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REGN.OQ - Q3 2024 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good morning, and welcome to the Regeneron Pharmaceuticals third-quarter 2024 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 IR & 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 third-quarter 2024 earnings conference call. An archive and transcript of this call will be available on the Regeneron Investor Relations website shortly after the call ends.

Joining me on today's call are Dr. Leonard Schleifer, Board Co-Chair 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, Senior Vice President and Chief Financial Officer. After our prepared remarks, the remaining time will be available for your questions.

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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 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-Q for the quarter ended September 30, 2024, which was filed with the SEC this morning.

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 accessed on the Regeneron Investor Relations website.

Once our call concludes, Chris and the IR team will be available to answer any further questions you may have.

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

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

Thank you, Ryan, and thanks to everyone for joining today's call. Regeneron had a strong quarter, highlighted by 11% revenue growth and 8% non-GAAP earnings growth along with continued investments and advances across our broad pipeline.

For my remarks today, I'd like to review some of our key performance drivers and then briefly discuss near-term pipeline opportunities. After my remarks, George will provide further updates on our pipeline. Marion will then review our commercial performance. And finally, Chris will detail our quarterly financial results.

Third-quarter 2024 total revenues grew 11% to $3.72 billion, primarily driven by higher Sanofi collaboration revenues, reflecting the continued strong performance of Dupixent, continued growth for Libtayo and growth for combined EYLEA HD and EYLEA in the United States. DUPIXENT had another strong quarter with global revenues up 24% on a constant currency basis to $3.8 billion.

With this latest quarterly result, global DUPIXENT revenues are annualizing at over $15 billion, with over 1 million patients currently on treatment around the world across seven approved indications in patients as young as six months. In September, the FDA and Chinese regulators, both approved DUPIXENT for patients with uncontrolled COPD and an eosinophilic phenotype.

These approvals, along with the approval in Europe in June, enabled DUPIXENT to address several hundred thousand patients that are currently uncontrolled on maximum inhaled triple therapy. As Marion will discuss, early launch indicators have been positive with strong physician interest and initial favorable US payer coverage decisions.

As the only approved biologic for COPD, we anticipate these ongoing launches will represent a meaningful driver for DUPIXENT continued growth in 2025 and beyond. Net product sales for EYLEA HD and EYLEA combined were $1.54 billion, up 3% compared to the prior year.

EYLEA HD generated $392 million in its fourth full quarter on the US market. EYLEA HD and EYLEA maintained anti-VEGF category leadership with combined share of approximately 44% compared to 45% in the second quarter of 2024.

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As Marion will discuss, we are focused on increasing EYLEA HD share while preserving share for EYLEA in an increasingly competitive category, including a near-term biosimilar aflibercept 2-milligram launch and the recent launch of a branded prefilled syringe. The EYLEA HD clinical profile continues to look differentiated relative to EYLEA and other anti-VEGF products.

As George will soon detail, results from the recently reported PHOTON extension study in DME further underscore EYLEA HD's unprecedented durability while achieving vision gains and the safety profile typically seen with EYLEA.

Moving to our pipeline. We are excited about several upcoming readouts later this year and in 2025 to further inform programs that could support significant long-term growth opportunities. By year-end, we expect to share interim Phase II lung cancer data for the combination of fianlimab, our LAG-3 antibody, plus Libtayo as well as proof of concept data for our Factor XI antibodies in thrombosis, both of which will inform our Phase III plans.

Looking ahead to 2025, we expect to read out the results of our pivotal AERIFY studies for itepekimab our IL-33 antibody in former smokers with COPD.

We will also learn more about potential opportunity to improve the quality of weight loss in obese patients on semaglutide by blocking myostatin and or Activin A. Pivotal data for the fianlimab-libtayo combination in first-line metastatic melanoma are also anticipated, which could support regulatory filings in this setting. In addition, we expect to provide periodic updates on our novel treatment approach for reversing severe food allergies involving linvoseltamab, our BCMA by CD3 bispecific and DUPIXENT.

In closing, our pipeline continues to generate innovative and differentiated opportunities and now has approximately 40 programs in clinical development spanning many distinct therapeutic areas. We view our pipeline as the key to driving medium- and long-term shareholder value and our antibody platform technologies and the Regeneron Genetics Center database of over 2.5 million sequenced exomes linked to the de-identified health records is expected to provide an enduring competitive advantage that we will continue to invest in.

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

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

Thanks, Len. I'll start with EYLEA HD and the data from the PHOTON extension study in diabetic macular edema, that were recently presented at the American Academy of Ophthalmology Annual Meeting. In addition to demonstrating that the vision gains and anatomic achievements or improvements with EYLEA HD over two years could be sustained over a third year of treatment with EYLEA HD, the results of the extension study provided the first data for patients who switched from EYLEA to EYLEA HD.

For these switch patients who were dosed for 88 weeks with EYLEA every eight weeks following five initial loading doses, retinal fluid reaccumulation was substantially slower after a single EYLEA HD injection at week 96 as compared to these patients' previous rate of fluid accumulation with our EYLEA 2 milligram. In addition, after one year of EYLEA HD treatment, 83% of these switch patients had a last assigned dosing interval of at least 12 weeks.

