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REGN.OQ - Q3 2023 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals Third Quarter 2023 Earnings Conference Call. My name is Shannon, and I will be your operator for today's call.

(Operator Instructions) Please note that this conference is being recorded. I will now turn the call over to Ryan Crowe, Vice President, Investor Relations. You may begin.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

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 2023 earnings conference call. An archive and transcript of this webcast will be available on our Investor Relations website shortly after the call ends.

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 and Head of Commercial; and Bob Landry, Executive Vice President and Chief Financial Officer. After our prepared remarks, we will open the call for 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 businesses -- business, financial forecast and guidance, revenue diversification, development programs and related anticipated milestones, collaborations, finances, regulatory matters, payer coverage and reimbursement issues, 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 quarterly period ended September 30, 2023, 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 measures will be discussed in today's call. Information regarding our use of non-GAAP financial measures and a reconciliation of those measures to GAAP is available in our financial results press release and our corporate presentation, both of which can be accessed on our website. Once our call concludes, Bob Landry and the Investor Relations 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?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Co-Chairman

Thanks, Ryan, and thanks to everyone joining today's call. Regeneron delivered another strong quarter marked by continued execution across the company, which drove double-digit top line growth and notable progress across our innovative R&D pipeline. Total revenues increased by 15% on a reported basis compared to the prior year quarter, primarily driven by Sanofi collaboration revenues and LIBTAYO global net product sales, which grew by 50% and 62%, respectively. Dupixent global net product sales were $3.1 billion, up 33%, reflecting strong growth across all approved indications.

Non-GAAP net income per share -- diluted share -- increased by 4%, including an unfavorable $0.77 impact from acquired IPR&D.

Today, I will briefly discuss the launch of EYLEA HD, the progress we continue to make across our pipeline, and our latest thinking on capital allocation. I will then hand the call over to George, Marion and Bob, who will provide additional commentary on our pipeline developments, commercial execution and our financial results for the quarter.

Starting with EYLEA HD, which is off to a great start. We launched in late August shortly following FDA approval, and recorded $43 million of net product sales in the final 6 weeks of the quarter, which compares favorably to recent launches in the retinal disease category. Importantly, revenues were driven by strong initial demand with multiple reorders by distributors before the end of the quarter.

In addition, samples for EYLEA HD were made available shortly after the launch, enabling prescribers and patients to trial the product. Early EYLEA HD utilization has come from across the spectrum of wet age-related macular degeneration and diabetic macular edema patients, and momentum continues to build as positive real-world clinical experiences accumulate.

We have also made significant progress establishing access and reimbursement, and we will continue to work on positioning EYLEA HD, the highest dose anti-VEGF therapy approved by the FDA, as a new standard of care in these retinal diseases.

Moving on to the recent progress we have made advancing our pipeline. Within hematology oncology, in our CD3 bispecific platform, the BLA for odronextamab, our CD20xCD3 bispecific in certain lymphomas, was accepted by the FDA and granted priority review, which are -- with a March 31 PDUFA date assigned. We also remain on track to submit a BLA next month for linvoseltamab, our BCMAxCD3 bispecific for multiple myeloma. With pivotal trials now underway for both programs to support potential accelerated approvals, we are preparing for 2 commercial launches next year.

Last week, we reported a potential breakthrough for patients with profound congenital hearing loss. The first patient enrolled in the Phase I/II CHORD clinical trial of DB-OTO, an investigational cell selective adenovirus associated viral gene therapy designed to provide durable physiological hearing to individuals with profound congenital hearing loss caused by mutations in the otoferlin gene, experienced hearing improvement 6 weeks after treatment compared to baseline. We are looking forward to continued follow-up with this patient as well as enrollment of additional patients to further validate this gene therapy approach.

While otoferlin gene deficiency is an ultra-rare condition, we are hopeful that we can expand our approach to gene therapy in the ear to more common genetic causes of profound hearing loss.

Finally, regarding capital allocation. While we continue to prioritize internal R&D investment, given the strength of our balance sheet and anticipated future cash flows, we believe we have the flexibility to take additional actions to drive shareholder value. Beyond our ongoing share repurchase program, we continue to actively pursue emerging science and innovative platforms that complement our core R&D strengths.

In addition to the Decibel acquisition, we announced last month an expanded research collaboration with Intellia combining our proprietary antibody targeted viral vector delivery technologies with Intellia's CRISPR platform to jointly explore in vivo programs outside of the liver for neurological and muscular diseases.

We have always managed Regeneron with a focus on generating long-term returns, and we will continue to think carefully about how to strategically deploy our capital, with the goal of delivering breakthroughs to patients and value to shareholders.

In closing, we had a strong third quarter, the EYLEA HD launch is progressing well, our pipeline is delivering important innovations, and we continue to look at ways to efficiently allocate capital.

With that, let me turn the call over to George.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Thanks, Len. I'd like to start with our recent data update for EYLEA HD. At the EURETINA Meeting last month, we presented the 2-year results from the PULSAR study in wet AMD, which demonstrated that the vast majority of EYLEA HD patients randomized to 12- and 16-week dosing intervals continue to sustain vision and anatomic improvements through 96 weeks. 78% of all EYLEA HD patients were able to maintain at least every 12-week dosing intervals for the entire 2-year period, with 88% assigned to at least every 12-week dosing by the end of the 2-year period.

Similarly, 70% of patients randomized to every 16-week dosing at baseline were able to maintain at least that interval through 2 years with 78% assigned to at least every 16-week dosing at week 96. Moreover, during the second year, many patients met the criteria for extension to even longer dosing intervals, with 47% meeting the criteria for at least 20-week dosing intervals, including 28% who were eligible for 24-week dosing intervals.

