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REGN.OQ - Q1 2026 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

Company Summary

[Proofread by Regeneron Investor Relations]

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PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals first-quarter 2026 earnings conference call. My name is Kevin, and I'll be your operator for today's call. (Operator Instructions) Please note this conference 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 In - Senior Vice President of Investor Relations & Strategic Analysis

Thank you, Kevin. Good morning, good afternoon and good evening to everyone listening around the world. Thank you for your interest in Regeneron and welcome to our first-quarter 2026 earnings conference call. An archive and transcript of this call will be available on the Regeneron Investor Relations website shortly after our call concludes.

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

After our prepared remarks, the remaining time will be available for Q&A. I would like to remind you that remarks made on today's call may include forward-looking statements about Regeneron. Such statements may include, but are not limited to, those related to Regeneron and its products and business, financial forecast and guidance, development programs and related anticipated milestones, collaborations, finances, regulatory matters, payer coverage and reimbursement, changes to drug pricing, regulations and requirements and our drug pricing strategy, 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 March 31, 2026, 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 on our quarterly results press release and corporate presentation, both of which can be found on the Regeneron Investor Relations website. Once our call concludes, the IR team will be available to answer any further questions.

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

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

Thanks, Ryan. Thanks to everyone for joining today's call. We were pleased with Regeneron's performance to start 2026, highlighted by strong commercial execution across our key growth products, continued pipeline progress, a disciplined approach to capital allocation and our agreement with the US government to lower drug prices for American patients while preserving innovation.

Starting with the financials. We delivered double-digit growth across both revenues and earnings. Total revenues increased 19% compared to the first-quarter of 2025 and non-GAAP earnings per share increased 15%, demonstrating our ability to deliver strong operating performance while continuing to invest in our science and long-term growth opportunities.

Global Dupixent net sales increased 31% on a constant currency basis to $4.9 billion in the quarter. Growth was broad-based and driven by continued strong demand across multiple approved indications and geographies, reinforcing Dupixent's position as the foundation of our immunology franchise. We also continue to advance our efforts with next-generation therapeutic approaches to strengthen our leadership position in inflammation and immunology.

EYLEA HD US net product sales increased 52% year-over-year to $468 million. We continue to see encouraging physician adoption of EYLEA HD, reflecting confidence in its clinical profile and dosing flexibility. We resubmitted an application seeking FDA approval for filling of the EYLEA HD pre-filled syringe at Catalent Indiana, where the FDA has recently conducted a site reinspection.

In addition, the FDA did not act by the April 2026 PDUFA date for the company's regulatory application for a second contract manufacturer for the PFS; therefore, this application remains pending. Regeneron and both third-party filling manufacturers are working closely with the FDA to resolve all outstanding issues, and we anticipate a regulatory decision on one or both applications during this quarter.

In oncology, global Libtayo net product sales grew 54% to $438 million, driven by continued uptake in advanced cutaneous squamous cell carcinoma and advanced non-small cell lung cancer as well as early contributions from the adjuvant CSCC indication, which received FDA approval in the fourth-quarter of 2025. Turning briefly to our pipeline before George provides more details in his remarks, we've continued to make meaningful progress across multiple therapeutic areas so far in 2026.

Last week, we received FDA approval of Otarmeni for genetic hearing loss, marking an important milestone for patients with this ultra-rare condition, and we have committed to offering this product for free. While this may seem like an unconventional decision, we believe it's the right one for Regeneron, and reflects the ethos that we live by, pushing the boundaries of science to benefit humanity.

Moving to other advances in our pipeline. We presented positive Phase III data for cemdisiran, our investigational siRNA that targets C5 in generalized myasthenia gravis, which demonstrated a differentiated efficacy, safety and convenience profile relative to approved myasthenia gravis therapies. We submitted a new application utilizing a priority review voucher and anticipate an FDA decision in the fourth-quarter.

In metabolic disease, we and Hansoh announced positive Phase III data in China for olatorepatide, our in-licensed GLP/GIP receptor agonist with full data expected to be presented by Hansoh later this year. Dupixent achieved multiple regulatory milestones, expanding the eligible patient population to younger age groups and to new diseases.

In addition, the FDA accepted our biologics license application for garetosmab and granted priority review with the decision in August, representing another important step forward for our rare disease portfolio. Briefly on capital allocation. We continue to take an approach that balances internal investment, which we believe offers the greatest long-term return for shareholders, with direct return of capital through share repurchases and dividends as well as business development.In support of that approach our Board authorized a new $3 billion share repurchase program, reflecting confidence in our business and financial position. We also recently entered into strategic collaborations with Telix and TriNetX.

Finally, last week, we entered into a Most-Favored-Nation Pricing agreement with the United States government, achieving our shared goals of ensuring timely and affordable access to groundbreaking medical advancements for medical patients, maintaining the United States leadership in biotechnology, innovation and manufacturing, and addressing the imbalance in the distribution of cost for medical innovation, which we have long argued has placed a disproportionate burden on American patients.

In closing, the progress we've made so far in 2026 reflects the strength of our science and execution and sets a solid foundation for an exciting remainder of the year.