Importantly, mean visual and anatomic achievement improvements achieved with EYLEA were sustained following the switch to longer dosing intervals with EYLEA HD. For PHOTON, patients assigned to EYLEA HD treatment groups at baseline, visual gains and anatomic improvements achieved in the first two years were all sustained in three years, but many of these patients were able to meaningfully extend their dosing interval.

At the end of three years of treatment, nearly half were assigned a final dosing interval of at least 20 weeks. In summary, EYLEA HD achieved consistently longer dosing intervals as well as notably slower fluid reaccumulation as compared to EYLEA, a first for the category. When all other anti-VGEF agents were compared to EYLEA in head-to-head studies, these agents did not demonstrate slow fluid reclamation.

The safety profile of EYLEA HD has continued to be similar to EYLEA through three years and remain generally consistent with the known safety profile of EYLEA HD in its pivotal trials. Altogether, these data support our belief that our EYLEA HD has a best-in-class profile.

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Now moving to DUPIXENT, which achieved several first and only clinical and regulatory milestones since our second quarter earnings call in early August. First, we are pleased to receive US regulatory approval for DUPIXENT as an add-on maintenance treatment of adult patients with inadequately controlled COPD and the eosinophilic phenotype marking the first ever biologic approved to treat this disease and represent Dupixent's 6th indication approved in the United States.

Also in COPD, as Len mentioned, we're looking forward to pivotal results in the second half of next year for itepekimab, our interleukin-33 antibody. If approved in the United States, EU and Japan, itepekimab could address approximately 1 million former smokers with COPD regardless of eosinophilic phenotype. In terms of potential future indications for DUPIXENT, the Phase 3 ADEPT trial in moderate to severe bullous pemphigoid patients met the primary and all key secondary endpoints.

Five times more Dupixent patients achieved sustained disease remission at 36 weeks compared to those on placebo. DUPIXENT patients were far less likely than patients on placebo to relapse following steroid taper or need rescue therapy during the treatment period.

Based on these data, DUPIXENT is the first and only biologic to achieve significant improvements in disease remission and symptoms in bullous pemphigoid, and is the first medicine to show significant steroid sparing in this disease. We anticipate this Phase 3 ADEPT trial will support regulatory approvals around the world with the U.S. supplementary BLA submission expected by the end of the year.

We also announced results of a second Phase III study of DUPIXENT in biologic-naive patients with chronic spontaneous or uticaria, or CSU, confirming the results of a prior Phase 3 study in the same population. In this most recent study, treatment with DUPIXENT met the primary endpoint and in addition, resulted in a nearly 50% reduction in itch and uticaria activity scores from baseline with 30% of DUPIXENT treated patients reporting a complete response or no uticaria by week 24 compared to only 18% of those on placebo.

These data, along with the data generated in the first CSU study evaluating biologically naive patients supported our supplementary BLA resubmission earlier this month, and we look forward to a potential FDA approval early next year which would mark the first targeted therapy for CSU in a decade. Moving to oncology, starting with Libtayo, which provides a best-in-class foundation for combinations with our other oncology assets.

At the World Conference on Lung Cancer, we announced five-year results from the final prespecified overall survival analysis of the Phase 3 EMPOWER Lung 1 trial, which evaluated Libtayo monotherapy as a first-line treatment for adults with advanced non-small cell lung cancer with more than 50% PD-L1 expression.

The late-breaking data showed that at five years, Libtayo monotherapy nearly doubled median overall survival and reduced the risk of death by 41% compared to chemotherapy. There were also no new safety signals observed at five years among those patients.

These five-year outcomes data in advanced non-small cell lung cancer compare favorably cross trial to other PD-1 or PD-L1 antibodies and further support Libtayo's position as the anti-PD-1 backbone for Regeneron's ongoing oncology efforts.

Moving on to one such Libtayo combination. At the recent ESMO meeting, we presented updated results evaluating fianlimab, our LAG-3 antibody in combination with Libtayo in adults with advanced melanoma across three independent expansion cohorts of our first-in-human multi-cohort trial. With longer follow-up, these latest results showed persistent and deepening tumor responses across all cohorts. In a post hoc, pooled analysis, 57% of patients responded with 25% of these patients achieving a complete response.

Median progression-free survival was 24 months. Median OS was not reached in any of the individual cohorts or when the results were pooled. These fianlimab-libtayo proof-of-concept data showed nearly double the complete response rate with more than 5 times greater median PFS than previously reported for anti-PD-1 monotherapies.

The fianlimab-libtayo combination also showed robust clinical activity in subpopulations where there is currently no established standard of care, such as in patients previously treated with the anti-PD-1 therapy in the adjuvant or neoadjuvant setting. Of the 13 patients in this subgroup, 6 patients or 46% responded to therapy.

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Among patients receiving any adjuvant or neoadjuvant systemic therapy, 11 of 23 or 48% responded to the therapy, including six complete responses. The safety profile of the fianlimab-libtayo combination was generally consistent with the safety profile of the libtayo monotherapy and other anti-PD-1 agents, except for higher rates of treatment-related adrenal insufficiency.

