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REGN.OQ - Q4 2025 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals fourth-quarter 2025 earnings conference call. My name is Shannon, and I will be your operator for today's call. (Operator Instructions) Please note that this conference call is being recorded.

I will now turn the call over to Ryan Crowe, Senior Vice President, Investor Relations. You may begin.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

Thank you, Shannon. Good morning, good afternoon, and good evening to everyone listening around the world. Thank you for your interest in Regeneron and welcome to our fourth-quarter 2025 earnings conference call. An archive and transcript of this call will be available on the Regeneron Investor Relations website shortly after our call concludes.

Joining me on today's call are Dr. Leonard Schleifer, Board, Co-Chair, Co-Founder, President, and Chief Executive Officer; Dr. George Yancopoulos, Board, Co-Chair, Co-Founder, President, and Chief Scientific Officer; Marion McCourt, Executive Vice President of Commercial; and Chris Fenimore, Executive Vice President and Chief Financial Officer.

After our prepared remarks, the remaining time will be available for your Q&A. I would like to remind you that remarks made on today's call may include forward-looking statements about Regeneron. Such statements may include but are not limited to those related to Regeneron and its products and business, financial forecast and guidance, development programs, and related anticipated milestones, collaborations,

finances, regulatory matters, payer coverage and reimbursement, intellectual property, pending litigation, and other proceedings and competition.

Each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in that statement. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2025, which we plan to file with the SEC next week. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

In addition, please note that GAAP and non-GAAP financial measures will be discussed on today's call. Information regarding our use of non-GAAP financial measures and a reconciliation of those measures to GAAP is available in our quarterly results press release and our corporate presentation, both of which can be found on the Regeneron Investor Relations website. Once our call concludes, the IR team will be available to answer any further questions.

With that, let me turn the call over to our President and Chief Executive Officer, Dr. Leonard Schleifer. Len, take it away.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Thanks, Ryan, and thanks to everyone for joining today's call. Regeneron capped 2025 with another solid quarter of commercial execution with fourth quarter total revenue up 3% year-over-year driven by double-digit net sales growth for three of our leading products. Compared to the fourth quarter of last year, global net product sales for Dupixent, as reported by Sanofi, increased by 32% and Libtayo by 13% at constant exchange rates, while EYLEA HD in the United States grew by 66%.

Global Dupixent net sales were $4.9 billion in the fourth quarter and $17.8 billion for the full year 2025. Dupixent is currently the most widely used innovative branded antibody medicine with more than 1.4 million patients on therapy globally. Now approved in eight indications, most of which remain significantly underpenetrated, Dupixent is well positioned for future growth.

Global Libtayo net product sales were $425 million in the fourth quarter and $1.45 billion for the full year 2025. In the US, Libtayo continues to be the market-leading immunotherapy for advanced non-melanoma skin cancers. Following FDA and EC approvals of Libtayo for adjuvant CSCC in the fourth quarter, we are making great progress launching this potential blockbuster opportunity, with this indication expected to be a significant growth driver for Libtayo in 2026 and beyond.

Libtayo also continues to build share in advanced non-small cell lung cancer, where in the US, it is now the second most prescribed immunotherapy in the first line setting with new patient market share in this setting greater than Opdivo, Tecentriq, and Imfinzi combined. EYLEA HD net product sales in the United States were $506 million in the fourth quarter, up 66%, and $1.6 billion for the full year 2025 of 36%, despite continued patient co-pay affordability issues that have dampened branded anti-VEGF category growth.

In November, the FDA approved EYLEA HD for macular edema following retinal vein occlusion or RVO, and monthly dosing across all approved indications, further strengthening the EYLEA HD competitive profile. Our FDA submission seeking approval of the EYLEA HD prefilled syringe using a new manufacturer has been accepted for review, a standard pre-licensing inspection has been scheduled, and the decision on our filing is expected in late April.

In addition, as a backup, Catalent Indiana continues to work with the FDA to resolve findings from a previous inspection. We continue to believe that all three of these product enhancements are key to fully unlocking EYLEA HD’s commercial potential. While we anticipate continued growth in EYLEA HD this year, EYLEA 2 milligrams will continue to be under competitive pressure, which is expected to intensify in the second half of 2026 as multiple biosimilar products are launched in the United States.

Regarding patient affordability, we are pleased that we matched a $60 million donation to the Good Days Retinal Vascular And Neovascular Disease fund in the fourth quarter. Today, we reiterated our commitment to helping patients afford their medicines by extending our matching program through the end of this year, up to $200 million.

Turning now to our negotiations with the United States government regarding efforts to reduce drug costs for American patients. We are actively engaging in constructive discussions with the Centers for Medicare and Medicaid services and other federal agencies, and we anticipate reaching agreement that aligns with the framework previously established by other companies.

We remain optimistic about striking a deal with the administration to achieve our shared goals, ensuring timely and affordable access to groundbreaking medical advancements for American patients, maintaining the United States' leadership in biotechnology, innovation, and manufacturing, and addressing the long-standing imbalance in the distribution of costs for medical innovation, which has historically placed a disproportionate burden on American patients.

Finally, looking ahead to the next 12 months, Regeneron has several key objectives that I'd like to share. First, we anticipate at least four FDA approvals, including three for new molecular entities across three distinct modalities plus approval for the EYLEA HD prefilled syringe, as well as several additional regulatory submissions.

We expect registration-enabling data for multiple programs, including fianlimab, our LAG-3 antibody, in combination with Libtayo and advanced melanoma, as well as a combination of cemdisiran and pozelimab in PNH.

In addition to the ongoing clinical studies in key areas such as myeloma, anticoagulation, and complement-mediated diseases, 2026 will be an important clinical development execution year as we anticipate initiating 18 additional Phase 3 studies, with cumulative target enrollment of approximately 35,000 patients over multiple years, setting the foundation for Regeneron's next wave of potential blockbuster products.