The safety profile of EYLEA HD remain consistent with EYLEA, sustaining vision and anatomic improvements while maintaining such extended dosing intervals over 2 years in both wet AMD and DME is a remarkable advancement for the patients and their physicians. We believe that these results give EYLEA HD the potential to become the new standard of care for these retinal diseases.

Moving to our immunology and inflammation pipeline. On Dupixent in COPD, our first pivotal study BOREAS met the primary and all 2 secondary endpoints in a previously unprecedented success for a biologic in a Phase III study in patients with uncontrolled COPD and evidence of type 2 inflammation. Based on recent feedback from the FDA, in addition to the positive results from the BOREAS study, a positive interim analysis of the replicate Phase III NOTUS study would enable an sBLA submission. The independent data monitoring committee will conduct an interim analysis of the NOTUS study later this year.

For itepekimab, our anti-IL-33 antibody, the Phase III AERIFY-1 and 2 studies remain on track for readout and potential regulatory submissions in 2025, both itepekimab and Dupixent could transform the treatment paradigm for COPD by leveraging their distinct mechanisms of actions in reducing different types of inflammation that contribute to COPD disease progression, and we look forward to the results of these studies.

Moving to oncology and combinations with Libtayo. We remain on target and are currently enrolling our pivotal study of Libtayo combined with our LAG-3 antibody, fianlimab, in first-line metastatic melanoma. We believe this combination may provide a significant advance for patients in this setting based on our encouraging earlier-stage studies. At the annual ESMO meeting, we presented data from the Phase II trial of neoadjuvant Libtayo treatment for resectable cutaneous squamous cell carcinoma or CSCC, which demonstrated event-free survival for the vast majority, 89% of the patients at 1 year.

It is also noteworthy that of the 51% of patients who had a pathological complete response, none have since experienced disease recurrence. These results add to the growing body of evidence of Libtayo and other checkpoint inhibitors may have utility in earlier stages of CSCC and other malignancies. To further explore this, we are conducting a Libtayo trial in adjuvant CSCC for patients at heightened risk. We're also evaluating the combination of the Libtayo and fianlimab in adjuvant melanoma, and plan to initiate a study of this combination in the perioperative melanoma setting as well.

On to bispecifics. First in hematology/oncology. We are pleased that odronextamab, our CD20xCD3 bispecific, was recently accepted for review by both the FDA and European regulatory authorities in relapsed/refractory follicular lymphoma and diffuse large B-cell lymphoma. Based on the pivotal Phase II data from the ELM-2 study, we have initiated a robust OLYMPIA Phase III development program, investigating odronextamab as monotherapy as well as in combination with current standards of care in earlier lines of follicular lymphoma and DLBCL. We are looking forward to the pivotal data presentations from ELM-2 later this year.

We're also on track to submit our regulatory application for linvoseltamab our BCMAxCD3 antibody for relapsed/refractory multiple myeloma by the end of the year. This bispecific may potentially offer best-in-class efficacy and convenience. The LINKER-MM3 confirmatory Phase III study evaluating linvoseltamab monotherapy compared to a standard of care regimen is enrolling and studies in earlier lines of multiple myeloma and other plasma cell diseases will be enrolling soon.

Finally, in addition to the ongoing Phase I combination study of odronextamab in our CD22xCD28 co-stimulatory bispecific, we're also on track to initiate a study of linvoseltamab with a corresponding costimulatory bispecific next year.

Next, on to bispecifics for solid tumors, which are being investigated in combination with Libtayo and other modalities. At ESMO, we shared initial clinical data for the combination of ubamatamab, our MUC16xCD3 bispecific with Libtayo in advanced ovarian cancer. In these early data, promising durable responses were observed with ubamatamab monotherapy as well as encouraging combination activity with Libtayo with evidence of turnaround responses after initial progression on monotherapy lead-in, in multiple patients upon addition of the Libtayo.

A randomized Phase II expansion study is ongoing to evaluate 2 active monotherapy doses of ubamatamab, with the lower dose also tested in combination with Libtayo in order to optimize dosing and evaluate the potential added activity of Libtayo. In addition, we're exploring ubamatamab in multiple rare cancers that are known to express high levels of MUC16.

In terms of our costimulatory bispecifics for solid tumors, we are currently exploring multiple different CD28 costimulatory bispecific antibodies in early clinical trials in a variety of tumor settings in combination with Libtayo with corresponding CD3 bispecifics.

We are continuing development of our PSMAxCD28 co-stimulatory bispecific in advanced prostate cancer, focusing and identifying the window of opportunity for maintaining the remarkable antitumor activity observed with this treatment so far while minimizing serious toxicity. In order to explore this, we have expanded enrollment in the PSMAxCD28 monotherapy cohort, and we'll soon initiate cohorts in which investigators will have an option of adding a low dose of cemiplimab to the PSMAxCD28 treatment in certain patients.

Moreover, we plan to initiate a trial combining PSMA/CD28 with PSMA/CD3 since, based on preclinical data CD28 costims with appropriate CD3 bispecifics may yield antitumor activity without severe immune-mediated adverse events. We also hope to progress an additional prostate specific CD3 bispecific towards the clinic in the next year, which we may also combine with our PSMA costimulatory bispecific.