Ever since the exciting early data with individual checkpoint inhibitors were presented more than a decade ago, it's been widely hypothesized that combining multiple classes of checkpoint inhibitors might meaningfully enhance antitumor activity without exacerbating safety issues.

We have progress to date has been broadly disappointed. We believe the results generated so far in advanced melanoma for fianlimab and Libtayo suggests it might be the first checkpoint inhibitor combination to demonstrate meaningful additive clinical benefit without significantly exacerbating safety.

Our ongoing randomized Phase 3 trial of fianlimab-libtayo versus pembrolizumab monotherapy in preciously treated, unresectable, locally advanced or metastatic melanoma is ongoing with pivotal data expected to read out next year.

In addition to melanoma, we're exploring this combination in a variety of other cancer settings that have historically been responsive to anti-PD-1 therapy, including lung cancer, initial Phase II data for which are expected to read out by the end of this year.

Next, to our bispecifics for hematology oncology. We are pleased that the European Commission approved Ordspono or odronextamab, our CD20xCD3 bispecific for relapsed/refractory follicular lymphoma and diffuse large B-cell lymphoma, marking the first regulatory approval from our bispecific antibody platform. We continue to work on enrollment of our confirmatory studies to support resubmission of our BLA for follicular lymphoma, which we now expect to achieve in the first half of 2025.

Linvoseltamab, our BCMAxCD3 bispecific for myeloma, data from the ongoing linker MM1 study in patients with relapsed/refractory multiple myeloma continue to mature with responses continuing to deepen. Recall that 14 months of median follow-up among 117 patients, linvoseltamab continues to demonstrate a potentially best-in-class profile in terms of efficacy, safety, dosing as well as hospitalization burden with 71% of patients responding to therapy and 50% achieving a complete response or better.

Perhaps the most differentiating about our clinical development program for both odronextamab and linvoseltamab, in earlier line settings is our plan to evaluate each agent as monotherapy as well as in limited combinations.

While competing CD20 bispecifics are evaluating combinations with lenalidomide or lenolidomide plus rituximab in first-line follicular lymphoma regardless of tumor burden, our Phase 3 OLYMPIA 1 study is evaluating odronextamab monotherapy compared to R-CHOP.

Similarly, in first-line multiple myeloma, our ongoing Phase I/2 LINKER-MM4 study is evaluating linvoseltamab monotherapy. Furthermore, we are also conducting Phase 2 studies for linvoseltamab monotherapy in precursor conditions such as smoldering myeloma and monoclonal gammopathy of undetermined significance, or MGUS, in an attempt to prevent progression to myeloma.

Now to our non-oncology hematology pipeline, starting with our C5 program, which is the first combination of an antibody and siRNA that targets the same protein. We expect to present updated results for one potential indication, paroxysmal nocturnal hemoglobinuria, later this year and expect to read out pivotal results and generalized myasthenia gravis in the second half of next year.

We also initiated our Phase 3 program in geographic atrophy, in dry age-related macular degeneration, with initial patient screening now underway. We believe that our systemic approach has several significant advantages over currently approved agents. First, it may avoid the risk of rare but severe eye inflammation and irreversible vision loss that has been observed with currently approved intravitreal treatments. And our systemic approach has the potential to offer convenient treatment of bilateral disease as well.

Regarding our Factor XI antibodies, we remain on track to report top line results by year-end of our proof-of-concept studies for our A2 domain targeting and our catalytic domain targeting antibodies in the setting of prevention of venous thromboembolism following knee replacement surgery.

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Results of these studies will inform whether to proceed to registration-enabling studies with one or both of these antibodies, with the possibility that both antibodies will advance to Phase 3, but in different thrombosis indications or patient populations.

In summary, we continue to drive forward our innovative development pipeline and anticipate reading out several pivotal and proof of concept data sets in oncology, immunology, obesity, hematology and genetic medicines over the next 12 to 18 months while our early research engine has never been more productive, with multiple novel programs potentially advancing into the clinic over the same time frame.

And with that, I will turn the call over to Marion.

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

Thank you, George. Our third quarter performance demonstrates Regeneron's ongoing leadership across therapeutic categories. We continue to advance the strength and diversity of our product portfolio. And as George described, our pipeline is advancing with several potential regulatory filings and approvals on the horizon, creating both near and longer-term opportunities. I'll begin with EYLEA HD and EYLEA.

In the third quarter, combined US net sales were $1.54 billion, a 3% year-over-year increase. EYLEA HD and EYLEA net sales were favorably impacted by approximately $40 million as a result of higher wholesaler inventory levels for EYLEA HD at the end of the third quarter partially offset by lower inventory levels for EYLEA.

As a result, we expect fourth quarter EYLEA HD net sales to be negatively impacted as this increase in wholesaler inventory is absorbed. Together, EYLEA HD and EYLEA captured 44% of the total anti-VEGF category in the third quarter, demonstrating retina specialists experience and confidence in both brands.