We also plan to begin clinical development of at least three first-in-class antibodies that address novel targets, of which two were discovered and validated by the Regeneron Genetics Center, as well as our long-acting IL-13 antibody in atopic dermatitis. We expect strong commercial execution to continue, maximizing the potential of our leading brands across key therapeutic areas.

And finally, we plan to continue to prudently deploy capital through share repurchases, dividends, and complementary business development, all with the goal of driving long-term shareholder value. Obviously, a busy, and ambitious year ahead, one that I'm particularly energized and excited to [embark upon]. We look forward to reporting our progress on these goals as we move through the year.

With that, I'll turn the call over to George.

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

Thanks, Len. Earlier this month at the JPMorgan conference, we highlighted the breadth and depth of our pipeline, which is expected to generate clinical data over the next few years spanning oncology, hematology, complement mediated diseases, anticoagulation, and obesity as well as in other areas.

In 2026, we plan to build on our established leadership in ophthalmology as well as immunology and inflammation, while advancing key late-stage programs. Starting with ophthalmology, EYLEA HD was recently approved by the FDA for monthly dosing, and for the treatment of RVO, further strengthening its clinical profile. Data supporting these approvals will be presented at the upcoming Angiogenesis meeting, further highlighting the efficacy, safety, and durability of EYLEA HD, along with dosing flexibility designed to support more personalized patient care.

In terms of our ophthalmology pipeline, for our C5 program for geographic atrophy, we expect interim data from our Phase 3 study in the second half of 2026. We are currently evaluating our C5 siRNA, cemdisiran, as monotherapy, and also with pozelimab, our potentially best-in-class C5 antibody, with the goal of providing a systemic treatment that avoids the safety issues from repeated intravitreal injections

associated with currently approved GA therapies. In case intravitreal delivery is required to adequately treat this disease, we've also begun clinical development of an intravitreal formulation of pozelimab to evaluate local C5 inhibition for appropriate patients.

Beyond GA and ophthalmology, we have initiated a study of a novel intravitreally delivered T-cell receptor-blocking antibody for non-infectious uveitis, a disease generally driven by autoimmune T-cells. This advance was made possible by our unique antibody capabilities, as we are not aware of any other company that's been able to generate such an antibody. This year, we also plan to initiate clinical development for a long-acting antibody targeting a novel genetically validated target for glaucoma, along with a long-acting antibody that aims to treat thyroid eye disease and Graves' disease.

Moving to immunology and inflammation, we are committed to strengthening our leadership by advancing several next-generation therapeutic approaches. As we first revealed at the JPMorgan conference, in addition to exploring longer dosing intervals for Dupixent, we are progressing VelocImmune-derived, fully human, long-acting antibodies with enhanced binding properties that target the IL-4 receptor alpha, the same target as Dupixent, as well as antibodies targeting IL-13, IL-4, and a bispecific antibody targeting both IL-4 and IL-13. All of these approaches are designed to enable extended dosing.

Our long-acting IL-13 antibody is expected to enter the clinic in the coming months, embarking on an expedited development plan in atopic dermatitis that we believe will enable us to remain competitive as other industry players are pursuing related approaches.

Our other long-acting antibodies are expected to enter the clinic by 2027, each with a custom development plan. At the same time, our Regeneron Genetics Center has utilized its large-scale genetics approaches to identify several exciting new immunology and inflammation targets.

Similar to Dupixent, we believe these may represent future pipeline-in-a-product opportunities. The first of these antibodies is expected to enter clinical development in the first half of this year. After initially evaluating healthy volunteers, we plan to rapidly advance this candidate to establish proof of concept in several genetically linked diseases such as lupus, Sjögren's, and primary biliary cholangitis.

Turning now to allergy. Our initial cat and birch Phase 3 study demonstrated that allergen-specific monoclonal antibody cocktails can meaningfully address ocular endpoints, adding to earlier data that showed significant reductions in nasal, respiratory, and skin endpoints. These Phase 3 data from the cat and birch programs will be presented at the upcoming AAAAI conference. We anticipate initiating the confirmatory Phase 3 study for cat allergy in the first half of the year, while the confirmatory Phase 3 study for birch allergy is already underway.

We are also advancing an innovative strategy with the goal of eliminating all IgE-mediated allergies. Our initial clinical effort is in patients suffering from severe food allergies, involving transient Lynozyfic treatment followed by long-term Dupixent maintenance. This approach demonstrated proof of principle, with the first four treated patients all achieving over 90% sustained IgE reductions.

These results validate our approach of first removing IgE-producing plasma cells and then preventing their return. Building on this, we are developing next-generation agents specifically targeting IgE-producing cells, with the first expected to enter clinical development over the next year for potentially more rapid and broader allergy applications.

On to oncology and fianlimab, our LAG-3 antibody combination with Libtayo. Our pivotal study in first-line metastatic melanoma remains on track to read out in the first half of this year. Early clinical data from our first in-human study across multiple advanced melanoma cohorts suggested a potentially differentiated investment class profile. Also, in the first half of this year, we're expecting an interim analysis for our study in adjuvant melanoma, as well as Phase 2 data in advanced non-small cell lung cancer, a more speculative setting in which clinical validation has not yet been established for LAG-3 and PD-1 combinations.

Moving to heme-onc, Lynozyfic, our BCMAxCD3 bispecific, is establishing a new benchmark in multiple myeloma. In late-line disease, and with the caveat of cross-trial comparisons, Lynozyfic has demonstrated nearly double the complete response rate compared to other BCMAxCD3

bispecifics at similar follow-up times, with lower rates of cytokine release syndrome, shorter hospitalization requirements, and more convenient dosing intervals.