With that, I'll turn the call over to George to discuss our R&D progress in more detail.

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

Thanks, Len. I'll start with our differentiated approach to treating complement-mediated diseases, which was highlighted last week at our latest Regeneron Roundtable investor event. Our core strategy is to deploy customized approaches using an siRNA, an antibody or a combination approach, depending on the level and durability of complement inhibition required for each disease.

For example, it appears that in generalized myasthenia gravis or gMG, the partial blockade with the C5 siRNA alone delivers optimal efficacy, safety and convenience. While in PNH, complete blockade requiring a combination of the siRNA with our C5 antibody is required to optimize efficacy. For myasthenia gravis, we presented results from the Phase III NIMBLE trial at the American Academy of Neurology Conference, which were also simultaneously published in The Lancet.

Cemdisiran, our investigational C5 siRNA as monotherapy, met the primary and all key secondary endpoints, with subcutaneous delivery every 12 weeks delivering a 2.3 point placebo-adjusted improvement in the MG-ADL endpoint at week 24. In registrational clinical trials for the leading approved C5 inhibitors, which are administered as large volume intravenous infusions dosed every two weeks or every eight weeks, placebo-adjusted improvements in the same MG-ADL endpoints have ranged from 1.6 to 1.9 points at similar time points.

For cemdisiran, clinically meaningful efficacy was demonstrated by week two. Moreover, these improvements deepened over time and were sustained through week 24 with no indication of waning efficacy between doses. The totality of the data, including mostly mild to moderate adverse events, support a compelling profile for cemdisiran as a stand-alone quarterly therapy for this disease.

These data have been submitted to the FDA, and we expect a regulatory decision in the fourth-quarter of this year. In PNH, our Phase III lead-in results reinforce the requirement for the combination of cemdisiran plus pozelimab, our C5 antibody, to deliver complete and sustained disease control. Lead-in results suggest that our combination will provide best-in-class control based on LDH measures, and that patients who are uncontrolled on ravulizumab can largely be controlled when switched to our combination. Enrollment in the registrational-enabling cohort of the Phase III study is now complete and results are expected late in the fourth-quarter of this year.

Additionally, in PNH and as part of our ongoing complement strategy, we recently initiated a first-in-human study evaluating siRNA that targets Complement Factor B. This approach is initially intended for the 20% to 30% of patients who, despite optimal C5 therapy remain anemic due to extravascular hemolysis, but also has the potential to expand to a broader PNH population. If successful, siRNA targeting of CFB could overcome the limitations associated with current CFB inhibitors, which require daily dosing and carry the risk of catastrophic hemolysis if doses are missed.

In ophthalmology, our C5 approach in geographic atrophy is on track to deliver interim data from the exploratory cohort of our Phase III study in the fourth-quarter of this year, which will help inform our pivotal strategy. As a reminder, we are evaluating cemdisiran with or without pozelimab administered systemically with the goal of slowing the growth rate of GA lesions while avoiding ocular safety issues that have been observed with certain approved intravitreal therapies. However, to ensure that we have optionality depending on what we learned clinically, we have also recently begun clinical development of an intravitreal formulation of pozelimab, and we'll also follow up with a co-formulation of pozelimab with aflibercept since some of the patients also develop wet AMD while being treated for their GA.

Now turning to immunology and inflammation, and starting with Dupixent. In the United States, Dupixent was recently approved as the first and only medicine for allergic fungal rhinosinusitis, or AFRS in adults and children six years and older. AFRS is a specific type of chronic rhinosinusitis with nasal polyps that more often requires surgery and is associated with higher rates of post-operative recurrence.

Dupixent was also approved in the United States and Europe as the first targeted medicine for children 2 to 11 years of age with chronic spontaneous urticaria, expanding the eligible patient population beyond adolescents and adults. This approval reinforces the expanding role of Dupixent across diseases driven in large part by type two inflammation and across a broad range of ages.

Regarding our efforts to develop next-generation approaches to the Dupixent pathway, we have previously disclosed that we have developed innovative VelocImmune-derived, fully human, long-acting antibodies and bi-specifics that target the IL-4 receptor itself as does Dupi as well as the IL-13 and IL-4 cytokines that act through this receptor.

We are on track to initiate a first-in-human trial for our IL-13 antibody by the middle of this year, both in healthy volunteers and in patients with atopic dermatitis, with plans to execute an expedited path to regulatory approvals. Beyond Dupixent life cycle opportunities, we continue to advance our next wave of immunology and inflammation programs.

Our goal is to keep exploring genetically validated targets that have the potential to become future pipeline in a product opportunities. We're initiating a first-in-human study of an antibody to a target identified by the Regeneron Genetic Center as being genetically linked to several diseases such as lupus, Sjögren's and primary biliary cholangitis.

We're also continuing to evaluate the best path forward across respiratory and sino-nasal diseases for itepekimab, our interleukin-33 antibody. In chronic rhinosinusitis with nasal polyps, our Phase III studies are ongoing with the results expected in 2027. Regarding COPD, we, Sanofi and global regulators continue to discuss a potential third Phase III study, but no decision has been made on whether to move forward.