In terms of our MUC16xCD28 costim in combination with Libtayo in ovarian cancer, we are planning on presenting initial data by the end of the year. Regarding our EGFRxCD28 costim in combination with Libtayo, we are planning on presenting updated dose escalation data in 2024. We will

soon commence enrollment across 8 tumor-specific expansion cohorts in the study, including colorectal cancer with or without liver metastasis, as well as EGFR mutant non-small cell lung cancer.

Now to genetic medicines. We and Intellia recently announced expansion of our research collaboration to include Regeneron's proprietary antibody targeted delivery technology, with the goal of expanding the reach of in vivo gene editing to neurological and muscle diseases. The aim of this expanded collaboration is to address a current bottleneck in genetic medicine, the inability to deliver genetic payload beyond the liver.

Our proprietary preclinically validated antibody-directed AAV approach will initially test 2 in vivo non-liver targets. Additionally, we and Intellia announced FDA clearance to start a pivotal Phase III trial of NTLA-2001 for the treatment of ATTR amyloidosis with cardiomyopathy. The first time an investigational in vivo CRISPR-based gene therapy editing is clear to enter a late-stage clinical development in the United States. The trial is expected to initiate by year-end 2023.

Moving to our Alnylam collaboration. Alnylam recently presented updated interim ALN-APP data in early onset Alzheimer's disease. Updated data showed that single doses of ALN-APP achieved sustained robust reduction in APP alpha and APP beta measured in the CSF up to 10 months after administration, as well as reduction of amyloidogenic peptides implicated in Alzheimer's disease and cerebral amyloid angiopathy.

Alnylam has also announced that a first patient has been re-dosed with ALN-APP in the multi-dose portion of the study currently proceeding outside of the United States. We and Alnylam plan to initiate additional clinical programs for neurodegenerative diseases, including for amyotrophic lateral sclerosis next year.

Finally, I would like to highlight DB-OTO, our otoferlin gene therapy, Regeneron's first clinical program for genetic hearing loss, which we've developed over the last few years in collaboration with Decibel Therapeutics, a company we recently acquired. Last week, we announced the first preliminary results from this trial. A child who received an intraocular injection of DB-OTO in 1 ear experienced improvements in hearing tests in that ear through week 6 compared to baseline, including both auditory brainstem responses as well as behavioral audiometry.

We are looking forward to continuing evaluation of this innovative approach in the ongoing trial for the ultra-rare otoferlin gene related hearing loss, as well as in other planned clinical programs, which include more common forms of genetic hearing loss.

In conclusion, Regeneron's R&D engine continues to grow and deliver differentiated late and early-stage opportunities, and we are looking forward to progress in the remainder of this year and looking ahead to 2024.

With that, I will turn it over to Marion.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Thank you, George. I'm delighted to share details of our commercial performance in the third quarter, including very encouraging early signals for EYLEA HD as well as ongoing results from our in-line brands.

Starting with our anti-VEGF retinal franchise, Regeneron achieved $1.49 billion in total net sales for the quarter in the U.S. We were excited to rapidly launch EYLEA HD in late August following its U.S. approval and total net sales for the quarter were $43 million. Early launch indicators have been very positive. Physician enthusiasm was extremely high prior to EYLEA HD launch and that interest has translated into early use in a broad range of patient types across wet AMD and diabetic eye disease.

It is noteworthy that physicians are prescribing EYLEA HD in recalcitrant switch and naive patients. We are already hearing anecdotal case reports from physicians whose recalcitrant patients are returning. Many of these patients have now been able to achieve drying that they were unable to obtain with other products.

To accelerate this early launch momentum, our highly experienced team is rapidly advancing reimbursement and market access. We have confirmed paid claims from 100% of Medicare jurisdictions and many large payers have recently published coverage policies for EYLEA HD. This includes both Medicare Advantage and commercial plans. While early, the speed of EYLEA HD coverage is significantly outpacing recent competitive launches.

In addition, we continue to be on track to have a permanent J-Code by April 1, 2024, which we anticipate will drive additional uptake.

These early reimbursement successes and positive physician experiences are being shared by prescribers with our team and more broadly with the retina community. These initial results bode well for the future of EYLEA HD, and substantiate our belief that EYLEA HD will rapidly become the new standard of care across its approved indications. EYLEA HD's unsurpassed safety and durability demonstrated in clinical trials, coupled with prescriber confidence in EYLEA's efficacy and safety record, is expected to drive continued category leadership.

In summary, while the launch is still in early days, we are pleased with our progress and look forward to providing future updates. EYLEA remains the category leader with 45% anti-VEGF share for the quarter in an increasingly competitive market. With over 70 million injections worldwide since launch, EYLEA continues to demonstrate a strong and consistent safety profile, a key differentiator given retinal vasculitis and intraocular inflammation events with certain new products introduced in the retinal category. With both EYLEA HD and EYLEA, our formidable retina franchise is poised for sustained leadership.

Next, to Dupixent. Global net sales grew 33% year-over-year to $3.1 billion, and U.S. net sales grew 30% to $2.4 billion. This impressive third quarter performance demonstrates Dupixent's clinical and safety differentiation across all approved indications as well as its continued growth potential.

In the third quarter, more than 50,000 new patients are taking Dupixent in the U.S. alone, and there are now more than 750,000 patients on Dupixent worldwide. In atopic dermatitis, Dupixent's largest indication, we continue to see more than 20% growth 6 years post launch. Physicians have great confidence from the combination of efficacy, safety and ease of use across all age groups, including as young as 6 months.

Not only is the remarkable adherence once patients begin therapy, we also see Dupixent as being the clear treatment of choice for new patients with moderate to severe disease, with significant growth opportunity.