Building on its remarkable monotherapy activity across multiple lines of therapy, we are undertaking an ambitious development plan to simplify the existing myeloma treatment paradigm, which currently relies on highly complex, intense, and burdensome triple and quad drug combinations, by exploring Lynozyfic monotherapy as well as simple combinations in early-line settings.

In our Phase 2 study in newly diagnosed multiple myeloma, all nine evaluable patients treated with Lynozyfic monotherapy at the planned Phase 3 dose achieved MRD negativity, an endpoint the FDA recently endorsed as a registration-enabling for this malignant disease. Even more compelling are the early signals in myeloma precursor and related settings.

For example, in evaluable patients with high-risk smoldering myeloma, Lynozyfic once again achieved 100% MRD negative in all 12 evaluated patients, whereas the standard of care, daratumumab, achieved less than 10% complete response. Similarly, in second-line patients with light chain amyloidosis, Lynozyfic monotherapy normalized abnormal light chain levels in approximately two weeks, whereas in a separate study, a daratumumab-containing quad combo regimen took approximately five months to approach these levels in first-line patients.

Both of these promising results could herald marked advances to existing standard of care, which can involve complex and toxic multi-drug combinations. With four pivotal studies underway and four more initiating by the middle of this year, we are rapidly advancing our Lynozyfic development program with the hopes of transforming the myeloma treatment paradigm and ultimately preventing progression to malignant disease.

On to complement-mediated diseases, our C5 program consists of customized approaches to treat different diseases, which require different levels of target inhibition to maximize efficacy for each condition. I previously summarized above our C5 efforts in geographic atrophy.

In our pivotal study for generalized myasthenia gravis, we showed that cemdisiran alone achieved differentiated efficacy and convenience with every three-month subcutaneous dosing, delivering a potentially best-in-class profile with a placebo-adjusted improvement in the Myasthenia Gravis Activities Of Daily Living Score of 2.3 points at 24 weeks, the primary endpoint of the study, and the best result among C5 inhibitors to date based on cross-trial comparisons. We remain on track to submit our US regulatory application in the first quarter, with potential approval anticipated later this year or early next year.

In paroxysmal nocturnal hemoglobinuria, or PNH, where our Phase 3 lead-in data showed the combination of cemdisiran and pozelimab was necessary to achieve potentially best-in-class disease control, with 96% of patients controlled in the pivotal trial lead-in cohort, and with the ability to rapidly rescue patients previously treated with ravulizumab, who had not been well controlled. These results once again have the potential to deliver a best-in-class profile, with pivotal data expected late this year or early next year, positioning this combination of C5 complement inhibitors as a new standard of care for PNH.

Moving to anticoagulation, clot prevention remains a critical unmet need, since less than half of eligible patients receive anticoagulant therapy, primarily due to concerns about their bleeding risk. To address this, we are developing two complementary Factor XI antibodies, one optimized for maximal antithrombotic activity, and the other designed to further reduce bleeding risk, enabling a tailored approach based on individual patients' benefit-risk profile.

Initial clinical data support this strategy, showing impressive efficacy and a favorable bleeding profile compared to current standards of care. Pivotal studies are already underway in prevention of post-surgical venous thromboembolism, or VTE, with pivotal studies of cancer-associated VTE prevention, catheter-associated thrombosis, stroke prevention in patients with atrial fibrillation, and peripheral artery disease, all expected to initiate this year.

Moving to obesity, we continue to pursue a differentiated strategy that includes olatorepatide, our in-licensed GLP-GIP agonist, entering pivotal monotherapy studies in 2026, as well as a co-formulation of olatorepatide with PRALUENT, our antibody to PCSK9. Since current GLP agonists

do not meaningfully lower LDL cholesterol, this co-formulated combination is designed to treat the large population of people living with obesity who also suffer from hyperlipidemia, with a single, convenient, and similarly affordable once-weekly subcutaneous injection, analogous to the currently approved GLPs.

Moreover, imagine if someone had invented a new GLP that, in addition to delivering profound weight loss, could also lower bad cholesterol by 50% to 60%. It would create an important and differentiated opportunity for the many obese patients simultaneously suffering from hyperlipidemia with elevated cardiovascular risk. Our clinical program for this novel combination, that we believe can deliver these same dual benefits, is expected to begin later this year.

Before I turn the call over to Marion, I would like to quickly address a couple of additional developments in our pipeline. In rare diseases, our DB-OTO gene therapy continues to produce transformative outcomes, with meaningful hearing gains in 11 of the 12 treated children born with profound genetic deafness. This program was selected as the first new molecular entity to receive the FDA Commissioner's National Priority Voucher Designation, and we are awaiting a regulatory decision in the first half of this year.

In fibrodysplasia ossificans progressiva, or FOP, a debilitating disease in which the soft tissues of the body are progressively replaced with abnormal bone, our garetosmab program demonstrated a more than 99% reduction in abnormal bone formation at 56 weeks, an unprecedented result, and we are awaiting on regulatory decisions in the US and EU in the second half of this year.

Our commitment and dedication to these types of rare diseases, particularly those that affect children, not only speak to the heart and soul of Regeneron but have also proven to pave the way for broader opportunities in the future, as we would hope would be the case here.

In summary, our scientific and clinical momentum continues to accelerate across the R&D enterprise with multiple pivotal readouts, regulatory milestones, and first-in-class programs advancing in 2026. I have never been more excited about the breadth, depth, and potential impact of our pipeline.

With that, let me turn it over to Marion.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Thank you, George. The fourth quarter delivered a strong finish 2025, completing a successful year across our commercial portfolio, our market-leading brands, EYLEA HD, Dupixent, and Libtayo continue to deliver sustainable growth based on their clinical profile as well as our ability to execute effectively in competitive markets.

