing. Recently, we have initiated 2 additional Phase Ib studies investigating xaluritamig in the upfront management of more localized disease. The first study evaluates neoadjuvant xaluritamig therapy that is prior to radical prostatectomy in patients with newly diagnosed, localized, intermediate or high-risk prostate cancer.

The second study evaluates xaluritamig in high-risk nonmetastatic hormone-sensitive prostate cancer after definitive therapy. We are particularly excited about the potential of xaluritamig, now our third bispecific T cell engager entering late-stage clinical development. Beyond our T cell engagers, we have completed enrollment of FORTITUDE-102, a Phase III study of bemarituzumab, our first-in-class fibroblast growth factor receptor IIb directed monoclonal antibody combined with chemotherapy and nivolumab in first-line gastric cancer.

In the coming months, we expect to read out the results of FORTITUDE-101, a Phase III study of bemarituzumab combined with mFOLFOX6 chemotherapy versus chemotherapy alone in first-line gastric cancer. This study was designed based on the successful Phase II FIGHT study, which reported numerically longer progression-free survival and overall survival.

Lastly, we are also rapidly advancing AMG 193, our oral PRMT5 inhibitor developed for MTAP-null solid tumors. We recently initiated a Phase II study of AMG 193 in patients with MTAP-null previously treated advanced non-small cell lung cancer. This study will help to address regulatory agency requirements for dose optimization and selection. In September, we presented encouraging data from a Phase I dose escalation and initial dose expansion study, demonstrating promising monotherapy activity and an acceptable safety profile.

Turning to inflammation. Based upon encouraging Phase II data from TEZSPIRE in patients with COPD, we are planning to initiate Phase III studies in collaboration with AstraZeneca. These trials will target patients with moderate to very severe COPD with blood eosinophil counts greater than or equal to 150 cells per microliter. We expect to begin enrollment in the first half of 2025.

TEZSPIRE is also being investigated in separate Phase III studies of patients with eosinophilic esophagitis and in chronic rhinosinusitis with nasal polyps, where top line data are expected later this year. In

September, we announced positive results from the Phase III Horizon study of rocatinlimab in atopic dermatitis. The study met its co-primary endpoints and all key secondary endpoints.

We anticipate additional data readouts from the ROCKET program will deepen our understanding of rocatinlimab profile. Beyond atopic dermatitis, we continue to explore rocatinlimab in moderate to severe asthma and prurigo nodularis. To expand the impact of our CD19 directed therapeutics for even more patients suffering from serious inflammatory diseases, we have initiated Phase II studies of blinatumomab our CD19 targeting BiTE molecule approved as BLINCYTO and inebilizumab, our CD19 targeting monoclonal antibody approved as UPLIZNA. These studies build on mounting evidence of therapeutic benefit for B-cell depletion in autoimmune diseases from small investigator-sponsored trials of blinatumomab in systemic sclerosis and refractory rheumatoid arthritis. Our initial focus will be on systemic lupus erythematosus with nephritis with plans to expand into additional indications.

Shifting to rare disease. We recently presented potentially practice-changing results from the Phase III MINT study, the largest placebo-controlled trial for a biologic therapy in generalized myasthenia gravis. MINT evaluated UPLIZNA in both acetylcholine receptor autoantibody positive ACHR positive and muscle-specific kinase autoantibody positive or MuSK-positive populations.

At the reported 26-week time point, UPLIZNA demonstrated clinically meaningful and statistically significant improvements in the myasthenia gravis activities of daily living score after just 2 doses compared to placebo. This efficacy was observed in the combined ACHR and MuSK-positive populations as well as in each population separately. UPLIZNA also achieved statistically significant improvements in the quantitative myasthenia gravis score, compared to placebo at week 26 in the combined populations.

Importantly, in the MINT study, patients taking corticosteroids were tapered down starting at week 4 to a 5-milligram per day dose by week 24. MINT is the first and only Phase III placebo-controlled myasthenia gravis trial for a biologic that tapered corticosteroid use. As such, the efficacy observed with UPLIZNA in patients with generalized myasthenia gravis offers a chance for meaningful benefit without the burden and toxicity of chronic steroid use.