In asthma, Dupixent is differentiated from all other medicines in the category based on its rapid and sustained effect on lung function, reduced exacerbations and reduced corticosteroid use. In the U.S. Dupixent continues to lead new patient prescriptions, and we are quickly approaching our goal of being the #1 prescribed medicine for asthma.

Together with our partner, Sanofi, Regeneron continues to advance recent launches in eosinophilic esophagitis and prurigo nodularis, which are already meaningfully contributing to Dupixent's growth. Since FDA approval, approximately 20,000 new patients with eosinophilic esophagitis have been initiated and demand is also robust for prurigo nodularis where Dupixent is rapidly becoming the standard of care within a year of approval. We also look forward to offering Dupixent to even more patients in the future with anticipated regulatory approvals of pediatric eosinophilic esophagitis as well as multiple near-term Phase III data readouts on COPD, chronic spontaneous urticaria and bullous pemphigoid.

In summary, Dupixent continues to be a key driver of our growth, and we look forward to seeing its transformational benefits extending to even more patients with type 2 inflammatory diseases across indications, demographics and geographies.

And finally, to Libtayo. Third quarter global net sales grew 59% year-over-year on a constant currency basis to $232 million, with U.S. net sales up 52% to $144 million. Global growth was driven by our non-melanoma skin indications coupled with increased utilization in both monotherapy and chemotherapy combination settings in lung cancer. We're working to expand access and use in many additional countries following recent regulatory approvals. We continue to see a growing number of prescribers choosing Libtayo when treating their patients.

In conclusion, Regeneron's performance in the third quarter continues to deliver growth and value for patients and shareholders with opportunity for sustained growth. We're encouraged by favorable early indicators from the EYLEA HD launch and continue to deliver compelling performance from our in-line brands, including EYLEA, Dupixent and Libtayo.

Now I'll turn the call over to Bob.

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

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

Regeneron performed well in the third quarter, with execution across the business continuing to drive strong top and bottom line growth. Third quarter 2023 total revenues increased 15% year-over-year to $3.4 billion, primarily driven by sales growth for Dupixent, coupled with improving margins within the Sanofi collaboration as well as continued growth from Libtayo.

Third quarter diluted net income per share grew 4% to $11.59 on net income of $1.3 billion. This included a $100 million acquired IPR&D charge incurred in the third quarter of 2023, which decreased growth by approximately 7 percentage points.

Moving to collaboration revenue and starting with Bayer. Third quarter 2023 ex-U.S. EYLEA net product sales were $872 million, up 6% on a constant currency basis versus the prior year. Total Bayer collaboration revenue was $377 million, of which $350 million related to our share of EYLEA net profits outside the U.S. Total Sanofi collaboration revenue was $1.1 billion in the third quarter, up 50% versus the prior year, which included the final $50 million sales-based milestone.

Our share of profits from the commercialization of Dupixent and Kevzara was $863 million, an increase of 57% versus the third quarter of 2022, driven by Dupixent's continued volume growth and improving margins. As we guided last quarter, third quarter reimbursements for the manufacturing of commercial supplies from Sanofi, a component of Sanofi collaboration revenues, declined sequentially, primarily due to the ongoing phase-in of a new higher-yielding manufacturing process. In the fourth quarter, we expect a continuation of this trend with reimbursements from manufacturing of commercial supplies expected to be sequentially lower by approximately $40 million.

Other revenues were $138 million in the third quarter of 2023, up 62% versus the prior year and inclusive of $34 million of reimbursements from BARDA for ongoing development of our next-gen COVID antibody as per the agreement announced in August 2023.

Moving now to our operating expenses. Third quarter 2023 R&D expense grew 17% year-over-year to $954 million, representing continued investment in our expanding pipeline. R&D growth was primarily driven by higher head count and related costs in funding our advancing late-stage pipeline, as well as increased clinical manufacturing activity.

SG&A grew 14% from the prior year to $534 million in the third quarter, reflecting higher head count in related costs and higher contributions to an independent not-for-profit patient assistance organization.

In the third quarter, we recorded acquired IPR&D of $100 million, reflecting the payment of a development milestone to our collaborator, Alnylam, related to the Phase I ALN-APP program in early onset Alzheimer's disease. This impacted both GAAP and non-GAAP EPS by approximately $0.77.

Third quarter COCM was $212 million, up 20% versus the prior year, driven by manufacturing costs associated with higher sales volumes from collaboration products, partially offset by lower Dupixent manufacturing costs. Fourth quarter COCM is expected to be the lowest quarter of the year as we continue to transition to the higher-yielding manufacturing process for Dupixent.

Now to cash flow and the balance sheet. Through the third quarter of 2023, Regeneron generated approximately $3 billion in free cash flow and ended the third quarter with cash and marketable securities less debt of approximately $13 billion. We continue to deliver on our capital allocation priorities, buying back $507 million and $1.9 billion of our shares in the third quarter and the first 9 months of 2023, respectively, with $1.8 billion remaining authorized under our existing share repurchase program.

Additionally, in the third quarter, we also announced and completed the acquisition of Decibel Therapeutics for approximately $100 million, to strengthen our genetics medicine portfolio. As Len mentioned, we continue to evaluate opportunities to utilize our strong financial position and build upon our core competencies with the goal of delivering long-term shareholder value.

Finally, we've made some minor changes to our full year 2023 financial guidance based on our year-to-date results and our latest outlook, updating the guidance ranges for SG&A, R&D, gross margins, COCM and capital expenditures. A complete summary of our latest full year 2023 guidance is available in our press release issued earlier this morning.