In 2025, we expanded use of our existing brands and successfully launched new medicines and indications across multiple therapeutic areas and geographies. We begin 2026 well positioned to advance our portfolio and are excited by upcoming opportunities to change the lives of even more patients.

Starting with our retinal franchise of EYLEA HD and EYLEA, which delivered combined US net sales of $1.1 billion in the fourth quarter. EYLEA HD net sales reached $506 million, representing 18% sequential growth.

Performance was driven by a 10% increase in physician demand compared to the third quarter, highlighting EYLEA HD's strong clinical profile and commercial momentum, despite a 7% sequential decline in the overall anti-VEGF category. This fourth quarter dynamic is typical for the anti-VEGF category.

For full year 2025, the category maintained approximately 5% growth versus 2024, while the innovative branded segment, which excludes Avastin and biosimilars, declined by approximately 12%. Importantly, EYLEA HD represents a growing proportion of Regeneron's total anti-VEGF franchise, now contributing nearly half of total net sales.

Following recent label enhancements to include monthly doses and retinal vein occlusion, EYLEA HD now has the broadest label and greatest dosing flexibility of any anti-VEGF medicine. Physicians were eagerly awaiting both label enhancements, and we are seeing positive early launch signals in our efforts to get this important medicine to even more patients.

The combination of this new dosing flexibility with EYLEA HD's demonstrated durability further strengthens its position in the anti-VEGF retinal category. New real-world market data shows that on average, patients with ongoing anti-VEGF therapy who switched to EYLEA HD, we're able to extend their treatment duration by almost four weeks. This underscores EYLEA HD's durability profile in addition to its well-established efficacy and safety. We look forward to the potential FDA approval of our prefilled syringe, which if approved, will provide additional convenience for retina specialists and further enhance EYLEA HD's profile.

While EYLEA HD grew, EYLEA 2 milligrams fourth quarter US net sales declined 15% sequentially to $577 million. Together, EYLEA HD and EYLEA continued to lead the innovative branded anti-VEGF category.

Looking ahead, we remind you of two separate factors that will impact early 2026. The first quarter is typically impacted by patient reauthorizations. And as we disclosed earlier this month, wholesaler inventory levels were elevated by approximately $30 million at the end of the fourth quarter for EYLEA HD as well as EYLEA. We expect first quarter net sales will be negatively impacted as the inventory is absorbed.

For EYLEA HD, we anticipate high single-digit sequential demand growth in the first quarter, while EYLEA demand is expected to decline at a double-digit rate, based on competition and importantly, ongoing conversion to EYLEA HD.

Turning now to Dupixent, which delivered $4.9 billion in the fourth quarter global net sales, representing 32% year-over-year growth on a constant currency basis. US net sales grew 36% year-over-year to $3.7 billion based on broad demand growth and strong performance across several ongoing launches. Dupixent is now approved in eight Type 2 inflammatory diseases and is the number one prescribed biologic among dermatologists, pulmonologists, allergists, ear, nose, and throat specialists based on the combination of its differentiated efficacy, safety, and treatment experience.

Across Dupixent's established indications, including atopic dermatitis, asthma, nasal polyps, and eosinophilic esophagitis, Dupixent continues to deliver robust demand growth supported by strong physician preference in each of these indications. We've also seen remarkable uptake in our more recent launches, including COPD, chronic spontaneous urticaria, and bullous pemphigoid, and with physicians regularly sharing their experiences on how Dupixent has changed the lives of their patients, many of whom previously had no approved treatment options. With many indications still significantly underpenetrated, Dupixent continues to be well positioned to deliver near, medium and long-term growth.

Turning to oncology and hematology. Libtayo reported $425 million in global net sales in the fourth quarter, up 13% year-over-year on a constant currency basis. In the US, net sales grew 14% year-over-year to $285 million, based on strong demand growth across all approved indications. Libtayo is the leading immunotherapy for advanced non-melanoma skin cancers our recent launch in adjuvant CSCC is off to a great start, including the recent addition of Libtayo in the NCCN guidelines as the only Category 1 preferred immunotherapy in this setting.

In advanced non-small cell lung cancer, Libtayo is now the second most commonly prescribed treatment for patients receiving their first immunotherapy. Physicians increasingly recognize Libtayo as a preferred treatment option based on clinical experience, versatility as a monotherapy in combination with chemotherapy, supported by an increasing body of robust clinical data including recently reported five-year survival results.

Briefly turning to Lynozyfic, our new treatment for relapsed refractory multiple myeloma. We are encouraged by the launch progress to date. With physicians appreciating Lynozyfic's differentiated clinical profile, less burdensome hospitalization requirements, and convenient dosing regimen, we expect adoption to continue to steadily build over time in this late-line setting, with the larger commercial opportunities in earlier lines of therapy.

In summary, in the fourth quarter, we delivered strong growth across EYLEA HD, Dupixent, and Libtayo, and we continue to progress several launches, including Lynozyfic. In 2026, our commercial portfolio is well positioned to capitalize on many near-term growth opportunities, enabling us to deliver more treatments to patients.

With that, I will turn the call to Chris.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Thank you, Marion. My comments today on Regeneron's financial results and outlook will be on a non-GAAP basis unless otherwise noted.

Fourth quarter 2025 total revenues of $3.9 billion grew 3% compared to the prior year, reflecting higher collaboration revenue driven by strong global Dupixent sales growth, continued growth in net sales of EYLEA HD and Libtayo, as well as higher other revenue, partially offset by lower net sales of EYLEA 2 milligrams. Fourth quarter diluted net income per share was $11.44 on net income of $1.2 billion.

Beginning with the Sanofi collaboration, fourth quarter total Sanofi collaboration revenues were approximately $1.6 billion, of which $1.5 billion related to our share of collaboration profits. Regeneron's share of profits grew 42% versus the prior year, primarily driven by Dupixent and improving collaboration margins.