We look forward to 52-week data for the ACHR positive cohort and results from both ACHR positive and MuSK-positive patient populations. In the open-label period of the MINT study, where UPLIZNA has the potential to demonstrate durable efficacy.

Moving beyond generalized myasthenia gravis in August, the FDA granted UPLIZNA Breakthrough Therapy designation for the treatment of immunoglobulin G4-related diseases, or IgG4-related disease based upon data from the Phase III MITIGATE study. This data will be presented at the American College of Rheumatology Conference in November. We are extremely encouraged by the potential of UPLIZNA in both myasthenia gravis and IgG4-related disease and are actively working to file these data with regulatory authorities.

In closing, I want to thank my Amgen colleagues for their unwavering commitment to patients facing grievous illnesses for the focus and for the collaboration during this productive year.

I'll now turn it over to Peter for the financial update.

Peter H. Griffith
Executive VP & CFO

Thank you, Jay. We're pleased with our strong third quarter performance and are on track with our 2024 full year goals and long-term objectives. We have a strong long-term growth outlook with breadth and depth across each of our 4 therapeutic areas, including our innovative pipeline and in-market products, serving patients with serious illnesses around the globe.

We will continue to allocate capital to innovation first and with our strong cash flows, also intend to fund our other capital allocation priorities. Starting with our third quarter results as shown on Slide 28 of the slide deck, we delivered \$8.5 billion in total revenues, a 23% year-over-year increase.

Excluding the addition of Horizon, product sales increased 8% year-over-year, driven by 12% volume growth. In the U.S., our sales in the quarter were impacted by \$173 million and unfavorable changes to estimated sales deductions. In the third quarter, we delivered a non-GAAP operating margin of 49.6% as a percentage of product sales with total non-GAAP operating expenses increasing 27% year-over-year, largely driven by the addition of Horizon.

Non-GAAP R&D spending in the third quarter increased 35% year-over-year to \$1.4 billion as we invested in the rapidly advancing late-stage pipeline including MariTide, bemarituzumab and olpasiran as well as Horizon acquired programs. Non-GAAP SG&A expenses increased 21% year-over-year, primarily driven by the addition of Horizon, excluding the addition of Horizon, non-GAAP SG&A expenses were relatively flat year-over-year.

The Horizon integration is progressing well, and we expect to reach \$500 million in pretax cost synergies by year 3 post-acquisition with more than 50% to be realized by the end of this year. The acquisition is accretive to non-GAAP EPS year-to-date, and we expect it to be for the full year as well. Our non-GAAP OI&E resulted in a \$554 million expense, up \$329 million year-over-year, almost entirely due to increased interest expense from the Horizon acquisition. We continue to strengthen our balance sheet with \$2.5 billion of debt retired in the third quarter and expect to return to our pre-Horizon acquisition capital structure by the end of 2025.

Our non-GAAP tax rate decreased 2.7 percentage points year-over-year to 13.4%, primarily due to the change in earnings mix from the inclusion of Horizon. In the third quarter of 2024, the company generated \$3.3 billion of free cash flow, an increase of \$2.5 billion from the previous year. Our strong cash flows enable investing in our business for long-term growth, including advancing our exciting pipeline opportunities and expanding capacity in our state-of-the-art manufacturing processes and facilities.

Our past investments enable us to serve a significant number of patients today. For example, with over 43 million units expected for Repatha and Prolia alone in 2024, ongoing and future investments will support MariTide and other products across the portfolio. In addition, we returned capital to shareholders as we paid competitive dividend of \$2.25 per share in the second quarter. This represented a 6% increase compared to 2023.

Let's turn to the outlook for the business for 2024 on Slide 30. We expect our 2024 total revenues in the range of \$33.0 billion to \$33.8 billion and non-GAAP EPS between \$19.20 to \$20. We do expect Q4 non-GAAP EPS to be lower than Q3 non-GAAP EPS, because of planned investment increases in our business, including key assets in our innovative pipeline beginning with MariTide and olpasiran and other strategic business investments. This sequential pattern is consistent with historical trends.