As we approach the end of 2023, I'd like to provide some commentary on the preliminary outlook for 2024. We expect continued improvements in profitability from the Sanofi collaboration, which will continue to accelerate the paydown of the antibody development balance, which as of September 30, 2023, was approximately $2.5 billion. Once this balance is fully repaid in the next few years, we expect a meaningful step-up in our share of Sanofi collaboration profits.

Separately, for Praluent, we expect significant category and competitive pressures that negatively impact U.S. sales in 2024.

Moving to our operating expenses. Consistent with our capital allocation priorities, we continue to invest in our growing internal R&D pipeline to drive long-term growth. As you just heard from George, our pipeline continues to broaden, while our infrastructure to support that growth continues to expand. R&D investment in 2024 will be driven by advancing strategically important late-stage programs such as our fianlimab and Libtayo combination, confirmatory hem-onc studies, including in earlier lines of therapy, our expanding collaborations in genetic medicines, as well as higher clinical manufacturing costs and the continued expansion of our R&D organization.

With this in mind, we expect year-on-year R&D growth in 2024 to be in the mid-teens compared to our anticipated 2023 spend. We also expect to make additional investments in our commercial business and G&A functions to support the launch of EYLEA HD, our planned hem onc launches and our international expansion.

In conclusion, Regeneron continues to deliver strong results, and our robust financial position allows us to make strategic investments to drive this growth over time. With that, I will now pass the call back to Ryan.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Bob. This concludes our prepared remarks. We will now open the call for Q&A. To ensure that we are able to address as many questions as possible, we will answer one question from each caller before moving to the next. Shannon, can we please go to the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Evan Seigerman with BMO Capital Markets.

Evan David Seigerman - BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

Congrats on all the progress. So you have over $15 billion of cash and marketable securities on your balance sheet. Maybe Bob, you could talk about how you think about capital allocation. I know interest rates are high. But how well could you spend that money to drive even higher returns for Regeneron shareholders?

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Yes. Thanks, Evan. I mean, I know having dealt with you and certainly many of our investors, this is certainly an issue that we've been tasked to solve. Now obviously, interest rates are a lot higher. So obviously, what we're returning on that is certainly much better than the kind of the days of 2020 and 2021. But we kind of stick to our knitting here with regards to our capital allocation. I mean George just went through a plethora of,

obviously, pipeline progress that we're making. Again, first and foremost, we're going to make sure that, that is fully funded to the extent possible on that.

And then with regards to acquisitions, you heard with Len's intro. I mean we continue to look at a lot of opportunities. Certainly, the market that is out there on the biotech space is not in the greatest shape as you know. So again, we think there are opportunities out there. But just because we have the means, it doesn't mean that we're going to kind of push into something that may not give us an optimal result. It may not be kind of -- we like franchises, as you've heard me say that before. So we need to make sure that it's the right fit with George and the team with regards to that. So we'll continue to do that.

And you've seen our share repurchases, of which we're $1.9 billion through 9-months. We've done that at a very good price with regards to how we're buying that back. We're very kind of scientific in our approach on that. We do think that stock continues to be undervalued given all the pipeline progress and the catalysts that we have. So we're going to continue to push that button going forward.

So we're going to stick to our knitting. But again, as Len kind of alluded to, we are looking at a lot of opportunities that are out there. And if the right one makes the necessary fit, then we'll move forward. And again, you kind of saw that with Checkmate and Decibel, albeit those were smaller, but again, those were nice kind of franchise fits into the business.

Operator

Our next question comes from the line of Mohit Bansal with Wells Fargo.

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

Congrats on the progress. My question is regarding the ulcerative colitis trial you are doing with Dupixent. Could you talk a little bit about the rationale behind that? And are you enriching this trial in any way on the basis of eosinophil counts or any other marker there?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Yes. So as you sort of hinted at, what we have realized is that all of the diseases that we are treating with Dupixent really are interrelated diseases that reflect a systemic disorder, that is upregulation of so-called type 2 inflammation, and in some cases it manifests in the lungs, in some cases in the skin, in some cases in the gut, and so forth all over the body. And in many cases, in most patients actually in more than one location.

And so in every disease that we're going after, including now, as you mentioned, in ulcerative colitis, we believe that there are a subset of patients who may be marked with type 2 inflammation in their gut. We are, as you say, indicating -- utilizing biomarkers that might select out these patients. And so we're going to see whether a subset of ulcerative colitis patients are driven by this type 2 inflammation that's driving all the other related manifestations of this systemic disorder.

Operator

Our next question comes from the line of Chris Raymond with Piper Sandler.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Yes. Just maybe on into COPD. I think the last time we talked to you guys on this, you were talking about the risk-reward on taking an interim look on NOTUS, just given the alpha hit. It looks like you've decided to take that step here. But can you give us a sense of the alpha hit you are taking by doing this interim look?

And I mean just looking at BOREAS with the 30% reduction in exacerbations, it would seem you have a decent amount of room here if NOTUS is tracking similarly. But if you can give us any more color on how you're thinking about this, the risk reward of this decision. And I assume you've got a press release that -- result of that if it's going to be the end of the year?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Co-Chairman

Yes. We're not going to get into the details of the statistical niceties on how you do this. An alpha sparing approach is what's typical for an interim analysis. We'll work closely with Sanofi on how to do this in the most efficient manner possible and get to the information as appropriate when it appears.

Operator

Our next question comes from the line of Colin Bristow of UBS.