The Sanofi development balance was just below $600 million at the end of the year, reflecting a reduction of approximately $300 million since the end of the third quarter, and over $1 billion in full year 2025. Dupixent's continued strength enabled a rapid reimbursement of the development balance in 2025, which we now expect to be fully reimbursed by mid-2026. Once fully reimbursed, Sanofi collaboration revenues will reflect our full share of global profits for Dupixent and Kevzara.

Moving to Bayer. Fourth quarter net sales of EYLEA and EYLEA 8 milligrams outside the US were $817 million, inclusive of $312 million of EYLEA 8-milligram sales. Total Bayer collaboration revenue was $319 million, of which $270 million related to our share of net profits outside the United States.

Other revenue, which includes profit share and royalties associated with license agreements as well as amounts earned for contract manufacturing, grew 33% in the fourth quarter to $239 million. This included $179 million related to royalty income from Ilaris plus our share of profits from ARCALYST.

Ilaris net sales exceeded $1.5 billion in 2025, achieving the top royalty tier of 15% for the first time. Per our agreement with Novartis, escalating royalty tiers, which range from 4% to 15% are applied to cumulative net sales from the start of each calendar year. This leads to the step-ups in royalty income each quarter as higher royalty tiers are applied to cumulative net sales.

Now to our operating expenses. R&D expense was $1.3 billion in the fourth quarter, reflecting continued investments to support Regeneron's innovative pipeline, including multiple late-stage opportunities. Fourth quarter SG&A was $691 million, inclusive of a matching contribution to the Good Days' Retinal Vascular and Neovascular Disease Fund of approximately $60 million.

Our effective tax rate in the fourth quarter was 17%. The increase in our tax rate from the prior year primarily reflects a lower tax benefit from stock-based compensation. Regeneron generated $4.1 billion in free cash flow in 2025 and ended the quarter with cash and marketable securities less debt of $16.2 billion.

We returned $3.8 billion to shareholders in 2025, primarily through $3.4 billion in share repurchases. We continue to be opportunistic buyers of our shares, with $1.5 billion remaining authorized for repurchases as of December 31.

We also initiated a quarterly dividend last year, providing us with additional flexibility to return capital to shareholders. In 2025, we paid nearly $400 million in cash dividends, and announced this morning that our Board of Directors has authorized a quarterly dividend of $0.94 per share payable in March, equivalent to $3.76 on an annual basis. We continue to view our dividend as a way to expand the pool of potential

Regeneron's shareholders to include funds with a dividend mandate, while share repurchases will remain the primary means of returning capital to our shareholders.

I will conclude with our financial guidance for 2026. Consistent with what was provided at the JPMorgan conference a few weeks ago, we expect 2026 R&D spend to be in the range of $5.9 billion to $6.1 billion. The increase versus 2025 is driven by cost to support our expanding late-stage pipeline including new Phase 3 studies in oncology and heme-onc, our Factor XI antibodies, and our obesity program.

In addition, as you heard from George, we plan on advancing several new molecules into the clinic across a number of different therapeutic areas, including ophthalmology and I&I. We expect 2026 SG&A to be in the range of $2.5 to $2.65 billion, reflecting investments to support the ongoing launches of Libtayo and adjuvant CSCC and Lynozyfic in late-line multiple myeloma, as well as other potential launches, including cemdisiran in gMG.

We expect our gross margin on net product sales to be in the range of 83% to 84%. This guidance reflects a change in product mix, as well as cost to support expanding our bulk manufacturing capacity and fill-finish capabilities. We also expect 2026 capital expenditures to be in the range of $1.1 billion to $1.3 billion, primarily related to the ongoing expansion of the R&D facilities at our Tarrytown headquarters and investments in our manufacturing network to support our growing commercial portfolio and pipeline.

Finally, we expect our 2026 effective tax rate to be in the range of 13% to 15%. It is important to note that our 2025 effective tax rate benefited from a favorable tax audit settlement, which reduced our 2025 ETR by 1.2 percentage points. A full summary of our guidance can be found in our earnings press release published earlier this morning.

In conclusion, Regeneron's strong performance in 2025 positions us well to continue investing in our differentiated pipeline to deliver significant advances for patients and deploying capital to drive long-term value for shareholders.

With that, I'll pass the call back to Ryan.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

Thank you, Chris. This concludes our prepared remarks. We will now open the call for Q&A. (Event Instructions). Shannon, can we please move to the first question.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Alexandria Hammond, Wolfe Research.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

So clearly, there's a ton of interest in the upcoming readout for Libtayo + fianlimab. So in metastatic melanoma and adjuvant, any update on when we could receive this data beyond first half? Should we expect to get an adjuvant interim update with the metastatic?

And I guess as a follow-up, we know there are several interims for the adjuvant. So if we don't get an update on the adjuvant with the metastatic readout, when could we expect that next interim?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

Thanks, Alex. We don't really have any additional clarity right now on the timing for the advanced melanoma readout. First half is the best estimate at this time.

In terms of the adjuvant timing, that's also in the first half. They may coincide. They may not. Once we have the data, we will read it out shortly thereafter.

Operator

Chris Raymond, Raymond James.

Chris Raymond - Raymond James - Analyst

Just a question on Dupixent IP. I'm sure you're aware of Sanofi's commentary yesterday about potential for taking the runway out well beyond the current thinking, and I think their commentary took things out maybe to the 2040 or beyond range. I know you don't want to get too much detail here, Len, but maybe any commentary you can provide in light of those comments yesterday.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

No. No additional comments. I thought Sanofi did a good job laying out what the realm of possibilities are.