Let me mention a few consideration as you model the remainder of 2024. We now project full year new asset sales at approximately \$400 million and other revenue at approximately \$1.4 billion. We expect TEPEZZA sales in Q4 to be flat to slightly down versus the third quarter, resulting in full year sales being up roughly 5% year-over-year as compared to the full year of TEPEZZA sales in 2023. Consistent with prior years, we expect Q4 non-GAAP operating expenses to be the highest of the year and expect approximately 28% of our full year operating expenses to be in the fourth quarter. This includes additional investments to drive momentum into 2025, for example, in key brands like Repatha and EVENITY.

For the full year, our total non-GAAP operating expenses are expected to grow approximately 25% year-over-year, including from the addition of Horizon. We still expect full year non-GAAP R&D growth of more than 25% year-over-year. We now expect OI&E to be approximately \$2.4 billion to \$2.5 billion, which includes the interest expense related to the \$28 billion of debt raised for the Horizon acquisition. We now expect the non-GAAP tax rate to be in the 14% to 15% range, including the full year benefits associated with the inclusion of the Horizon business and favorable items in the quarter identified in the return to provision process.

Finally, our capital expenditure guidance remains at \$1.3 billion for 2024. Our long-term growth outlook remains strong and I'm grateful to our colleagues worldwide for their dedication to serving patients. This concludes our financial update.

I'll now hand it back to Bob for our Q&A session.

Question and Answer

Operator

[Operator Instructions] Our first question comes from Salveen Richter from Goldman Sachs.

Salveen Jaswal Richter

Goldman Sachs Group, Inc., Research Division

The Phase II MariTide data clearly remains the key update into year-end. Can you help us understand what you will share with regard to this update in terms of actual data and also the Phase III developmental plan and timelines and when we might get an update from the other obesity programs?

Robert A. Bradway

Chairman, CEO & President

Okay. It sounded like a few questions there, Salveen. As we said, we're continuing to be very excited about the prospects for MariTide, and we added the disclosure on this call that we have begun the Phase II study in type 2 diabetes. The conduct of the trial is continuing to progress well, and we're expecting to have the data here by the end of the year. And when we have those data, we'll obviously look forward to being able to share that with our investors.

Justin G. Claeys

Vice President of Investor Relations

Julianne. Let's go to the next question, please.

Operator

Our next question comes from Olivia Brayer from Cantor Fitzgerald.

Olivia Simone Brayer

Cantor Fitzgerald & Co., Research Division

You are getting a lot closer to kicking off a Phase III MariTide program. So how do you think about the level of spend that will go into that kind of undertaking? I mean I assume we're looking at billions as it relates to investments just around R&D, but also manufacturing. But yes, hoping you guys can put some numbers around it or at least better characterize how you're thinking about things from here. Also hoping you can clarify whether or not you have seen those Phase II data in-house?

Robert A. Bradway

Chairman, CEO & President

So with respect to the Phase III trial, we would reiterate that we are expecting to pursue a broad Phase III trial in obesity-related conditions and type 2 diabetes. It will be, we would expect a large global trial, fully exploring the molecule. And Jay, I'd invite you to add any color you'd like about the Phase III program. But obviously, our investment will reflect our view that this is a differentiated molecule, and we look forward to having the full characterization of its safety and efficacy profile.

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Yes. Thanks, Bob. We're fully on track actively planning and expect to initiate a broad Phase III program. This will include obesity, obesity-related conditions and type 2 diabetes, as you've heard already, we're progressing the Phase II study to characterize dose response, tolerability efficacy in patients. Importantly, without obesity but having type 2 diabetes. So we're fully on track, actively planning the broad program.

Robert A. Bradway

Chairman, CEO & President

And we'll -- as part of our normal guidance process in the coming year, I'm sure we'll give an updated perspective then that reflects our plans for the Phase III trial. And then we'll also add any perspective that may be helpful on the capital expenditure front. I think what I just would remind you is that this molecule is designed on our existing antibody platform. It fits very well with our network as currently configured. And so again, we'll have more to say about that through time as necessary.

Peter H. Griffith

Executive VP & CFO

Maybe to suggest, Bob -- Olivia, it's Peter here. I would just remind you of Amgen's long history of being a leader in the science and manufacturing and process development that creates opportunities in terms of how we might view yield going forward. So while it might not just be bricks, mortar and steel, yield is really important, and we've got a really strong history in that.