EYLEA HD net sales grew 29% sequentially in the quarter to $392 million, driven by ongoing adoption across treatment experienced and treatment-naive patients. As treatment experience grows retina specialists pointing to EYLEA HD's durability, coupled with its efficacy and safety as important clinical differentiators. Recent late-breaking data presented at American Academy of Ophthalmology's annual meeting highlighted EYLEA HD's potential best-in-class profile.

As George highlighted, diabetic macular edema patients who switched to EYLEA HD consistently achieved longer dosing intervals and slower retinal fluid reaccumulation. While we anticipate the anti-VEGF category to continue to be highly competitive with both branded and biosimilar products in the marketplace, we plan to further strengthen the EYLEA HD product profile through the anticipated launch of our differentiated prefilled syringe by mid-2025 and a potential approval of the RVO indication, [for which] registration-enabling data are expected by the end of this year.

In the first year since launch, positive physician and patient experience has propelled EYLEA HD to achieve billion-dollar brand status. With additional growth catalysts expected in 2025, our team is focused on helping even more patients benefit from EYLEA HD.

Turning to Libtayo. We continue to make significant progress in the third quarter with global net sales increasing 24% year-over-year on a constant currency basis to $289 million the US net sales grew 35% to $195 million. In non-melanoma skin cancer, our work to expand the immunotherapy market has resulted in an even greater number of Libtayo patients.

And in lung cancer, we continue to gain market share. Outside the US, net sales were $94 million, which does not include $20 million in distributor purchases that shifted to the fourth quarter. We continue to see opportunities to increase Libtayo demand in 2025 with new launches in several markets. And finally, to DUPIXENT, which continues its remarkable growth trajectory. In addition to the positive data readouts and regulatory updates that George mentioned, we've reached an impressive milestone.

DUPIXENT has now surpassed 1 million patients on therapy across seven indications worldwide. In the quarter, DUPIXENT achieved global net sales of $3.8 billion, a 24% year-over-year increase on a constant currency basis, driven by uptake across all indications, age groups and geographies. In

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the US, net sales grew 19% year over year to $2.8 billion, and DUPIXENT continues to be the number one prescribed biologic for new-to-brand patients in all of its approved indications.

It's widely recognized by prescribers that DUPIXENT's differential dual mechanism of action targeting IL-4 and IL-13 addresses the underlying cause of these type 2 diseases. Demand is strong across the blockbuster indications of atopic dermatitis, asthma and nasal polyps, and there is opportunity for ongoing market penetration based on unmet patient need.

Uptake is also increasing across our recent US launches, new-to-brand prescriptions for prurigo nodularis are up approximately 30% compared to the prior year and EOE new-to-brand prescriptions, including the pediatric indication, are up approximately 40%.

In September, DUPIXENT's label was expanded to include patients as young as 12 years of age who have inadequately controlled chronic rhinosinusitis with nasal polyps, and we estimate approximately 9,000 additional US patients can now benefit from DUPIXENT. In recent months, DUPIXENT has been approved to treat COPD in more than 30 countries.

We are excited about the opportunity to extend DUPIXENT's leadership in respiratory KR, which we estimate may benefit more than 300,000 patients in the US alone with inadequately controlled COPD and an eosinophilic phenotype. In the first weeks of the US launch, we've been encouraged by the enthusiasm from physicians and patients for DUPIXENT as a treatment option in this underserved population.

Educational efforts are underway to highlight the importance of type 2 inflammation in COPD and supporting patient identification by prescribers and motivating patients to speak with their physician about DUPIXENT. We've made significant progress in securing access and reimbursement for patients, many of whom are covered under Medicare.

With DUPIXENT's unique clinical profile and first biologic to market advantage, we anticipate the COPD indication will drive meaningful growth for DUPIXENT. In summary, DUPIXENT continues to transform standard of care in lives of patients worldwide.

In addition to current approvals, we look forward to future potential launches in diseases, including COPD in Japan, pediatric EOE in the EU, and chronic spontaneous urticaria in the US, as well as global regulatory filings for bullous pemphigoid.

In conclusion, our commercial team continues to deliver on our goal to provide Regeneron medicines to an ever-expanding number of patients worldwide. There is significant growth potential within the current and future indications of our medicines and our pipeline provides meaningful opportunities for growth.

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

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior 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. Regeneron delivered strong financial performance in the third quarter with continued execution driving top and bottom-line growth. Total revenues increased 11% year over year to $3.7 billion, primarily driven by higher Sanofi collaboration revenue, continued growth for Libtayo and US growth of total EYLEA HD and EYLEA.

Third-quarter net income per share grew 8% from the prior year to $12.46 on net income of $1.5 billion. Third-quarter revenues from our Sanofi collaboration were $1.3 billion inclusive of $1.1 billion related to our share of collaboration profits.

Regeneron's share of profits grew 26% versus the prior year driven by volume growth for DUPIXENT and improving collaboration margins, with collaboration profitability reaching another all-time high in the third quarter.

The Sanofi development balance was approximately $1.8 billion at the end of the third quarter, reflecting a reduction of approximately $200 million from the end of the second quarter and approximately $520 million from the end of 2023. Moving to Bayer.