Turning to oncology. On fianlimab, our LAG-3 antibody in combination with Libtayo, our Phase III study in metastatic melanoma remains on track with results expected later in the second-quarter of this year. The primary analysis of progression-free survival will now consider all patients enrolled in the study with a minimum follow-up of six months.

In adjuvant melanoma, the study continues following the first interim analysis, with the second interim analysis and if necessary, a final analysis, both expected in the second half of this year. We also continue to advance pivotal studies for Lynozyfic in multiple myeloma and premalignant conditions and expect to have results by early 2027 from our study in multiple myeloma patients that have received at least one prior line of therapy, as well as MRD negativity results in 2028 from our study in first-line myeloma patients who are ineligible for stem cell transplant. Our first-line study for odronextamab in first-line follicular lymphoma is fully enrolled. This is the only study exploring a bispecific as monotherapy versus the current standard of care, which is R-CHOP, across this bispecific arena.

Moving to anticoagulation. We initiated additional Factor XI registrational studies in stroke prevention in patients with atrial fibrillation who are not candidates for direct oral anticoagulants as well as cancer-associated venous thromboembolism.

Additional studies in peripheral arterial disease, peripherally inserted central catheter-associated thrombosis, secondary stroke prevention as well as SPAF in DOAC eligible patients are all expected to commence this year. The initial registrational [results] from studies in venous thromboembolism prevention following knee replacement surgery are expected in the first-quarter of 2027.

Turning to obesity. In March, Hansoh reported positive Phase III results for olatorepatide, our in-licensed GLP/GIP agonist in Chinese patients with obesity, which compared favorably cross-trial to a previous Chinese study of tirzepatide for obesity. In this randomized, double-blind, placebo-controlled trial of 604 adults across 33 sites, olatorepatide met its co-primary endpoints and delivered up to 19% mean body weight loss at week 48.

We are also encouraged by the safety results, in particular, the gastrointestinal tolerability profile. Hansoh is planning on presenting these promising results at a medical meeting later this year. Building on this momentum, our olatorepatide Phase II study in obesity is enrolling rapidly and later this year, we expect to initiate two global Phase III programs, one in patients with obesity and another patients with obesity and type two diabetes. In parallel, our work on the olatorepatide Praluent combination continues with our first clinical study of weekly Praluent initiating shortly.

In rare diseases, Len already mentioned the FDA approval of Otarmeni, formerly known as DB-OTO. This was an incredibly meaningful moment for the company, as it is not only our first gene therapy approval, but one of the most striking successes with gene therapy in history, restoring for the first time a sensory function in humans.

As published in the New England Journal of Medicine, nearly half the children who are born profoundly deaf were able to regain hearing at normal levels within one year of treatment. The mother of one of these children recently told the President of the United States a heartwarming story of how her son was now able to hear her say that she loved him.

We decided to make Otarmeni free in the United States because we believe it was the right thing to do for these families. We hope this highlights and reminds the world that it is the biopharma industry, which is frequently viewed so negatively that is often responsible for delivering such medical miracles to humanity. Regeneron is a different type of company that attracts the best and the brightest to join our fight against disease because we have a heart and a soul as well as a mission and a willingness to play the long game.

Another rare disease that we have been studying for many years is fibrodysplasia ossificans progressiva, or FOP, a devastating condition in which muscle and soft tissues are progressively invaded and replaced by abnormal bone formation. The FDA has accepted for priority review the BLA for garetosmab, our Activin A blocking antibody with a PDUFA date in August of 2026.

If approved, garetosmab will become the first and only available treatment shown to prevent abnormal bone formation in FOP patients. In genetic medicines, our first-in-human trials testing siRNAs targeting Superoxide Dismutase or SOD1 in amyotrophic lateral sclerosis, alpha-synuclein for Parkinson's disease and MAP tau for Alzheimer's disease are enrolling patients and our initial MASH siRNA program readouts targeting CIDEB, PNPLA3 and HSD17B13 are expected by the end of this year.

Concluding with recent early-stage research updates; the Regeneron Genetics Center recently announced a collaboration with TriNetX to access de-identified electronic health record data from a global network representing 300 million patients, creating an opportunity to connect large-scale genomic and proteomic cohorts to real-world clinical data in ways that can accelerate drug discovery, translation, development as well as providing new ways of addressing digital health issues.

Regeneron also announced a strategic collaboration with Telix to co-develop and co-commercialize next-generation radiopharmaceutical therapies combining Regeneron's antibody discovery and oncology capabilities with Telix' radiopharmaceutical development and manufacturing expertise. In summary, we remain focused on advancing our late-stage, mid-stage and early-stage programs as well as innovative research, which we firmly believe has the potential to continue to change the practice of medicine.

With that, let me turn it over to Marion.

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

Thanks, George. Our first-quarter results represent a strong start to 2026. Our market-leading brands, EYLEA HD, Dupixent and Libtayo, delivered ongoing growth based on their clinical profile and our ability to execute effectively in competitive markets. We begin 2026 well positioned to advance our portfolio and are excited by upcoming opportunities to change the lives of even more patients.