And we did raise the CapEx guide this year, as you know, to about \$1.3 billion. We're very thoughtful about that. And you also heard me mention that research and development spend up 35% quarter-over-quarter to the prior year. We expect it to be up over 25% for the year. So we certainly are investing where we always say we will in innovation and MariTide is right at the front of that, and we look forward to investing to be a key player in this global public health crisis.

Justin G. Claeys

Vice President of Investor Relations

Julliane, let's take the next question, please.

Operator

Our next question comes from Michael Yee from Jefferies.

Michael Jonathan Yee

Jefferies LLC, Research Division

Maybe for Jay, it sounds like you guys are quite confident about MariTide, and yet you are also building a greater portfolio I think you announced 513. And yet you also don't have an oral, I don't believe so. Can you just comment about your philosophy or thinking about the totality of the portfolio given 133 is so far in the Phase III, but the other things are so early, and whether you believe you have the portfolio today to be competitive with everybody else who have so many things at late stage?

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Thanks, Mike. I really appreciate the question. With MariTide, we're really pleased with the execution of the study await data later this year, fully focused as I shared on setting up the broad Phase III program. The development of additional medicines for obesity and obesity-related conditions is a source of really active investigation here, preclinically and clinically now with 513 as you nicely mentioned. We've not as yet disclosed the mechanism of action of 513, which is a very interesting program.

And as you note, and this is on clinicaltrials.gov, the SAD/MAD ascending dose study has been announced is enrolling and feature subcutaneous or intravenous administration. To reach smaller segments, other segments within the obesity landscape to serve all the patients with obesity and it's related conditions. We, like many others, are interested in both injectable as well as oral non-injectable medicines. We're very interested in incretin pathway as well as non incretin pathway mechanisms of action, and our portfolio reflects each of these.

Justin G. Claeys

Vice President of Investor Relations

Julliane next question, please.

Operator

Our next question comes from Courtney Breen from Bernstein.

Courtney Breen

Sanford C. Bernstein & Co., LLC., Research Division

Just anchoring on some of the conversations that you shared around the Horizon products and specifically TEPEZZA. Can you please provide some more context on the path to growth and when you expect to see the impact of the sales team there, particularly in the context of the final comments that we shared in terms of expectations for Q4 relative to Q3.

Robert A. Bradway

Chairman, CEO & President

Yes. Let's take it in a couple of pieces. First, as you heard us say, the quarter grew 8%. Vikram, why don't you just remind our investors of the plans for expanding Salesforce and then also perhaps speak to Japan or international more general?

Vikram Karnani

Executive VP and President of Global Commercial Operations & Medical Affairs (Rare Disease)

Yes. Thanks, Bob. So as Bob just said and as I said in my prepared remarks, TEPEZZA grew 8% year-over-year. And as we have also said previously, we're continuing to focus on growth coming not only from the high CAS patients, but also the 80,000 -- roughly 80,000 patients that suffer from low CAS disease. What we have learned over our time serving these patients and these prescribers is that in order to most effectively reach these low CAS patients, we need to have a dedicated effort towards both comprehensive ophthalmologists and ocular specialists as well as endocrinologists.

And what we have found is that type of coverage is necessary in order to serve the 80,000 or so low CAS disease patients that we have discussed previously. This approach reflects an optimized footprint. We believe that this approach will allow us to not only help the right physicians and new prescribers find the right patients for TEPEZZA, but also help to enable access to TEPEZZA the most appropriate way.

Finally, what I would say here is we -- this is something that has been -- we've been working on for a little bit here. And this change occurred in the third quarter. So we do expect the momentum to play out here in the next several quarters. In the last few weeks, the teams have been actively focused on establishing new relationships with these new prescribers, and we look forward to updating you as we go.

Final point on the global aspects of TEPEZZA. As you're aware, beyond the U.S., we are also looking forward to bringing to TEPEZZA to patients around the globe, including Japan. Japan is a really important country for us in terms of our next launch. Let me remind you that we received approval in Japan for TEPEZZA with high CAS patients in September, and we're actively working to an early 2025 launch there as well.

Justin G. Claeys

Vice President of Investor Relations

Julianne. Next question, please.

Operator

Our next question comes from Umer Raffat from Evercore ISI.