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Third quarter ex-US net sales of EYLEA and EYLEA 8 mg were $932 million, up 9% on a constant currency basis versus the prior year. Total Bayer collaboration revenue was $391 million, of which $368 million related to our share of net profits outside the US. We recorded $35 million of sales for Inmazeb, our antibody cocktail for Ebola, in the third quarter related to deliveries to the US government under our existing agreement.

We still expect 2024 Inmazeb sales to be in line with 2023 sales of approximately $70 million. Other Revenue in the third quarter was $114 million. We expect Other Revenue will increase sequentially in the fourth quarter of 2024, but on a full year basis, is expected to be lower than 2023. Now to our operating expenses. R&D expense was $1.1 billion in the third quarter.

The increase in R&D expense versus the prior year was driven by ongoing investments in our pipeline, including late-stage oncology programs and increased clinical manufacturing costs to support ongoing programs. SG&A grew 15% from the prior year to $613 million in the third quarter, primarily reflecting ongoing investment to support the launch of EYLEA HD.

Third-quarter 2024 gross margin on net product sales declined to 89% compared to 90% in the prior year, primarily reflecting higher start-up costs for our fill/finish manufacturing facility.

Now to cash flow and the balance sheet. Regeneron generated approximately $2.6 billion in free cash flow through the first nine months of 2024 and ended the quarter with cash and marketable securities less debt of approximately $15.6 billion.

Through the first nine months of 2024, we have repurchased over $1.6 billion of our shares, including $738 million in the third quarter. Given our long-term growth potential, we continue to see share repurchases as an efficient use of capital and had approximately $2.9 billion available for repurchases as of the end of the third quarter.

Finally, we made some minor changes to our full year 2024 financial guidance based on our year-to-date results, narrowing ranges across most guidance items. A complete summary of our latest full year 2024 guidance is available in our press release issued earlier this morning.

In summary, Regeneron delivered strong financial results in the third quarter, and our focused investments continue to position us to drive long-term growth.

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

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

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Chris Schott, JPMorgan.

Taylor Hanley - JPMorgan - Analyst

This is Taylor Hanley on for Chris Schott. We just had a question on EYLEA. So with Amgen launching their biosimilar, how are you thinking about EYLEA going forward? And what levels can you pull to potentially accelerate conversion to high-dose EYLEA? And how are you thinking about pricing for the franchise more broadly?

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Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

So Marion may have some extra comments on that. But look, EYLEA is a fantastic product. We have delivered probably somewhere in the neighborhood of around 100 million or more injections with EYLEA. And so the performance and safety of the product, our transparency with safety issues that may arise over the past decade, I think, has given physicians and their patients, a lot of comfort with EYLEA, and you see some stickiness of that product.

Nonetheless, we think that EYLEA HD is a differentiated product, and we are continuing to work on using the standard approaches of education and informing the doctors about the potential use in patients, providing them with more data, as George referred to, some of the long-term data is rather striking. We know that there is a biosimilar in the market for EYLEA, not for EYLEA HD, and we know it will be competitive, but we think we'll be able to compete well.

Operator

Evan Seigerman, BMO Capital Markets.

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

Maybe we'll come back to Evan. Shannon, why don't we go to the next.

Operator

Tyler Van Buren, TD Cowen.

Tyler Van Buren - TD Cowen - Analyst

Congrats on the quarterly results and all the progress. Can you reiterate your confidence in EYLEA HD quarter-over-quarter growth going into Q4 despite the negative impact due to wholesaler inventory? And are you seeing a tailwind with the overall franchise yet due to the removal of product from a major supplier of Avastin?

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

So let me take both of those, Tyler. First, as I described to you the performance in the quarter showed growth for EYLEA and EYLEA HD. And then more specifically to your comment related to EYLEA HD, we have very strong confidence in the product's profile, the interest of the retina community, the quality of our safety, clinical data, durability are all being seen. But I did want to call out that we did see an inventory matter take place in the quarter that I wanted to comment on. We're not going to give fourth quarter guidance.

But specifically, I wanted to be an awareness related to the favorable impact of approximately $40 million as a result of higher wholesaler inventory levels for EYLEA HD at the end of the third quarter, partially offset by wholesaler inventory levels that were lower -- a bit lower on EYLEA. So we wanted to share that information, but certainly we have every confidence in EYLEA HD performance, but that inventory obviously will be used in the fourth quarter of this year.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

Looking forward, Tyler, to next year, I think Marion may have mentioned that bringing our prefilled syringe to market around -- by the middle of the year, I think, will be a nice catalyst for acceleration I think that we've taken a lot of pain to make sure that when we bring something to the market,

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it's going to withstand the test of millions and millions of injections. Our competition may have brought something forth that, for example, needs a filter needle because they must be trying to filter something out, we presume.

We are hoping to not have to have that issue and we are looking very carefully to make sure that we bring something that really will not result in inflammation. Remember that in this marketplace, products have been really killed if you have too much inflammation, which leads to potential for retinal vasculitis and even occlusive retinal vasculitis with loss of vision.