Starting with EYLEA HD and EYLEA, which delivered combined US net sales of $942 million in the first-quarter. EYLEA HD net sales were $468 million, representing 52% year-over-year growth. During the quarter, physician demand for EYLEA HD increased sequentially by 10% despite typical first-quarter seasonality. Additionally, in the first-quarter, wholesaler inventory levels were reduced to the normal range.

EYLEA HD now has the broadest label and greatest dosing flexibility of any anti-VEGF medicine following recent label enhancements to include retinal vein occlusion and additional dosing options that range from every four weeks through every 20 weeks. We are encouraged by physician adoption following these label enhancements.

Importantly, we also look forward to the upcoming FDA decision for the EYLEA HD pre-filled syringe, which if approved, would bring what we believe is a best-in-class device to retina specialists and help drive continued uptake for EYLEA HD.

In the first-quarter, EYLEA US net sales were $473 million, representing a 36% year-over-year decline.This reflects ongoing conversion to EYLEA HD, competitive pressures and patient affordability issues. Additionally, during the first-quarter, there was only a modest reduction in EYLEA inventory and continued inventory absorption is expected to negatively impact net product sales in the second-quarter by approximately $20 million.

Looking ahead to the second-quarter, we expect to achieve sequential unit demand growth for EYLEA HD that is consistent with the 10% sequential demand growth in the first-quarter. Conversely, for EYLEA, we anticipate that demand will decline in the mid- to high teens in the second-quarter ahead of the potential launch of additional biosimilars in the second half of the year, coupled with the factors that I highlighted earlier.

Together, EYLEA HD and EYLEA lead the innovative branded anti-VEGF category with more than 100 million injections of EYLEA HD and EYLEA administered worldwide since launch. Additionally, in the US, EYLEA HD now contributes half of net sales for our retina franchise. Turning to Dupixent, which continues to transform the lives of more than 1.4 million patients worldwide with type two inflammatory diseases that are currently on treatment.

In the first-quarter, Dupixent net sales were $4.9 billion, representing 31% year-over-year growth on a constant currency basis. US net sales grew 35% year-over-year to [$3.6] billion . We continue to see growth across all nine indications, including recent launches, making Dupixent the number one biologic medicine prescribed by dermatologists, pulmonologists, allergists and ENTs.

Across the blockbuster indications of atopic dermatitis, asthma, nasal polyps and eosinophilic esophagitis, Dupixent continues to drive strong growth based on its differentiated clinical efficacy, safety profile and physicians' strong preference for this brand. Uptake is also strong across more recent launches, including chronic obstructive pulmonary disease, chronic spontaneous urticaria, bullous pemphigoid and allergic fungal rhinosinusitis.

These launches across a growing range of age groups provide a runway for even more patients to benefit from Dupixent. With annualized global net sales of nearly $20 billion and significant room for further market penetration across indications, Dupixent is well positioned for sustained growth over the near and long term.

Turning to Libtayo, which delivered $438 million in global net sales in the first-quarter. In the US, net sales were $286 million as Libtayo continues its strong trajectory as the leading immunotherapy for advanced non-melanoma skin cancers. The recent launch of Libtayo in adjuvant CSCC is also an emerging growth driver, with encouraging uptake and positive feedback on this paradigm-changing treatment.

Libtayo is the only NCCN Category one preferred immunotherapy option for eligible adjuvant CSCC patients. In non-small cell lung cancer, Libtayo is established as the second most prescribed first-line immunotherapy treatment in the US, and we expect continued growth through 2026 as we gain incremental share in lung cancer and drive uptake in adjuvant CSCC.

On to Lynozyfic, which is in its second full quarter on the market. Early launch momentum has been driven by positive physician experience, a differentiated clinical profile, lower hospitalization requirements, and convenient dosing schedule. We expect continued gradual uptake as we work to advance our clinical program in earlier lines of therapy.

I also wanted to spend a moment highlighting our expanding rare disease portfolio. Evkeeza is now in its fifth year on market in the US and delivered net sales of $46 million for the quarter, representing 48% growth year-over-year. Evkeeza is well established as a leading treatment for homozygous familial hypercholesterolemia with more than half of all diagnosed US patients currently on Evkeeza or in the process of starting Evkeeza.

As highlighted by Len, we are also launching Otarmeni, which is the first and only gene therapy for children born with genetic hearing loss. In addition, we look forward to the anticipated FDA decision on garetosmab in August. Garetosmab is our potential treatment for FOP and has been shown to prevent 99% of abnormal bone formation.

In closing, our strong first-quarter results demonstrate growth potential across our portfolio. We continue to advance our in-line brands while also preparing for multiple potential indications and new product launches including for cemdisiran for generalized myasthenia gravis, where there is significant commercial opportunity in this large and growing market.

We remain well positioned to deliver meaningful benefit to patients worldwide across a growing number of diseases.