Umer Raffat

Evercore ISI Institutional Equities, Research Division

I had a 2-part question on MariTide, if I may. Perhaps, first, from a vomiting profile perspective, I recall in the Phase I trial, specifically in Phase I, the vomiting profile was generally fairly consistent between low and high doses, which would imply perhaps titration in and of itself may not solve for vomiting. But Jay, I'm curious, is there anything super important in the design of Phase I which wasn't incorporated that could have addressed that vomiting. That's #1. And then secondly, on the cadence of weight loss, is there

any reason to expect the plateau in weight loss to not happen before -- do not happen past month 7 or so because we've seen other GLP trials kind of do that in 6 to 7 months post titration.

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Yes. Thanks, Umer. I really appreciate it. The Phase I study published now in January has been pretty thoroughly considered. This was a standard Phase I dose escalation study that did not have antecedent dose titration. So if that answers your question, I suppose there's only so much that can be learned from the Phase I. We're honestly just really focused on these Phase II data, where at the interim, we saw the differentiated profile. And as you know, we're in Phase III planning. Regarding weight loss plateau, this will be an interesting thing to observe and learn from the data, which we wait later this year.

Justin G. Claeys

Vice President of Investor Relations

Julianne. Next question, please.

Operator

Our next question comes from Jay Olson from Oppenheimer.

Jay Olson

Oppenheimer & Co. Inc., Research Division

Congrats on the quarter. Maybe I'll shift gears to oncology. Congrats on all the progress and impressive growth, especially for BLINCYTO. For subcu BLINCYTO, it looks like the registrational study is now going to initiate in the second half of next year. Can you talk about what may have changed there and maybe share some color on the plans for that study?

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Yes. Thanks, Jay. This is Jay. The subcutaneous development of BLINCYTO is a major priority for us. We're very encouraged by the efficacy that we've seen with subcutaneous BLINCYTO in prior studies. You'll remember perhaps that this medicine is dosed 3 times a week. We did a Phase I study back in 2022 at ASH with striking data, among 21 evaluable patients, we saw 67% CR rate within 1 cycle.

There's been further data in the American Journal of Hematology since that time, 27 patients with an 85% CR rate, 75% of whom were MRD negative. And this is all without any grade for CRS. So subcutaneous BLINCYTO was a major priority for us. It is progressing in clinical investigation. And there's really nothing to read into the timing that you allude to in your excellent question.

Justin G. Claeys

Vice President of Investor Relations

Julianne. Next question, please.

Operator

Our next question comes from Terence Flynn from Morgan Stanley.

Terence C. Flynn

Morgan Stanley, Research Division

Two part on MariTide as well. Just wondering if you can confirm if the data disclosure will be a press release or it will be at a conference. I think the Phase I data were presented at the insulin resistance conference in December. So just wondering the venue. And then for the Phase III, Jay, do you think you're going to have to make any changes to the titration schedule you employed in Phase II? I know Lilly had extended their tirzepatide titration schedule when they move from Phase II to Phase III. Do you think that's something that could be necessary here?

Robert A. Bradway

Chairman, CEO & President

In terms of the release, Terence and how we share that with investors. Well, again, we're focused on getting the data in hand and when we have them, we'll try to do whatever in best interest of the shareholders. So stay tuned as soon as we have them. We look forward to being able to report those. And Jay, do you want to address the question on Phase III?

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

The Phase III planning, as we've shared, is fully on track, and we won't today give any news or insights into our approach to dosing, but we feel confident it will be well informed by the Phase II study that is ongoing, and we'll read out later this year.

Justin G. Claeys

Vice President of Investor Relations

Next question, please, Julianne.

Operator

Our next question comes from Carter Gould from Barclays.

Carter Lewis Gould

Barclays Bank PLC, Research Division

I want to maybe switch it up a little bit and ask you around the PAVBLU launch. Amgen's biosimilars have some have gone really well, others a little bit less so. You've historically talked about the importance of being first. But how do you think about adoption ahead of a Q code and in discussions with any payers, your expectation or step edits for biosimilars ahead of some of the other newer entrants?