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

Congrats on the quarter. Not surprisingly, we've been getting an increasing number of questions on your obesity assets. And I was wondering if you could just talk to your strategy and level of enthusiasm here, and maybe frame out some of the time lines, you've got the GRP75, the leptin receptor antagonist. I think you shared some pretty provocative data at ADA on the myostatin blocker and the activin A blocker. Maybe you could just tell us your level of enthusiasm. Is this something that you're going to go full force and plan to have a major presence in down the road? Just some color there would be helpful.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Yes. As you said, we're very excited about, I guess, 2 of the approaches that we've been taking in obesity. One is our unique collection of targets that we've either been the first to discover, like the GPR75, genetically identified target that came from our Regeneron Genetics Center, which is a very exciting new target for obesity, as well as our new approaches such as our leptin receptor agonistic antibody.

But one thing we're doing is moving those programs forward and understanding exactly what their potential is in the field of obesity. But as you said, right now, the field, which is dominated by the GLP-1 agonists, also is recognizing increasing problems with this type of weight loss, meaning that about 40% of the weight loss is due to muscle loss. That means if you lose 20 pounds, 8 pounds of that approximately, on average, will be muscle. Most patients will never get that muscle back. This can, over time, especially if patients go off these drugs and regain the weight as fat, can create potentially a very large public health problem and dilemma.

So we also have been, as you pointed out, very active in the field of muscle preservation and muscle growth agents. We've developed some of, I think, some of the most exciting candidates in the field that have the ability to do this. And we are certainly considering how to study these muscle preservation and muscle growth agents in combination with existing weight loss agents to see whether we can maintain or even grow muscle in the setting of weight loss. Hopefully, perhaps increasing the quality of the weight loss, maybe even resulting in greater weight loss. But most importantly, making sure that the patients in terms of their muscle and so forth, do a lot better. And we will be talking about our clinical trials in this area, we hope, very shortly.

Operator

Our next question comes from the line of Tyler Van Buren of TD Cowen.

Tyler Martin Van Buren - TD Cowen, Research Division - MD & Senior Equity Research Analyst

Congrats on the tremendous quarterly results. It's great to see the early EYLEA HD sales, of course. And you mentioned that naive and switch patients are being treated. But are you seeing switches from Vabysmo specifically? And to what extent are you guys sending samples out as we think about assessing additional demand beyond sales?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Thanks, Tyler. So let me address the first part. And the positive anecdotal case reports we're getting back really carry across the theme of better vision, better drying than they've seen with other anti-VEGF products. They also comment on very frequently the tremendous confidence that they have in the safety of EYLEA and the experience over many, many years.

In terms of the switches, it's early days. We are seeing switches from EYLEA, as you would expect, and of course, we're the category leaders, so there are more potential patients to consider as well. But we are also hearing switches from faricimab, we're hearing also switches from Avastin and other products in the category. And the early reports have been quite encouraging.

To your other part of your question related to sampling, we do have a sampling program for EYLEA HD. It's intended to give physicians experience with EYLEA HD in an appropriate way. The program is constructed on an on-demand basis. We don't disclose the number of samples or things of that sort, and certainly, that's not what you were asking. But I can share with you that we have seen a high conversion rate from practices ordering EYLEA HD samples and then subsequently placing orders of commercial products through commercial channels.

Operator

Our next question comes from the line of Terence Flynn of Morgan Stanley.

Maxwell Nathan Skor - Morgan Stanley, Research Division - Former Research Associate

This is Max Skor on for Terence Flynn. A quick one from us. Could you provide an update on the timing or relative implications of the biosimilar EYLEA litigation with Mylan?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Co-Chairman

Yes. So we had a trial in West Virginia, a bench trial, and we are waiting for a decision from the judge. Out of our control. And as soon as it comes, it will come. It's been several months, so it could come soon or not. It's one of those things where it's really beyond our ability to predict and control.

Operator

Our next question is from the line of Carter Gould with Barclays.

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

Congrats on the progress. Maybe a follow-up for Marion. Thanks for all the color on the commercial dynamics for high-dose EYLEA. Can you -- one thing you didn't touch on as much though is sort of how maybe some of the step edit language has evolved? Is that sort of tracking in line with what you were seeing with standard dose EYLEA, or any broader commentary on how that's tracking relative to your expectations?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. So as a quick reminder, as we get into payer mix. I'll remind everybody that these are approximate based on typical patterns in the category. It's a little bit different when you look at a product that just launched. But about 45% of our overall business is in Medicare fee-for-service. And as I mentioned to you in the call today, we've made great progress there, not only in coverage, which is the first step to get coverage but then taking the extra step to make sure that claims are being paid.

So we're seeing now that 100% of Medicare fee-for-service jurisdictions have coverage and demonstrated paid claims. When we go over to Medicare Advantage, which is roughly about 25% of anti-VEGF category business and commercial, which is about 20%, what we're seeing so far, and we are making good progress with payers. We're seeing that EYLEA HD is being positioned consistently with EYLEA and other brands in the category. And there are plans, as you know, that have a step edit or utilization management. The good news is that EYLEA HD is being positioned consistently with EYLEA and other brands. We don't see a differentiation there.

Operator

Our next question comes from the line of Robyn Karnauskas with Truist Securities.