So we are very sensitive to all that. I think doctors will be sensitive to that with any new launch despite biosimilars. They're going to probably want to look carefully and they know EYLEA and EYLEA is something I think they can trust in. So we will be methodical about how we do this, and we're in this for the long game.

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

Tyler, I also want to cover your question related to Pine and they are coming away from support of Avastin in the marketplace. So we're very well aware of that.

And certainly, our teams are actively involved in retina offices supporting staff and working with them on any challenges that present. I would share that at this point, there still is Avastin inventory from Pine in the market. I think it's anticipated to run out within a couple of weeks. So we haven't seen a material uptake in EYLEA HD or EYLEA related to that yet, but we're staying very close to that situation and support to our customers.

Operator

Brian Abrahams, RBC Capital Markets.

Brian Abrahams - RBC Capital Markets - Analyst

On the HD prefilled syringe, can you talk about the potential inflection in use that that could catalyze next year, including how the differentiation of that prefilled string might resonate. And maybe also elaborate on some of the gating factors to development there, timeline sounds like they've been pushed out a little bit.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

Yes. As I said, we anticipate bringing that to the market by the middle of next year. I believe already or almost immediately, Bayer will be bringing the same device to the market with EYLEA HD outside of the United States. So we have a high degree of confidence. There are some additional requirements that you have to do inside the United States, which we're working through.

And as I said, we think we'll have a differentiated product opportunity there. So you're right, Brian, it's possible that there could be an inflection when that comes to market because there is a preference for the prefilled syringe.

Operator

Carter Gould, Barclays.

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Carter Gould - Barclays - Analyst

Maybe for Leonard and Chris, just now in the wake of Amgen potentially being on the market, has this driven any sort of change in, sort of, conceptually how you're thinking about the pace of R&D investments going forward or your capital allocation priorities, you're potentially leaning into buybacks or further rolling out or delaying a potential dividend? Any color on that front would be helpful.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

Well, we're -- they say imitation is the best form of flattery. So we're glad to be flattered by Amgen that they're spending their time imitating our products. We're spending our money trying to bring new products to market which where we think is what this industry really is built for. It's really not built -- biosimilars are fine, but we think the industry is best built and Regeneron is best built to bring innovative products to market. As I mentioned, we have over 40 products in clinical development, many of which are in Phase III.

As George detailed, there are a lot of exciting programs in there with lots of data readouts. We're not going to gate spending based upon a biosimilar entry, we're going to spend what's appropriate based upon the opportunities that we see. We have a strong balance sheet. We have good earnings. We have the capability to make significant investments.

And George has built, I think, the most prolific research and development organization in the industry. So it would be fool hardy not to invest in that, and you'll probably see some investments to go up. The big question in this game always is, will these investments pay off. I think our past performance, while not guaranteeing to anything in the future, the more than 10 or 12 products that George and gang have bought market there's a good harbinger of things to come.

And as I said, with more than 40 things in development, we couldn't be more excited about our future product profiles.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - Morgan Stanley - Analyst

Great. I know you have some upcoming Factor XI readouts here before the end of the year. Maybe you could just tell us what you're looking for to make the decision about whether to advance those into a Phase III program and how you're considering them versus each other and also versus the standard of care.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

Yes. This is George. We're very excited about our Factor XI program because we think it's very different from anything else that's out there. we chose to take a different approach where we attack Factor XI in two different ways, what we call our A2 domain antibody and our catalytic domain antibody. Our A2 domain antibody is not a complete blocker of Factor XI. It actually is more like a complete Factor XII blocker.

It's expected to not have as profound effect on the coagulation pathways, but to have a much milder safety profile. In contrast, we believe that our catalytic domain antibody is the best-in-class blocker of Factor XI it will come with the best ability to control coagulation among all agents that are attacking this pathway. But of course, it will also have presumably a higher safety load than our A2 domain antibody.

So we think it's very exciting to have these two parallel but very distinguished approaches. We actually hope to be able to show that both of these substantially control thrombo formation in the clinical trials that we now have running.

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And we hope to then in the future, decide based on how well they each control and their expected safety profile, we expect the ability to consider multiple indications that we can evaluate each one for different potential indications for one versus the other.

So these are sort of a pipeline in and of themselves, able to attack, we believe, a variety of different coagulation settings, and each one of them can be used differentially and provide a different profile of efficacy versus safety as might be needed in the different clinical settings.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

One second. I just wanted to add to that. What George has taught me over the years is that not all antibodies are created equal. And I would not -- not all blockers of the pathway are created equal. And we have in-house pharmacodynamic data, which suggests that the antibodies that Regeneron has created and selected, we really have a competitive advantage in how we do that, outperform other Factor XI antibodies or small molecule competitors.

Of course, with the small molecule competitors, it's hard to get to the high dose because you have off-target problems. And with the antibodies, people can't always get the best antibodies. We think we have the technology and these things are not all created equal. So the proof of the pudding will be in the eating when we get the data and see how that performed.

Operator

Chris Raymond, Piper Sandler.

Chris Raymond - Piper Sandler - Analyst

Maybe just a follow-up on the Avastin supply issue with Pine and potentially others exiting the market. Maybe just stepping back, compounded Avastin has seen supply and quality issues before. Do you see this episode as different from prior disruptions?