Robert A. Bradway

Chairman, CEO & President

Yes. Thanks, Carter. Murdo, why don't you share your thoughts in general on the biosimilar franchise. We don't often get a chance to talk about it, but please also on PAVBLU.

Murdo Gordon

Executive Vice President of Global Commercial Operations

Thanks, Bob. We're obviously quite excited about the next wave of launch is not just PAVBLU, but our other biosimilar launches that we are expecting in the not-too-distant future, as I mentioned in my opening remarks, with WEZLANA and BEKEMV. On PAVBLU, as you mentioned, Carter, it's important to be first or in the first wave. And clearly, we're in that position now as we're launching this product as we speak. And we expect there to be strong interest in PAVBLU pretty much early on in the launch phase. Obviously, having permanent Q codes in this case, given that it's biosimilar are important, but there's a lot of interest out there even as we may have a temporary reimbursement code.

Robert A. Bradway

Chairman, CEO & President

And generally, Carter, as we've built what we think is industry-leading biosimilar franchise. It's a franchise that is performing very well, and we think it's earning attractive returns for our shareholders.

Justin G. Claeys

Vice President of Investor Relations

Next question, please.

Operator

Our next question comes from Chris Schott from JPMorgan.

Christopher Thomas Schott

JPMorgan Chase & Co, Research Division

Just a quick question on TEZSPIRE in COPD. Obviously, some really nice Phase II data earlier this year, but just was interested of how you think about the potential landscape here as we consider both DUPIXENT potentially the IL-33 is coming to market ahead of you. It seems like you might have a broader program and some interesting data. But just help me a little bit about how you're just commercially seeing that fitting into the landscape?

Peter H. Griffith

Executive VP & CFO

Well, Chris, why don't I start and this is Jay and Murdo hand off to you. So TEZSPIRE, as all here knows our TSLP monoclonal antibody that we're developing with AstraZeneca. And recently, we had a chance to read out a very compelling Phase II study in moderate to very severe COPD. This is a 337 patient study. They have -- these patients were having exacerbations despite triple therapy. And we went head-to-head against placebo over a 52-week period of time. The population actually broader even than DUPI and Murdo perhaps invite you to reflect on that. The data were quite positive with a numerically reduced exacerbation rate by 17%.

We learned a lot from biomarker studies of blood eosinophils as to which subsets of patients, all pre-planned stand to benefit the most. And with these learnings, we're now pleased to announce that we're planning to initiate Phase III studies together with AstraZeneca. This trial is well structured and set up to definitively answer the question around efficacy TEZSPIRE in COPD. And Murdo, would you like to reflect a little bit about our competitive posture?

Murdo Gordon

Executive Vice President of Global Commercial Operations

Yes. Thanks for the question, Chris. We're obviously really pleased with the performance of TEZSPIRE so far in uncontrolled -- severe uncontrolled asthma. We're actually now the second most prescribed product when it comes to new-to-brand prescriptions in that category. So I think it's clear now that allergists and pulmonologists appreciate the differentiated profile and the unique mechanism of action that is TEZSPIRE. And we also believe, as Jay has highlighted that, that ability to address a broader population of patients because of the unique mechanism of action and the upstream way in which it intervenes in the immuno inflammation cascade. We're hopeful that, that differentiation and will continue to play out in COPD and we feel really good about the opportunity to compete there.

With the combined resources of our partners at AstraZeneca and Amgen, we have a very strong share of voice currently in severe uncontrolled asthma, and we expect to be able to affect that same strong share of voice on the successful completion of the Phase III trial.

Justin G. Claeys

Vice President of Investor Relations

Julianne, let's take the next question, please.

Operator

Our next question comes from Evan Seigerman from BMO Capital Markets.

Evan David Seigerman

BMO Capital Markets Equity Research

I want to touch on the biosimilar launch for the [indiscernible] biosimilar. Maybe talk about some of the launch strategy and more specifically, how you can stimulate demand among Ophthalmologists who would otherwise use a branded product. Are you able to offer rebates or extended invoicing for these practices?

Murdo Gordon

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Executive Vice President of Global Commercial Operations

Thanks for the question. Obviously, I'm not going to talk about what we're doing commercially with respect to contracting. I will just say that we have a very broad deployed field force covering the key customers in this therapeutic area. We have very strong institutional organization that covers the purchasing groups and the large networks that treat a large percentage of the populations here. And the receptivity has been high. This isn't our first biosimilar launch, and we've been preparing effectively, and we're excited to be in the market.