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

Question on CSU. I know it's a big opportunity. Many patients are not controlled well with antihistamines and you have a CRL. Is Study C sufficient? Anything in particular you think the FDA is looking for? Is there a disconnect? Are they changing how they -- what they view for the bar for approval? What's your thoughts there?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Yes. Well, as you know, we had one very positive study. We had a second study, that actually had a P of 0.049, but for various statistical purposes just missed meeting its predetermined statistical hurdle, but it's certainly all the indicators are going in the right direction. And what the FDA indicated that they wanted to see the results of our ongoing Study C, as we call it, to make their decision.

And so what we're hoping is that study, which is in the same population of the very positive initial study, remember, the second study was in these recalcitrant patients who have failed Xolair among other therapies. But Study C is in the same population as our very first Study A, the very positive study. And we're hoping that if we get consistent data in that study, that the FDA will consider and look favorably upon it.

Operator

Our next question comes from the line of Salveen Richter with Goldman Sachs.

Salveen Jaswal Richter - Goldman Sachs Group, Inc., Research Division - VP

With regard to your cancer portfolio, as we look to additional data coming out at ASH and the proof-of-concept we've seen so far, but combination data that we're looking to with Libtayo, can you just talk to us about the optimization still required here and how you're thinking about positioning it in the context of emerging targets and competitive dynamics?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Yes. We have a very large collection of combination opportunities that we're very excited about. The first one that we hope has a chance of really crossing the finish line in a very significant way, in a very seen population, is our combination of Libtayo in combination with fianlimab, putting together these 2 checkpoints, the anti-PD-1 on the anti-LAG-3.

And I think in this case, we believe we have evidence that we have the best-in-class type of activity with both agents separately. And as you've hopefully seen in our earlier stage clinical trials, the data suggests that when we put them together, we really can make a remarkable advance for patients in terms of the number of patients who respond and the extent of their progression-free survival.

And we're now, as we announced in a pivotal trial where we hope that we will in the -- within the next year, perhaps be able to provide the results from that trial, which might confirm this remarkable advance for patients. If it works in this first-line melanoma setting, it really opens up the door to a whole series of other opportunities, both in related melanoma settings, such as an even earlier stage melanoma setting such as the adjuvant and perioperative settings, but we could be moving to other cancers as well with that proof-of-principle.

So that's the nearest term Libtayo checkpoint combination approach. As you know, with our bispecifics, the combination opportunities there are also very exciting, either with Libtayo or with each other. And we have, in that space, shown that our individual agents, the important thing is we have now validated so many of our individual agents as having once again the potential for best-in-class type of activity. Whether it's our agent for myeloma or our CD20 bispecific in, for example, follicular lymphoma and so forth and so on.

But we're also excited about our costim bispecifics. We've released the data about the incredible efficacy in at early stages that we see in combination with Libtayo. But that one, that one is countered by concerns with immune-mediated adverse events that we're seeing in these patients. It is hard to dramatically increase the extent of immunotherapy benefit without having it associated with increased autoimmune type reactions. We're working very hard on that, and we think, based on preclinical data, that the trick may be combining our costims with our CD3 bispecifics where we don't see these dramatic potential increases in the mechanisms that may lead to immune adverse events.

So in summary, our checkpoint combinations are very near term. Our bispecifics are single agents have been validated and hopefully will be being considered by the FDA for approval in the relatively near future. And the combinations are beginning to demonstrate exciting opportunity, and we're trying to tune that in order to try to present the best efficacy safety profile for patients.

Operator

Our next question comes from the line of Brian Abrahams with RBC Capital Markets.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Congrats on the good launch so far. You mentioned in the press release some impact of price on EYLEA. I was wondering if you could elaborate a little bit more on this, when you think this might stabilize? Any extent that this might affect high-dose EYLEA as well?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure, Brian. So I would comment that, in an increasingly competitive category, there, of course, there's been some pressure on EYLEA. I'd also reflect that in 12 years in the market, it's really modest rebating and discounting if you look at the history of the brand. And of course, that on a brand that has never taken a price increase.

But we will continue to be very much watching uptake of EYLEA HD, taking very responsible and appropriate and thoughtful measures on pricing. And certainly, as I reported to, early days, we're making some very strong progress in the marketplace in terms of making sure that physicians gain confidence in reimbursement of EYLEA HD as they initiate patients.

Operator

Our next question comes from the line of Yatin Suneja with Guggenheim.

Yatin Suneja - Guggenheim Securities, LLC, Research Division - MD & Senior Biotechnology Analyst

Question on Dupixent. Could you maybe share your views on the newer mechanism? For example, OX-40 or perhaps a longer-acting version of Dupixent on the franchise? Maybe if you can talk about your efforts in terms of life cycle management of Dupixent?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Yes. Maybe getting back to some of the comments that I made before. The collection of so-called allergic or type 2 conditions, which Dupixent addresses are all characterized by a systemic inflammatory problem increase in the so-called type 2 inflammation. Which if you look at the science and literature is really of this vestigial pathway that largely evolved and was one of the most active parts of the immune system, to fight things like fecal parasites, which are really not an issue now in the developed world.

This part of the immune system should essentially in the modern world be entirely quiescent. It serves almost no role. The problem is it becomes unleashed abnormally to do things that it shouldn't be doing, like fighting allergens or attacking the skin or the gut in atopic dermatitis or eosinophilic esophagitis.

What Dupixent does uniquely is that it controls, and the data now demonstrate this, the incredible effect, that it puts this useless angry tiger back in the cage where it belongs. And that is why it has this incredible profile of not only efficacy but safety. Because what's shutting down is it's shutting down a pathway that should be vestigial in the modern world, but becomes unleashed and attacks all different parts of the body.