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

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

Thank you, Marion. My comments today on Regeneron's financial results and outlook will be on a non-GAAP basis unless otherwise noted. Regeneron performed well in the first-quarter, highlighted by double-digit growth on both the top and bottom-line. First-quarter 2026 total revenues grew 19% from the prior year to $3.6 billion, driven by higher Sanofi collaboration revenue as well as strong growth in net sales of EYLEA HD in the US and Libtayo globally. First-quarter diluted net income per share grew 15% to $9.47 on net income of $1 billion.

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

We now expect the Sanofi development balance to be fully repaid by the end of the second-quarter. As a result, we expect Sanofi collaboration revenue to step up to reflect our full share of collaboration profits starting in the third-quarter.

Moving to Bayer. first-quarter net sales of EYLEA and EYLEA 8 mg outside the US were $729 million, inclusive of $333 million of EYLEA 8 mg sales. Total Bayer collaboration revenue was $287 million of which $240 million related to our share of net profits outside the US. Other revenue grew 109% in the first-quarter to $171 million. This included $101 million related to our share of profits from ARCALYST and royalty income from Ilaris.

Now to our operating expenses. R&D expense was $1.4 billion in the first-quarter, reflecting continued investments to support Regeneron's innovative pipeline, including pivotal programs across late-stage opportunities in hematology/oncology, complement-mediated diseases and anticoagulation. First-quarter SG&A was $560 million, reflecting investments to support the launch of Libtayo in adjuvant CSCC and to drive continued growth of EYLEA HD.

First-quarter matching contribution to Good Days, an independent nonprofit patient assistance foundation, were de minimis. We remain committed to matching up to $200 million in 2026 to support patient access and affordability.

Non-GAAP gross margin on net product sales was 86% in the first-quarter. Our GAAP gross margin was 76%, which was negatively impacted by costs incurred due to a temporary interruption in bulk manufacturing at our Limerick, Ireland site. We have now resumed initial production in the facility and expect to resume full production by the end of the second-quarter. As a result, we anticipate our GAAP gross margin will continue to be negatively impacted in the second-quarter as production returns to normal levels. This interruption has not impacted and is not expected to impact the availability of any products.

Regeneron generated $848 million of free cash flow in the first-quarter of 2026 and ended the quarter with cash and marketable securities less debt of $15.8 billion. We repurchased $800 million of our shares in the first-quarter and announced this morning that the Board of Directors has authorized a new $3 billion share repurchase program.

With this new authorization, we have approximately $3.4 billion available for share repurchases as of today, and we remain opportunistic buyers of our shares. We have made some minor changes to our 2026 financial guidance including updating our GAAP gross margin guidance to be in the range of 77% to 78%. This reflects actual and expected costs incurred as a result of the aforementioned temporary manufacturing interruption.

A full summary of our guidance can be found in our earnings press release published earlier this morning. In conclusion, Regeneron is off to a strong start in 2026 with financial results that position us well to continue investing in our pipeline delivering breakthroughs for patients and driving long-term value for shareholders.

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

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

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

Kevin, can we go to the first question, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Tyler Van Buren, TD Cowen.

Tyler Van Buren - Cowen and Company LLC - Analyst

So Dupixent continues to be a monster delivering strong performances quarter after quarter after quarter. And it now looks like it will well exceed $30 billion of global sales. So given that we get a lot of questions from investors, not just on life cycle expansion but the Sanofi collaboration. So can you discuss your willingness to work on life-cycle expansion efforts within the Sanofi collaboration or come to an agreement on commercializing these assets together in order to take advantage of the Dupixent rebate wall and the status of that as opposed to moving life-cycle expansion candidates for yourself and potentially further building out the commercial infrastructure?

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

Tyler, it's Len. Thanks for that very poignant question. Maybe it will give me an opportunity to publicly thank Paul Hudson for all the work he did on Dupixent since 2019. Thank you, Paul. We wish you good luck in your next chapter. Also, as of today, Sanofi's new CEO, Belén Garijo is officially, I think, the CEO today. So we want to welcome Belén and wish her luck, and we look forward to working with her and the rest of her team.

Tyler, you're right, Dupixent is a remarkable product. As Marion detailed and George outlined, it's helping so many different people... millions of people with different diseases and is a financial juggernaut for the company. We are always open-minded to transactions, certainly leveraging what we've built in terms of both development capabilities as well as commercial capabilities has merit to it.

We can do these things ourselves. We've had interest from many different places to, sort of, take on some of the next opportunities with us. But we're open-minded, and I look forward to talking with Belén and her team in the coming weeks and months, et cetera.

Operator

Terence Flynn, Morgan Stanley.

Chun Yu - Morgan Stanley - Analyst

Great. This is Chris, on for Terence. We have a question about fianlimab in metastatic melanoma. Is the PFS differentiation enough to capture majority share? Or do you think you need OS as well?

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

Well, it obviously depends on the results. It depends on exactly what the PFS results are. But the study is also designed so that, if we have a substantial OS benefit, we will see that as well. And so the hope, of course, is that the study will show both the PFS and an OS benefit. But the results remain to be seen.