Justin G. Claeys

Vice President of Investor Relations

Julianne, next question, please.

Operator

Our next question comes from Mohit Bansal from Wells Fargo.

Mohit Bansal

Wells Fargo Securities, LLC, Research Division

Congrats on the quarter. Maybe a question for Jay. So given that you have diabetes patients with obesity in the ongoing Phase II trial, do you think you would be able to look into the A1C profile of the drug as well? Or is it just too small a trial to make any conclusion about that at this point?

Murdo Gordon

Executive Vice President of Global Commercial Operations

Yes. Thank you, Mohit. As you know, type 2 diabetes runs regrettably with obesity and with overweight. And so we do hope and expect to have some insights into diabetic -- anti-diabetic activity from the Phase II study, but we need to have an experience in a dedicated Phase II study of diabetes, in particular, in patients without obesity. So more to follow there towards later this year.

Justin G. Claeys

Vice President of Investor Relations

Next question, please, Julliane.

Operator

Our next question comes from Yaron Werber from TD Cowen.

Yaron Benjamin Werber

TD Cowen, Research Division

Murdo, I got maybe a couple of questions for you. One, just on Enbrel, this quarter was that we didn't see the normal Q3 bounce back. It's just this a new normal now? Or is there any particular one-timers in the quarter?

And then secondly, you mentioned 12,000 accounts or 13,000 accounts ordering Prolia. I presume you're mentioning that on purpose is relating to the upcoming biosimilar launches late May next year. Can you talk about maybe just that dynamic in Prolia versus XGEVA, what to expect next year?

Murdo Gordon

Executive Vice President of Global Commercial Operations

Thanks for the question, Yaron. Yes, as you picked up, Enbrel was impacted by 2 negative trends in the quarter. One, of course, the regular decline in net price and then another one, which was a 30% adjustment in the quarter. So the quarter is a little softer than you normally see. Volume was up 4% in the quarter. So Enbrel continues to do quite well in terms of prescribers treating patients but we are expecting continued net price declines going forward.

When we look at Prolia, I mentioned that we have 13,000 provider accounts having treated patients with Prolia so far this year. This is just to give an idea of the breadth and utility of this important product. The other thing that we enjoy with Prolia is it's an important way for us to source potential patients for EVENITY, which we continue to see very strong growth in. So our presence in the bone community and the treating physician population that treat the many women who are trying to reduce their risk of fracture despite the effect of their osteoporosis, we feel really good about it. And yes, it could end up becoming something that helps us in terms of market presence in the face of biosimilar competition in the future.

Justin G. Claeys

Vice President of Investor Relations

Julliane. Let's take the next question, please.

Operator

Our next question comes from Gregory Renza from RBC Capital Markets.

Gregory James Renza

RBC Capital Markets, Research Division

Bob, maybe just looking at the rare disease franchise. And we've always mentioned -- you've mentioned it's certainly a different approach in this space. And to that, what is Amgen's approach on pipeline replenishment when it comes to the rare disease pillar? Certainly, being [indiscernible] discontinuation in IPF. Just curious how to think about specific disease areas in rare disease and also how you think about kind of supporting and following your current marketed products in the rare disease franchise.

Robert A. Bradway

Chairman, CEO & President

Yes. We take this in a couple of pieces. And we're obviously very excited about rare disease and what we think we can bring to the field. With respect to the molecules that are already on the market, each of them, as you know, is in an early stage of this life cycle and involves either diseases or molecular attributes that we think we can add a lot of value to over time. So we're excited about what we think we can do with those domestically and in international markets.

And we're also excited about, frankly, how our genetics resource, which you're familiar with has enabled us to glean insights both from existing molecules in the rare disease portfolio as well as potentially others that we might be able to add to it. But I'd invite Jay to share his thoughts. He's already brought a lot of energy to this topic with our rare disease organization.

So Jay, fire away.