We had a KOL tell us that he believes this marks sort of the beginning of the end for Avastin. I'd love to hear your thoughts on that. And maybe as a follow-up, if Avastin is likely to play less of a role here, does this not provide more of an opening for a biosimilar option?

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

So Chris, let me take the impact and the situation with Pine and say that I think that probably what we're hearing is that because of the prior Avastin shortages last year around this time that the same thing occurred, offices and practices are getting used to how to deal with the situation. And obviously, the confidence in Avastin goes down in the supply.

So certainly, it's important. And I see -- I think the evolution that you're hearing is because it's a situation that has been dealt with before. We certainly want physicians to have choice in prescribing the anti-VEGF category product brand that they think is best for their patients.

And certainly, I think it is a competitive marketplace, but as we show in growth of our franchise, this quarter, we did last quarter as well, we certainly think that both EYLEA HD and EYLEA are both positioned very well in this competitive marketplace.

Operator

Salveen Richter, Goldman Sachs.

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Salveen Richter - Goldman Sachs - Analyst

Can you just elaborate on the drivers for the pricing pressure noted for EYLEA HD and whether these pressures are going to be ongoing on the forward? And just in that context, maybe just kind of your outlook for overall growth of the branded anti-VEGF market in the context of the biosimilars.

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

So as we reflect on anti-VEGF category pricing pressure, that is something, Salveen, has an impact on all products in the category, branded products, biosimilar products as well, and it's not inconsistent with other competitive categories.

What's really important to note though is what often prevails is the product that physicians most often want to prescribe, meaning what has been their experience, what is the safety profile of the product, what is the efficacy?

And now in the case of bringing EYLEA HD to the marketplace, the durability. So we think those factors are very important and allow us to compete successfully in the anti-VEGF category. As to overall category growth, I would say that it's probably roughly in -- and this is overall, not just branded, it's roughly in the mid-single-digit range.

And then come back again just to say a little bit more about the pricing pressure. Obviously, that's something that's been more apparent for EYLEA and probably the product now having been on the marketplace for over a decade is understandable.

The differentiation for EYLEA HD is the clinical profile, the product that is giving physicians the opportunity not only for the confidence in clinical aspects, results and safety as they have with EYLEA, but also now this really demonstrated durability that we're seeing more and more of. And obviously, our clinical data is supporting in the longer term as well.

Operator

Mohit Bansal, Wells Fargo.

Mohit Bansal - Wells Fargo - Analyst

I just want to understand how high dose EYLEA uptake so far is tracking versus your own internal expectations, given that, I mean, it seems like about 25% conversion has happened yet at this point. And at the same time, compared to -- Vabysmo has been growing really rapidly. So just trying to understand what are the dynamics that we need to look at here and if there are any levers you can pull going forward to help increase uptake?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

So Mohit thanks for the question. Obviously, we don't give specific guidance on conversion or the size of the market, but we do talk about what we think the catalyst can be -- and I do feel that we have a bunch of catalysts next year, the potential approval and data for RVO, more importantly, perhaps the prefilled syringe by mid-year.

So I think that next year, we could see a little bit of an acceleration. Obviously, we're working very hard. It's a great product. But there are -- these things don't happen overnight because people do love EYLEA. And it is more sticky than one might have anticipated but I think the progress is solid and we expect it to keep going.

Operator

Trung Huynh, UBS.

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Unidentified Participant

This Ting for Trung from UBS. So we want to switch gears to the obesity program and about the ongoing Phase 2 [trevogrumab plus garetosmab] and GLP1 study. Seems like you recently increased the trial size from 625 to nearly 1,000 with three new arms added. And now the study has total 13 investigational arms. Does seem like you want to very comprehensive [answer here]. Could you provide more granularity why the protocol changes here are necessary? And why would you like to further expand the trial.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

Can we have somebody to repeat that question because I really couldn't understand it at all -- Go ahead.

Unidentified Participant

Definitely. Yes. Just the ongoing Phase 2 obesity study of [trevogrumab plus garetosmab with or without GLP1]. So you recently increased the trial size to nearly 1,000. Previously, I think it was 620-plus. You also added three new arms. So why do you think like those protocol changes are necessary? And why would you like to further expand the trial?

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

Yes. I think what you're probably referring to is that we added additional dosing arms in our trial to explore different doses of the, hopefully, muscle-enhancing treatments. And that's the major reason that the trial was enlarged. So that we would have broader information on different doses and their effects on muscle preservation.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

Right. And just to remember, we didn't see any -- in the healthy volunteer study, we were able to do that because we didn't see any new safety signals. So I think it's just a matter of exploring additional doses.

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

Trying to find the right mix of antibodies with semaglutide to maximize the quality of the weight loss.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - BMO Capital Markets - Analyst

Sorry about the earlier mishap. Just a follow-up on obesity. I know, George, you've spoken a lot about the really need for quality of weight loss, and I think that's very important. Have you talked to the regulatory environment for muscle preservation or muscle building assets. I know FDA has been kind of hesitant there. And they're really focused on weight loss, but maybe how you talk about how those will evolve in the coming years.