We believe that any of this current competition that's ongoing doesn't share these remarkable features that give Dupixent its incredible broad efficacy across the spectrum of diseases with its unique safety profile. Because all of these other approaches, including, for example, the OX-40 approach and so forth, are addressing different fundamental immune pathways that are important in the immune system's function to do a lot of actual useful things in the modern world. Like, for example, fighting viral infections and cancer and so forth.

So Dupixent really has a very unique profile, which if we can help explain and if all physicians and patients can understand it, make it the perfect drug for this condition. It uniquely blocks this vestigial pathway that gets out of control inappropriately and causes disease all over the body. Dupixent shuts down this what should be a vestigial pathway, and it helps disease, whether in the same patients, it could be manifesting in the skin in the lungs, in the nose, in the gut and so forth, it shuts it down without really untoward effects with regards to the ability of the body to actually fight infections and so forth.

In fact, if you look at our clinical studies and some of the data that we published, in many, if not most cases, you actually see unbelievably reduced infections in the setting of the Dupixent treatment. Because what you're doing is you're putting the bad part of the immune system back under control and you're allowing the rest of immune system to do its function.

All of these other approaches are trying to attack critical parts of the immune system that have important other functions, and they don't address the widespread problem that occurs systemically and causes all of these diseases. So as you've seen already with various agents, they may work in one of Dupixent's indications, but they don't work, they failed in other indications. And if they work, they also often come with the concerns about safety because they're designed to be immunosuppressive, which Dupixent is not.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Co-Chairman

So just to add a small point to what George's eloquent explanation of why Dupixent is such a special drug and the prediction that it would be safe because it's attacking this vestigial part of the immune system, you're looking at somewhere in the neighborhood of three-quarters of a million people on the drug, many more than that so that have demonstrated the safety that is predicted by the science.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Including in children, as we know, as young as 6 months is approved there where it's been demonstrating not only incredible safety but incredible efficacy.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Great points, thank you. Shannon, I think we have time for 2 more questions, please.

Operator

Our next question comes from the line of Dane Leone with Raymond James.

Dane Vincent Leone - Raymond James & Associates, Inc., Research Division - MD & Biotechnology Analyst

Congratulations on a strong quarter. Just actually really 2 quick ones for me. First one being, can you just comment whether you saw any impact from increased utilization of biosimilar ranibizumab during the quarter on EYLEA sales. A number of high-volume clinics had highlighted favorable margin opportunities from using more biosimilar ranibizumab which seems to be potentially a transient impact and use of some of the brands, but it would be interested in your commentary there.

And then we've gotten just a lot of inbounds in terms of ongoing patent litigation of EYLEA. Could you just maybe state for us what your current expectation is for EYLEA patent life? And just any thoughts you have on how the ruling that we're awaiting could actually impact your base case.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Co-Chairman

Yes. So I'll cover the patents and then Marion can cover any additional insight into the marketplace. On the patents, we're involved in litigation. There's a couple of key patents that have evolved in this case that both relate to formulation as well as dosing. On the base case is that, for us, assuming that the exclusivity will expire in May, but we will see what happens in the litigation, which could be an upside, obviously, for the franchise.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

All right. And on the ranibizumab impact, it's relatively early in their launches, and -- so there hasn't been a notable impact to the category. The Lucentis biosimilar shares in the low single-digit area in the third quarter, and certainly, the impact has been seen more relative to Lucentis, which has declining share. But certainly, this is not extended to EYLEA or EYLEA HD.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

We'll just take our last question, please, Shannon.

Operator

Our last question is from the line of Brian Skorney with Baird.

Brian Peter Skorney - Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst

It looks like J&J had a really good first quarter of their myeloma bispecific. So it definitely seems like there's a good demand there. But also an element of them having control of a lot of offerings for myeloma. So obviously, head-to-head superiority would always dominate each in oncology, but with the initial launch of your bispecific next year. I'm just wondering what your strategy is for competing in the initial late line as a third-to-market? Do you think that there is differentiated enough data here to kind of take share? Or is the focus really on generating data in earlier line of combos to kind of move up market share?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Co-Chairman

Well, of course, it's both. We do believe that data rules, the best, both efficacy, safety profile but also convenience profile. And we will be continuing to show our evolving and maturing data, which we believe could result in best-in-class in terms of efficacy, in terms of response rates and complete response rates in terms of safety, in terms of the frequency of cytokine release syndrome and so forth. And in terms of differentiation in terms of mandated hospitalization.

So we will be continuing to present our data. Of course, we'll see exactly ultimately what gets in the label and what the FDA supports but there's the potential here for best-in-class differentiation in terms of efficacy, safety and convenience and schedule. And of course, as you said, we're also moving with, we think, an exciting program in earlier lines of therapy. And all of this is also going to be combined with the opportunities for our future combinations. We have a variety of costim bispecifics that we're excited about combining specifically with this agent in the plasma cell dyscrasia setting.

So we think it's a very exciting opportunity. As you said, unfortunately, there's a large opportunity out there because there's a lot of patients that are still in need. I think that if you have the best agent for late-stage patients, a lot of people will want to use it. And then if we figure out the best program to demonstrate how it can be utilized in earlier-stage patients that can certainly enhance that opportunity let alone if we come up with one of our magic combos that really takes it to the whole next level.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Okay. Thanks, George, and thanks to everyone who dialed in today and for your interest in Regeneron. We apologize to those remaining in the queue that we do not have a chance to hear from. But as always, the Investor Relations team here is available to answer any remaining questions you may have. Thank you once again, and have a great day.

Operator

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