Operator

Chris Raymond, Raymond James.

Samuel Alexander Leach - Raymond James - Analyst

This is Sam Leach, on for Chris Raymond. Just one on the EYLEA pre-filled syringe. So any commentary on why FDA missed the April PDUFA? And was that a request for more information or a backlog issue? And then you noted there was a reinspection at Catalent Indiana, and you've resubmitted. Can we read in between the lines and assume that means the site inspection was positive? And what's kind of your overall guidance on timing for either of these applications?

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

Yes. So thanks for the question. I think we've told you what we know. We don't -- if the inspection turns out to be positive, then I think they will approve the drug. So we await and both applications are pending. And the only thing I can say is that based on our conversations and how hard everybody is working at this, and the FDA, I think, desire to get these sites up to the standards they want as well as get the products out there that are waiting, that we anticipate action on one or both of these during this quarter.

Operator

Cory Kasimov, Evercore ISI.

Cory Kasimov - Evercore Inc - Analyst

I wanted to ask about Lynozyfic and kind of the outlook in the multiple myeloma space. When we talk with docs, there's obviously excitement about the potential of BCMA bispecifics, the main pushback on widespread adoption is the infection risk they carry, especially in earlier-stage patients. So curious what you make of the debate and how you're trying to mitigate this in your trials going forward?

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

So the debate of their use compared to what?

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

Existing standards of care like Darzalex, et cetera.

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

So obviously, all of these approaches carry significant infectious risks. As we've shown in our study, the disease itself carries substantial infectious risk. And if you actually look at our detailed data and publications on the matter, it actually turns out that the longer you treat these patients, the more you control their disease, the more functional their bone marrow becomes, actually infectious risk goes down over time, which is actually quite stunning.

So I think that the profile, if you really look at it, of the bispecifics in general and our bispecific in particular, are very, very, promising not only in terms of their impressive efficacy. But in terms of their overall side effect and tolerability profile, including, of course, the infectious risk. So we think that this is going to become the dominant class for the treatment of this disease as well as its precursors.

And we believe that if you look at the data, that our agent is certainly competitive, if not indeed best-in-class across all parameters here.

Operator

Tazeen Ahmad, Bank of America.

Tazeen Ahmad - BofA Merrill Lynch Asset Holdings Inc - Analyst

As you think about next-gen Dupi, how are you thinking about the importance of having a late-stage program clearly defined before the US IP for Dupixent goes away whenever that might be, just given the increasing number of potential long-acting injectables and other oral agents that might come online?

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

Yes. Look, we don't know how long the patent life will be for Dupi because we have lots and lots of intellectual property out there, lots of different types of patents, use patents, formulation patents, in addition, obviously, to the composition patent. In terms of how we think about this, to us, we want to leverage our knowledge in immunology. We don't necessarily think about having to exactly replace or work on...

We have nearly 50 things in the pipeline, and we're looking forward to bringing as many important ones forward as we can. But we do have a number of these that George, I think, talked about: the extended interval Dupixent, going after long-acting IL-13, IL-4, other diseases that we haven't even covered with Dupi, such as allergic diseases, in general, food allergies and so forth.

So I think there's a lot of opportunity and one shouldn't just focus on a simple replacement or what have you, and one shouldn't assume when the patent for Dupi will actually expire.

Operator

Carter Gould, Cantor.

Carter Gould - Cantor Fitzgerald LP - Analyst

Maybe to change it up a bit. For George, as you spoke about the co-injection of C5 with aflibercept, should we think about that as more of a convenience play, sort of with the co-administration or potentially more of, I guess, a label expansion as you think about potentially preventing wet AMD, I guess, forming for lack of a better term?

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

I think those are both interesting possibilities. It could be used to actually prevent the development of the wet AMD and/or to treat the patients who develop it. And very importantly, as you probably know, there's a lot of evidence and suggestions about the causes of the occlusive retinal vasculitis that is seen with the other agents that are, for example, totally different kinds of molecules and PEGylated and so forth. And these -- some of the characteristics of those molecules are associated with this occlusive retinal vasculitis.

We hope and we believe based on our experience with biologics, with EYLEA and with this particular antibody that we may not only have these convenience benefits. But perhaps most importantly, we may also avoid the very tragic, very horrific side effects that are seen with the existing agents, which would allow them to be much more broadly used.

Moreover, we would think, once again, as our experience indicates, the history with EYLEA that we can have much longer-acting versions. And moreover, depending on how the data looks with the systemic as well as the local, one could imagine even combined the two to allow

for a very long-acting injections in the eye. So there's a lot of possibilities that could address better safety profile, as well as convenience, as well as potential even efficacy.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - Bank of Montreal - Analyst

I'd love for you to walk me through the commercial considerations for developing your combo GLP-1/GIP plus Praluent. And how can you accelerate the development to remain competitive in this rapidly evolving market?