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George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

Yes. I guess what you're referring to is obviously we all know, and it's been widely noted and acknowledged that in the setting of the very rapid weight loss that can be caused by these GLP related agents, you get significant lean body and muscle loss up to 30%, 40% of the weight loss, especially because most of these patients actually go off these treatments and then often cycle, this can actually lead to cumulative loss of muscle over time, which can actually be quite catastrophic.

We may be creating a secondary problem here over time as people cycle on and off these treatments. So our approaches are intended to maintain the muscle. That said, the agents because they're promoting muscle.

Remember, muscle is the major nonessential spender of energy that is renowned for its ability to expend energy. We've seen in the animal models that it can also cause, our approaches, when you maintain muscle, you're increasing the metabolic rate.

So you're actually expending more calories, so you actually can lose more weight while you're gaining the muscle or preserving the muscle because the muscle itself is eating up the calories or using up the calories. So the easiest regulatory path will be if our approach is, as has been seen in the preclinical studies, actually result in more weight loss but a better composition of that weight loss.

So that one won't even have to actually rely on a muscle regulatory end point, just on the increased weight loss itself. Of course, one will then hopefully be able to describe, and this is all part of ongoing discussions with regulatory agencies, that not only might you be seeing increased weight loss, but the body composition results will be better.

So the simplest regulatory path will be just by increasing the actual weight loss, and then you'll be able to show secondary end points that you're doing better on composition of the weight loss as well. That said, we are going to be measuring metabolic parameters. And we're also going to be measuring functional outputs as well.

And those are, of course, regulatory paths as well that will be more complicated and probably require a larger and longer studies than just the weight loss studies themselves. So of course, we expect to be improving metabolic endpoints. We expect to be improving functional endpoints whether we're going to be needing those as exploratory or descriptive endpoints or whether we're going to end up relying on them for approval remains an open story.

But the goal, of course, is to show these benefits in the setting of maintenance of the muscle while maintaining or actually getting greater weight loss. I should also point out that in our pipeline, we have a variety of what we call unimolecular solutions, a whole series of molecules that have the ability all within the same molecule to do all of these things.

And obviously, those will all have their own and different regulatory path, some of which might be much more expedient in terms of what endpoints you can use for approval and so forth.

Operator

David Risinger, Leerink Partners.

David Risinger - Leerink Partners - Analyst

So I have -- I'll just keep it to one question, please. Regarding next-gen product development. So clearly, Regeneron was extremely successful in creating EYLEA HD. Could you talk about your efforts to develop a next-gen Dupixent, including whether it would be a less frequently administered product?

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George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

All we can say is that we are constantly working on both improving approaches for something where we already have important products such as in the DUPIXENT class as well as coming up with entirely new and different products and approaches as well.

And as you might imagine, we delivered with HD, I mean, this is what we're trying to do all the time. We're trying to improve the current approaches but we're also trying to come up with an entirely different next-gen approach as well. That's what we do here at Regeneron.

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

Thanks, George. There's time for two more questions, Shannon.

Operator

William Pickering, Bernstein.

William Pickering - Bernstein - Analyst

Do you think that the rate of biosimilar erosion for Lucentis is a good proxy for what we can expect for EYLEA. I think they saw about 25% of volume switch over in the first 12 months. And are there any important differences in the commercial dynamics to keep in mind?

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

Just would say that it's very -- and way too early to comment. And I think that through the conversation today, we've gone through the factors that create such confidence in EYLEA, the demonstrated use of the product on a worldwide basis, but very early to try to make any comment about a product that hasn't been used in the real-world setting yet.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer

Well, I think it's also important. The situation is very different because at the same time, there are patients on EYLEA who might have a choice of going to a biosimilar, staying and EYLEA, or actually moving to a differentiated product profile, which is EYLEA HD. So that's a very different sort of situation than you had with just the Lucentis erosion situation.

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

Shannon, let's take our last question.

Operator

Cory Kasimov, Evercore ISI.

Cory Kasimov - Evercore ISI - Analyst

I wanted to follow up on Carter's question earlier about capital allocation priorities. I'm sure you're pretty frustrated by the market reaction to recent developments around EYLEA. I know you have nearly $3 billion left in your authorized share repo.

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But have you given any thoughts to an ASR? And what are your evolving views around a dividend given that you already have over $15 billion in net cash on hand? And obviously have another significant inflection in additional cash generation not too far down the road.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Founder

So we have lots of discussions on this. We don't really have anything more to add than we've said publicly, which is perhaps the best opportune time to think about the dividend is when we have paid off the development balance to Sanofi, which we anticipate should be somewhere around the end of 2026. But beyond that, how we repurchase stock, when whether, et cetera, et cetera, is something that we really don't discuss until it's happening.

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

Okay. Thank you, Len, and thanks to everyone who dialed in for your interest in Regeneron. We apologize to those remaining in the Q&A queue that we did not have a chance to hear from. As always, the Investor Relations team here at Regeneron is available to answer any remaining questions you may have. Thank you once again. Happy Halloween. Happy Diwali. Have a great day.

Operator

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

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