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

I think we should highlight the fact that we have also a lot of exciting follow-on opportunities in this space, particularly with our collection of what we hope will prove to be the best-in-class long-acting IL-13, IL-4, and IL-4, 13 bispecifics as well as what we call a new "Supi-Dupi" molecule, that is a new version of Dupixent that was naturally selected, that might have even more improved properties.

I think it's worth just highlighting again because a lot of people don't realize how special Dupixent is. In terms of -- not only its remarkable efficacy, how I mean, it delivers -- it doesn't just help a little. It really dramatically benefits patients across the eight now approved diseases. But the thing that I think is underappreciated is its incredible safety profile.

And I think that -- we've all seen now so many people are trying all sorts of other approaches to go after some of the same diseases like atopic dermatitis. We're seeing data, let's say, with OX40 and OX40 ligands which I think most people now realize they're somewhat disappointing not only from the efficacy side, but perhaps even most importantly, from the safety side. What people, I think, don't appreciate and understand is when we discovered Dupixent in this whole -- understood this whole pathway -- we realized that this was a specific pathway that was driving only allergic disease and it was a vestigial, largely a vestigial part of the immune system that was no longer required to fight most pathogens.

That's why unlike most other immunomodulators, it doesn't suppress overall immunity. When you suppress overall immunity with things like JAK inhibitors or things like OX40 ligand, you suppress everything and then you raise concerns and fears the possibility that the general immunosuppression will now subject the patients to more infections, which is generally actually what we see. And remarkably, with Dupixent, you don't see these sorts of things.

So you don't see generalized increases in infections. We don't have black box warnings on sections because we're not generally suppressing the immune system. We're only suppressing the part of the immune system, which is largely vestigial and is largely aberrantly activated in our modern world for reasons we have theories about, but won't get into now, that drive allergic inflammation. So it's a very special approach and you don't have to worry about, for example, getting Kaposi sarcoma or things like that with treatment with Dupixent.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - Goldman Sachs International - Analyst

Just a follow-up here on the frontline metastatic melanoma data in the first half. Is there any way you could frame for us how to think about the bar on hazard ratio here? And just any commentary about the PD-L1 expression levels of these patients as we look to this first interim read?

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

I think as we've discussed before, this study is largely powered to get an effect in terms of the primary endpoint, which is the PFS, analogous to the current combination standard of care. I hope -- of course, we hope that we might actually achieve better. We have two dose groups in the study and so forth. But we're also powered that if we were to hit at that level as the current standard of care, we would also hope to demonstrate a benefit as the study is appropriately powered to pick up an overall survival benefit. That is the minimum hopeful expectations, and we might see better than that as well.

Ryan Crowe: And regarding PD-L1 status of the enrollment, we are not -- we are screening patients, but we are not using it as an inclusion or exclusion criteria. There's no floor or cap, meaning the patients with high expression or low expression. So this population, we expect would represent a true first-line advanced melanoma population. And we look forward to the results.

Operator

Tyler Van Buren, TD Cowen.

Tyler Van Buren - Cowen and Company LLC - Analyst

I wanted to ask about broader R&D strategy. In your presentation, you have the slide where you divide your pipeline among the six therapeutic areas and I&I has expanded significantly as of late as well as ophthalmology, which is not terribly surprising, and I would argue is necessary given the history of the company. So would you say that these two areas in addition to oncology, will remain a bigger focus than the three others? Or are you committed to remaining relatively balanced across all six areas over the next few years?

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

Well, Tyler, thanks for bringing that up. First of all, I do want to point out that we are somewhat disappointed with the industry in that we invent a great leading drug like EYLEA and then you get literally dozens and dozens of companies just trying to come up with a me-too and take a little bit of that business or the same thing with DUPIXENT. They're just trying to come up and try to mimic Dupixent and maybe try to make a little incremental improvement.

What our goal is to really do what I think this industry should be doing, which is taking advantage of the most innovative approaches to come up with new drugs for new indications. And what we do is we take an agnostic approach that is generally guided by genetics, which has proven to be so successful in our history.

This is perhaps one of the first, if not the first company that bet its entire future on the power of genetics, first mouse and now human genetics. So we make our choices based on the most powerful available data and technology that can guide decision-making, which is large-scale human genetics, which allows us to use AI in ways that other people can't. And that allows us to pick targets.

So many of the targets that we've now described, for example, in ophthalmology and in immunology and inflammation, but across other areas as well are driven by the same kind of genetics that allows us to know whether Dupixent will work in an indication enough. That is the genetics says that if you're missing that genetic pathway, you're likely going to help your disease and if you have increases in that genetic path, you're going to get more of that disease. And that has proven very powerful for us to make decisions.

That's how we find indications. We are therapeutic agnostic, but obviously, we have capabilities broadly across all these areas, but we are very excited about these new programs because, like our previous successes, they are driven by human genetics, telling us that these targets if we can make, and we believe we have the most powerful technologies to address these targets, whether it'd be antibodies bispecifics, genetic medicines.

If we properly can target these genetically validated pathways, we can create new opportunities, new drugs for new indications, not just also protecting our existing franchisees by making sure that we always have the best anti-VEGF approach and portfolio. We have the best anti-allergy portfolio and so forth. When we want to break new ground, we're doing it across all these therapeutic areas, we're very excited about.

Operator

Dave Risinger, Leerink Partners.

David Risinger - Leerink Partners LLC - Analyst

So my question is for George. George, could you talk a little bit more about the souped-up version of Dupixent that's in development, including the event path ahead?

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

Yes. Obviously, Dupixent is a very unusual antibody. I don't know if everybody remembers the history of it, but some of the biggest companies in the world tried to make a molecule like Dupixent and failed in clinical trials, for example, Amgen using an inferior humanized mouse approach tried to make a Dupixent that is targeting the same receptor as we did and their antibody completely failed in all their clinical trials.