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

Well, the way we look at it, and I think Len came up with this terminology, imagine if you invented a GLP that was as good as the currently best-in-class agent, let's say, tirzepatide, and acted very much the same, but also lowered your bad cholesterol by more than 50% and was shown to decrease your risk of cardiovascular outcomes like heart attacks and death, that GLP would become the preferred GLP on the planet, especially if you priced it at a very similar price. Why would anybody take any other GLP.

We are very buoyed the data that we see coming from our collaborators in China, where the cross trial comparisons show that as we predicted based on our due diligence of the molecule, that it behaves if anything as well as tirzepatide. And of course, our folks in the lab have been busy working developing co-formulated forms of this GLP together with our Praluent, which we believe we can be delivering by a very similar convenient auto-injector approach using the same approach as the GLPs are delivered as well.

And we believe that we can price it very competitively to the GLPs. And we would think that, honestly, any physician prescribing it or any patient thinking about it would say that why would they ever take a GLP, especially since we know of the profound co-morbidities associated with cardiovascular risk and hyperlipidemia in the same population.

Why would they ever take a GLP if they had an option of taking a GLP that also lowered their lipids and also decrease the risk of bad cardiovascular outcomes. So us, honestly, it sort of seems like a no-brainer. Obviously, there will be competition, but we believe we have potentially a best-in-class GLP and a best-in-class PCSK9 and the convenience for many people of these auto-injectors is now becoming so pervasive that we think a large segment of the population, will offer them.

Now this is, of course, not even presuming that the side effect profile that we see in China more broadly pertains in our upcoming global studies. So we think this is a very, very exciting and a very, very large opportunity.

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

George, could you just correct the misunderstanding about weight loss, not lowering lipids?

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

Yes. So it's -- thank you, Len. It's a great point. As many people obviously know, weight loss and the GLPs can provide cardiovascular outcome benefits. But they do this by creating benefits across a wide variety of different risk factors, and they only lower your bad cholesterol by a few points in contrast to the 50% to 60% lowering that we see with the PCSK9 blockers.

So this will be a real add-on in terms of the cardiovascular benefit and the lipid benefit compared to just GLP alone, which, by themselves, though they benefit outcomes, they do very little in terms of your lipid profile. So many patients are obviously left with still high risk, based on their lipid profile if they're either obese or especially obese with type 2 diabetes where dyslipidemia there is a very serious and common comorbidity concern.

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

Finally, the use of cholesterol-lowering drugs is now finally catching up, I think, to the science, where the recommendations are to start earlier and longer. So I think that the indicated population to lower cholesterol and lose weight is going to be even broader. So as George said, this is a really significant opportunity.

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

Well, and very importantly, from the public health perspective, though recommendations are all about how focus on your lipids, much earlier, widespread use of lipid-lowering medications. They are dramatically underutilized in the world. Unfortunately, this causes incredible morbidity and death. Heart disease is still the leading cause of death in the United States.

In part because of the underutilization of these incredible weapons we have; we think in a Trojan horse sort of way, this will provide incredible public health benefit by having all the people who are really so worried about their weight loss also get the lipid benefit, which will have this dramatic benefit, which is unfortunately underutilized and underappreciated.

Operator

Alexandria Hammond, Wolfe Research LLC.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Can you share a little bit more on your clinical strategy to expedite development of your next-gen I&I assets, particularly Supi-Dupi? How do you expect to be able to kind of leverage the changes within FDA to further speed this development up? And has there been an ongoing dialogue with the regulators?

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

Well, we've obviously -- we're world leaders in this field. We created the field. We did the first studies in atopic dermatitis in the field. And we are well positioned, we believe, to expedite and accelerate the programs as rapidly as possible, and we feel very good about our position and our plans here.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Just regards to the life cycle strategy for Dupixent, which is broad and multipronged, where do you feel you have the most line of sight? And how are you optimizing the IL-4 agent or Supi-Dupi?

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

Yes. I think what George said is that we have a lot of experience here. We don't need to give out all of our details to help any competition that might be out there. But the team knows what they're doing. Supi-Dupi is one that Sanofi and Regeneron, by mutual agreement can add to the collaboration. We have the knowledge, the capabilities and the desire to do this as efficiently as possible.

Operator

Chris Schott, JPMorgan.

Taylor Hanley - JPMorgan - Analyst

This is Taylor Hanley on for Chris Schott. We were just wondering on Libtayo. Can you provide any color on the drivers of performance this quarter? Was there anything onetime in there? How much of this was driven by the new indication, CSCC? And is this a good baseline to think about growing off of going forward?

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

Sure, very happy to take the question. And I think the Libtayo performance certainly is strong. I would characterize the strength based on certainly the advances that we've seen in our skin indications. Now with adjuvant CSCC, very exciting to help this group of patients with Libtayo. There's been a lot of enthusiasm. And certainly, the clinical profile of Libtayo in this indication is highly distinguishing.

We also see performance in our lung cancer indication. US and international performance are strong. I would characterize the quarter though by comparison to a year-over-year comparison in a quarter that had some movement in inventory. We can certainly go back and share more of the details with you on that. But it's a very strong quarter, but there is some comparison that favored this quarter.

Operator

David Risinger, Leerink Partners.