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Thanks, Bob, and thanks for Gregory for the question. The acquisition of Horizon has really activated and energized our staff in R&D. I think inspired by the mechanistic repositioning of a TEPEZZA for thyroid eye disease, the capacity to bring rare disease medicines expertly to patients around the world has really activated the imagination of our R&D colleagues, and we've had multiple new project launches since the acquisition of Horizon.

Second, I would say that the integration has gone very smoothly. And the staff who've joined us through the Horizon acquisition have both seamlessly executed the development priorities for the rare disease portfolio and also have brought a lot of really interesting ideas. We have now a rare disease initiative with dedicated leadership.

We have dedicated leadership in rare disease drug development. And we hope and expect to continue just the best-in-class external innovation that Horizon was really known for in this space. So a blend of internal and external innovation will, I think, more than replenish the rare disease mid- and early-stage pipeline in the years to come.

Robert A. Bradway

Chairman, CEO & President

We're also very excited about the talent that joined us from Horizon, particularly on the research and the medical side. So we feel really well equipped now to continue to invest in this area and make a difference for patients.

Justin G. Claeys

Vice President of Investor Relations

Great. So Julianne, as we're getting to the half hour here, maybe we'll take 2 more questions.

Operator

Our next question comes from Matt Phipps from William Blair.

Matthew Christopher Phipps

William Blair & Company L.L.C., Research Division

Just wanted to confirm if the 420 mg dose is that's going to be taken COPD trials. And is that something that you can formulate into a single injection given it's twice, I believe the current size? And then just to confirm, this is 2 separate Phase III trial? Will they be identical in design?

James E. Bradner

Executive VP of Research & Development and Chief Scientific Officer

Yes, Matt, thanks for the question. They're good questions, but none that we can address here today. Together with our colleagues from AstraZeneca, we'll have a chance to describe in full the design of the Phase III program that will support the consideration of TEZSPIRE and COPD soon to come.

Justin G. Claeys

Vice President of Investor Relations

All right, Julianne. I think we have time for one more.

Operator

Our last question today will come from Chris Raymond from Piper Sandler.

Christopher Joseph Raymond

Piper Sandler & Co., Research Division

Just back on PAVBLU. We've gotten some interesting doc feedback on this with a decent amount of receptivity to this option. And one thing that's kind of a new development, I think, at least in the U.S. market has been a recent supply disruption to Avastin which may actually provide maybe more of an opening for this launch. Maybe just curious, as you looked at the market, talk about how you looked at the role of biosimilars in this predominantly buy and bill market with a very inexpensive option on Avastin, but one that seems to be fading at least in terms of suppliers wanting to provide the drug I guess, bottom line, does this Avastin supply issue make this even more interesting to you guys?

Murdo Gordon

Executive Vice President of Global Commercial Operations

Thanks for the question, Chris. But first and foremost, obviously, when you're treating serious illness, you want to have -- as a provider, you want to have a reliable supply of the product that you and your staff get used to handling. And I can say we are very fortunate to have world-class manufacturing here at Amgen, and we continue to have a highly reliable supply chain and manufacturing capability. We have benefited from shortages with other biosimilars including Avastin.

As I'll remind you, we have MVASI, our own biosimilar to that product. So we are seeing customers coming to us given some shortages here in the U.S. and around the world. And again, I'm thankful for our manufacturing colleagues here at Amgen who are putting us in a very strong position to be able to

speak to institutional customers to individual providers and obviously communicate with patients about the ability for us to supply and the reliability of that over time.

That being said, I think we're definitely looking at our own opportunity here in the market with PAVBLU. I think you mentioned that there's high interest in the customers that you've talked to. These retina specialists are sophisticated customers. They understand that if they're going to go with a manufacturer, they're going to want a relationship that is persistent over time, and we believe we're well positioned for that. We have a great device in a prefilled syringe. We also have vials. So we're able to supply this demand in this market. And that's what we intend to do, and that's what our teams are in the field establishing right now. But thanks for your interest.

Justin G. Claeys

Vice President of Investor Relations

Okay, Julianne, thanks for moderating our call, and thank you all for joining us. If there were any of you who didn't get a chance to ask your questions, Justin and his team will be around still for a few more hours. So we look forward to gathering with you when we next have relevant information. Thank you very much. Bye-bye.

Operator

This concludes our 2024 Q3 earnings call. You may now disconnect.

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