So Dupixent was apparently a special molecule. What we continue to do is use our best technologies, our best antibody generating technologies, starting with our best-in-class human immune system in a mouse generating millions and millions of versions over the last many, many years and testing them and comparing them.

And we think that we have one that might actually be in some ways, even better than Dupixent. It looks like it may be longer acting and they have some other advantages as well. So we're going to be moving it forward in the clinic as we announced and we'll be testing it, and we'll see whether indeed. We have been able to come up with an even better Dupi or Supi-Dupi, as we call it.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

And just to remind everybody that while not formally in the alliance with Sanofi, it is covered by the alliance, meaning that if it goes into full development that we'll be doing this with Sanofi.

Operator

Tazeen Ahmad, Bank of America.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

I wanted to spend a minute on geographic atrophy. You guys have a cohort, I believe, reading out in the second half of this year on your GA program. I think there was a lot of promise a few years back just given the number of patients with GA, but the two approved drugs have proven not to be able to get a ton of market share. So what do you think is differentiated in your program? Do you think that you'll need to show a visual acuity benefit? Or is it going to be, in your mind, it's just as good to show slowing of vision loss, given that you expect to have a better safety profile than both those drugs.

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

Well, let me just remind you that the first drug in the wet AMD space was Macugen, which was an aptamer. And if you compare the benefits that it provided compared to something like EYLEA, yes, it had a benefit, but it was just barely slowing down wet AMD disease as opposed to what we were able to do with EYLEA where we could actually reverse and improve vision even, and maintain or maintain the restored vision for years thereafter.

So obviously, the approaches that we have at our disposal, things like our antibodies and our siRNAs have historically proven to be much more powerful at blocking pathways, than technologies approaches such as aptamers, pegylated aptamers and pegylated peptides and so forth. So one possibility and opportunity, of course, is that by providing more profound blockade, one might actually see better benefit.

Another, of course, important aspect of our program is we are trying both systemic blockade as well as local blocking. So one of the problems with the existing therapies and why they're not so widely used, they're largely preventative, but they come with very dangerous side effects in that they can cause essentially problems that might result in immediate blindness like retinal vasculitis with occlusive vasculitis disease.

So, imagine you're taking something to prevent blindness that can actually cause blindness. So, the systemic approach, now of course, they may have its own problems, there's always risk. So they come with its own problems in terms of systemic infection, but it should be free from causing these local potential blinding risks in the eye. So you may end up either with better efficacy or the same efficacy but with a better safety profile in terms of avoiding these blinding risks.

And also, in the case of right now, the current treatments, most patients actually have bilateral disease. So you have to inject both eyes. And many of them also suffer now, and in fact, these drugs can actually, in some cases, cause wet AMD, progression of wet AMD, they need the injections in both eyes, and they also need injections with anti-VEGF.

So obviously, a systemic approach would avoid all these complications, you wouldn't have to give two sets of injections to both sets of eyes and so forth. So we're very excited because there's many, many opportunities here.

And I also remind you that we are testing both the monotherapy, in terms of cemdisiran alone, which works so spectacularly in myasthenia gravis, as well as the combination of cemdisiran with the antibody, which worked so beautifully and was required to optimally work in PNH.

We don't know because we, collectively, society, the medical system does not understand why in one case, you need complete blockade. In the other case, you need this sort of cemdisiran type of an effect. We're exploring both. So there's many, many, many ways to provide improved benefit for these patients who really need an improved way of treating their disease.

It could be something that really addresses the tremendous burden that's inflicted by bilateral disease, layered with anti-VEGF requirements and so forth. It could be better efficacy, it could be better safety. And it could also be for example, a systemic approach that does not completely

inhibit the complement system. So many, many, many ways to imagine delivering a better outlook for patients who really need it here, especially if more of them will choose to undertake this preventative approach.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Just to add one point, which George always emphasizes: VEGF is made locally. And so you give a local drug to block a local problem. The C5 is made systemically primarily in the liver. So it may require systemic blockade as opposed to intravitreal. But we have all the tools to dissect what the best approach is.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

And final note on this, Tazeen. The primary endpoint of our initial pivotal study is the growth rate in GA lesion area, but I would note that we do have a prospective secondary endpoint that will measure 15-letter loss of visual acuity. So we will have an endpoint that looks at visual acuity at year one and year two of this study, unlike incumbent therapies, who looked at this on a post-hoc basis.

Operator

Geoff Meacham, Citi.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Thanks, for the question. I just want to talk about EYLEA HD for a sec. Maybe just talk about the trends for growth for this year. I wanted to get maybe your perspective as you kind of exit '25 and going to '26, the sources of growth with regard to new patients, switches versus competition? And then on the prefilled syringe related, would you characterize that as kind of a tipping point? Are there ophthalmologists, are there practices that are sort of waiting for that? I want to get a sense for how much of a gating factor that is to ultimate demand.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

And I'm going to start with the last portion on EYLEA HD and the prefilled syringe potential approval that we talked about today. And as you know from the numbers that we shared, we're making good progress with EYLEA HD in the marketplace, the recent label enhancements with Q4 weekly dosing in RVO have been very well received. And of course, prefilled syringe, as I mentioned, will be a convenience factor for offices.

So some that find that to be incredibly important. Obviously, we'll have a new opportunity to use EYLEA HD, but obviously, we have a lot of users today. It will only get better when we get and potentially have the prefilled syringe approval.

Operator

Akash Tewari, Jefferies.

Akash Tewari - Jefferies LLC - Analyst

On your PCSK9 GIP/GLP combo, can you talk about the co-formulation here? How are you able to deliver both drugs in a single auto-injector versus something akin to an [on-body] infusion? And what are the chances you partner this asset out to share the development cost? Can you characterize any of those discussions so far?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

We don't comment on the status of discussions. We're always open minded to deals that enhance our shareholder value.