David Risinger - Leerink Partners LLC - Analyst

Yes. Len and George, my question is for you. So Regeneron spends aggressively on R&D, but the investment community lacks confidence that the company's candidates will move the needle commercially in particular versus established competitors. So could you please highlight the pipeline candidates in late-stage development that will have cards turning over in the near term or relative near term, ie, in the next... I don't know, 18 months or so, that you have the greatest confidence in that can generate multibillion-dollar peak sales that investors will be able to see more clearly in the next 18 months or so.

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

That's perhaps the most penetrating, in the 160-odd conference calls I've done, penetrating and detailed question. But unfortunately, David, it will probably take several hours to answer. We have a robust pipeline. We do have, obviously, highlighting the C5 franchise, where we'll have more data and an approval action. We will have 11, I think, Phase III trials ongoing in our anticoagulation program which is a massive opportunity.

We have our Lynozyfic and our odronextamab, our bispecifics in myeloma and lymphoma, are ongoing. I think George just talked about our ola, and ola plus ali as a near term. And obviously, even in this quarter, we have fianlimab plus Libtayo in metastatic melanoma. So we -- maybe that I'll leave that for openers, but we -- and we have more and more things.

But we've got some exciting data coming out that we haven't even talked about, and I didn't just mention. So lots going on when you have 48 exciting things in development.

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

Can I just say, I mean I want to comment that past performance should be the strongest indicator of future performance. There's only one company in recent history that have its own labs produced two $10 billion-plus blockbusters. And let me remind you that I think you and probably a lot of other investors never saw those coming, or ignored what we were saying about them.

So I think that investor confidence, I think, should in large part be reflecting historical performance and the recognition that where blockbusters come from sometimes for the investor community can't be directly anticipated. And the best way of producing very important big drugs is by having very exciting molecules across all stages of development that have enormous opportunity.

And if you just look at our oncology programs, whether it's the fianlimab Libtayo, whether you look at Lynozyfic, whether you also look at odronextamab in follicular lymphoma. These are all potential blockbusters. The C5 franchise is a pipeline in a franchise, multiple blockbuster opportunities there. Our Factor XI customized approaches are looking more and more exciting, especially based on competitor data using, we think, inferior and less convenient approaches.

And we just covered the obesity opportunity, which arguably could become the preferred obesity approach that not only addresses obesity, but more aggressively addresses cardiovascular morbidity. So I don't know, it's hard to think of a more exciting pipeline in the entire industry.

Operator

Geoff Meacham, Citi.

Geoffrey Meacham - Citibank Cameroon SA (Douala Branch) - Analyst

On fianlimab and lung, I just wanted to see if you guys can give us a bit more context for not moving to Phase III, maybe what was observed in the data, and from a tolerability perspective, is there any read-through to melanoma or broader solid tumor in terms of strategy?

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

Yes. I think that we've been talking about this for a long time. I mean we never indicated that we were excited about this opportunity. Our data from earlier-stage studies was always pointing us to the melanoma opportunity. Once we see that data, it will certainly guide our thinking forward and in terms of going into additional cancer settings as well. But as we've been saying for a while, we never had any reason to really believe that this was going to be a game changer in the lung cancer space.

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

And Geoff, there's no negative read-through from any new side effects or anything unanticipated.

Operator

Brian Abrahams, RBC Capital Markets.

Brian Abrahams - RBC Capital Markets Inc - Managing Director

We were intrigued by the inclusion of milder patients in your long-acting IL-13 study versus contemporary AD trials. So I was wondering if you could talk about the potential untapped opportunity for systemic biologics here and the degree to which you can broaden the market even beyond where Dupi is used now?

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

Certainly, in patients with mild disease, there's a lot of unmet need. So this is a potential area for greater understanding and advance for treatment. I think we'll have to wait and take a look at clinical profile and opportunities and determine from there, but it is a large population. And [for] the patient or the parent of the child with mild disease, it really isn't mild, it's aggravating, it's difficult. And certainly, there's a lot of unmet need and potential.

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

Yes. And I have to say there was certainly in the early days of bias by investigators and the agency against using “a powerful biologic”. It could be immunosuppressive. Remember, we didn't find it to be immunosuppressive. In fact, in the moderate to severe cases of atopic dermatitis, we actually saw less infections in patients who had skin lesion healing.

It is not immunosuppressive on the side of the immune axis which deals with the kind of infections that people are used to with biologics or might be with some of the orals that suppress both arms of the immune system, as George has talked many times, the type 2 immunity is not something we rely on to keep us healthy from infections. It might play some role in parasitic infections. But you've got so many people having been treated now and now thinking about going earlier makes some sense.

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

All right. That's all the time we have for today. Thanks to everyone who dialed in for your interest in Regeneron. We apologize to those folks remaining in the Q&A queue, who we did not have a chance to hear from today. As always, the Investor Relations team at Regeneron is available to answer any remaining questions you may have. Thank you once again, and have a great day.

Operator

Thank you. Ladies and gentlemen, this does conclude today's presentation. We thank you for your participation. You may now disconnect, and have a wonderful day.