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

But as you touched on it, that's the magic, and that's the secret of our capabilities best-in-class formulations group that delivered unprecedented formulation capability with EYLEA and EYLEA HD. It's the same people doing the same things that have figured out how to magically be able to get into an auto injector a very similar [to] injection is just for GLP, similar sort of volume, for both the antibody and a peptide.

And so we're very excited because, Len's the one who, he put it this way. Imagine inventing a GLP, that in addition to doing what -- the leading GLP does, it also just lowers cholesterol, bad cholesterol, by 50% to 60%... Wouldn't everybody want to take that, because we understand that so many people who suffer from obesity also suffer from cardiovascular risk. And while losing weight helps your cardiovascular risk, it also is dramatically driven by the bad cholesterol, which weight loss doesn't appreciably impact.

So it's a very, very exciting opportunity. We're very excited that our scientists were able to figure out how to make this magic happen, and we think it's going to offer patients a really differentiated way of not only having their desirable weight loss, but also dramatically improving their hyperlipidemia associated cardiovascular risk as well. So we're very, very excited to be able to offer this opportunity and move forward with our clinical program to see if it's a reality.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

Okay. We have time for two more questions, Shannon.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Bayer is going to be presenting some Phase III SSP data for their oral Factor XI inhibitor, asundexian, next week. Just wondering anything you'll be focused on in that data set as it pertains to your Factor XI antibody program in terms of development, et cetera.

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

Yes. I mean it is very hard to compare these small molecules with antibodies. As we know, historically, and as is the case here, small molecules suffer from both lack of specificity that we know they inhibit multiple proteases, including the target of interest here. And they also have off-target effect as well.

And so, the hope here is by having an antibody, which we think is very, very different than a small molecule, the specificity as well as the efficacy may allow you have a very different profile where you will actually have better anticoagulation, but also, hopefully, better safety, less bleeding, which we think what it's all about. And so there will be some read-through, there will be some usefulness to following that.

On the other hand, we believe our antibody has a very substantially differentiated and potentially advantageous profile. And so the key thing is if our antibodies really can deliver what we believe they can with dramatic decreases in the overall bleeding risk, then they should allow

somebody to essentially get an occasional shot once after a procedure, let's say, or once a month [eventually], things like that, that won't require these patients to be either having worried about making sure they stay on their meds or monitoring them and so forth.

So very different opportunity. Of course, there's some read through, but we think our antibody is going to be very different.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

Shannon, let's go to the last question, please.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - BMO Capital Markets - Analyst

I'd love you to talk a little bit about the confidence that gives you to move your GLP-1/GIP to Phase III clinical trials globally, just given how rapidly this market is evolving. Put it another way, what's differentiated about this asset from currently available standard of care and other advanced assets in development?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

So I think if you go back and listen carefully to what George is saying that the biggest advance here from our perspective is the ability to combine this with our PCSK9 inhibitor, there are only two approved PCSK9 antibodies and the ability to combine this antibody with these peptides in the same syringe at the same dosing interval, I think that's highly differentiated for the 15% -- the 50% or more people who are obese and have high cholesterol.

We know several hundred thousand people already take both a GLP and a PCSK9 inhibitor. And that's without the convenience of having to put that together in a single shot and without really focusing any marketing on the obese group. So I think, Evan, that's what the core of the differentiation could be.

Obviously, we're considering putting it together with other assets in our pipeline, other combinations; we can't imagine directly competing, but I do think we should have data that's competitive to the best-in-class. But the commercial strategy is not directly compete, with that combination. George, do you want to add something?

George Yancopoulos - Regeneron Pharmaceuticals Inc - President, Chief Scientific Officer, Director

Yes. So remember, one of the reasons we have confidence is [ola] has already been extensively studied in China. And it's designed to be and the clinical data suggests it is very tirzepatide-like in its efficacy and safety profile when compared to the same population. And it is already in advanced Phase III trials in China.

That's why we think we have very much a tirzepatide-like or a best-in-class type agent. But as Len said, we don't necessarily want to just compete just for the weight loss. A lot of people are just so focused on the weight loss and they're trying to say, let me get a little bit more weight loss. A little less nauseousness, a little less vomiting.

They're all competing around the weight loss. They're all fighting in that space. We want to take this to a whole other place where we're adding a completely new benefit, a completely different benefit to the weight loss. So let everybody else fight for an extra 1% or 2% of weight loss, we're going to give you 50% to 60% LDL lowering with the associated expected cardiovascular benefit.

That's highly differentiated. So we didn't get this to compete just by itself in the obesity space, though we think we have an agent here that is very similar to the best-in-class type of reagent. It's all about the combinations.

And the first combination that we're rolling out, we think is this very, very exciting one. And frankly, honestly, every obese patients should take it, okay, regardless of their lipid status because lower lipids is better. And that would be better. It would, frankly, be better for the entire population.

Why do we know? Because cardiovascular disease driven by hyperlipidemia is still the number one killer in America and people are not taking it. So it may be almost a Trojan horse. Imagine, they just -- they want to lose their weight and they're not even going to realize that they're going to be helping their hearts, they can decrease the overall rate of cardiovascular disease and death in this country. A Trojan horse to really make an impact for society.

This is what we're trying to do. Everybody, frankly, in America should be on a PCSK9. This is a way to actually do it, and do it in a way that people will actually want to take. And we think we have a variety of other ways, not to compete on the weight loss side, but to give another important benefit on top of the weight loss.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategic Analysis

Thank you, George, and thanks to everyone who dialed in today for your interest in Regeneron. We apologize for those remaining in the Q&A queue. We do not have a chance to hear from today. As always, the IR team is available to answer any remaining questions that you may have. Once again, have a great day and a nice weekend.

Operator

This concludes today's conference. Thank you for your participation. You may now disconnect.
