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These statements concern, and these risks and uncertainties include, among others, competing products and product candidates (including biosimilar products) that may be superior to, or more cost effective than, products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates"); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties or other factors beyond Regeneron's control on the commercial success of Regeneron's Products and Regeneron's Product Candidates; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's Product Candidates and research and clinical programs now underway or planned, including without limitation EYLEA HD[®] (aflibercept) Injection 8 mg, EYLEA[®] (aflibercept) Injection, Dupixent[®] (dupilumab), Libtayo[®] (cemiplimab), Praluent[®] (alirocumab), Kevzara[®] (sarilumab), Evkeeza[®] (evinacumab), Veopoz[®] (pozelimab), Ordspono[™] (odronextamab), Lynozyfic[®] (linvoseltamab), Otarmeni[™] (lunsotogene parvec), other clinical programs discussed in this presentation, Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; 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changes to drug pricing regulations and requirements and Regeneron's drug pricing strategy, including in connection with our April 2026 agreements with the U.S. government; other changes in laws, regulations, and policies affecting the healthcare industry; unanticipated expenses; the costs of developing, producing, and selling products; Regeneron's ability to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; Regeneron's estimates of market opportunities for Regeneron's Products and Regeneron's Product Candidates; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2025 and its Form 10-Q for the quarterly period ended June 30, 2026. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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EDITED TRANSCRIPT

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Company Summary

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PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals second quarter 2026 earnings conference call. My name is Michelle, and I'll be your operator for today's call. (Operator Instructions) Please note that this conference call is being recorded. I will now turn the call over to Ryan Crowe, Senior Vice President, Investor Relations. You may begin.

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

Thank you, Michelle. Good morning, good afternoon, and good evening to everyone listening around the world. Thank you for your interest in Regeneron, and welcome to our second 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, Co-Founder, Board, Co-Chair, President and Chief Executive Officer; Dr. George Yancopoulos, Co-Founder, Board, Co-Chair, President and Chief Scientific Officer; Marion McCourt, Executive Vice President, Commercial; and Chris Fenimore, Executive Vice President, Finance and Chief Financial Officer.

For our call today, Len will briefly review key second quarter performance drivers, highlight important upcoming pipeline catalysts and provide a few comments on capital allocation. George will then detail our recent pipeline progress, followed by Marion, who will review our commercial portfolio. And finally, Chris will discuss our financial results and outlook.

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 June 30, 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 in our quarterly results press release and our corporate presentation, both of which can be found on the Regeneron Investor Relations website. Once our call concludes, the IR team will be available to answer any further questions.

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

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

Thanks, Ryan, and thanks to everyone for joining today's call. Before we begin, I would like to acknowledge with deep sadness the passing earlier this week of financial industry luminary and long-time Regeneron Director, Arthur "Art" Ryan. Art served on our Board for more than two decades and was a trusted adviser whose judgment, integrity and business insight helped guide the company through many important milestones.

Prior to joining Regeneron's Board, he built a distinguished career in financial services, including serving as Chairman and CEO of Prudential Financial and previously as President and COO of Chase Manhattan Bank. In addition, Art left an enduring legacy of civic engagement and philanthropy throughout Newark and Essex County, New Jersey.

On behalf of everyone at Regeneron, I want to express our gratitude for Art's many contributions and years of service. We join his family and all who knew him in celebrating his life and legacy. We will miss his wisdom and unparalleled support of Regeneron's mission.

Turning now to our business. Regeneron delivered another strong quarter with total revenues up 17% and non-GAAP earnings per share up 11% compared to the second quarter of 2025, marking our second consecutive quarter of double-digit growth on both the top and bottom lines.

Dupixent, EYLEA HD and Libtayo all set new all-time highs for quarterly net sales and are carrying strong momentum into the second half of the year. Dupixent global net product sales as reported by Sanofi, were \$6 billion, up 38% compared to the second quarter of last year on a constant currency basis. Demand trends across all approved indications remain robust and accounted for the majority of the year-over-year growth.

We and Sanofi continue to see a long runway for Dupixent growth driven by further penetration of existing indications, expansion into additional age groups and international growth opportunities. Beyond Dupixent, we are rapidly advancing a broad portfolio of next-generation programs that we believe can build on the foundation we've established with Dupixent.

George will discuss some of our recent progress in this area, including encouraging early clinical data from our long-acting interleukin-13 antibody. Our collaboration with Sanofi spans nearly two decades and has been one of the most successful in the biopharmaceutical industry.

Together, we have built a highly productive development and commercialization engine and the continued success of Dupixent in nine FDA-approved indications across specialties ranging from dermatology, pulmonology, gastroenterology, ENT and allergy highlights the value that this model can create.

Given that success, I can report that we have had productive early discussions with Sanofi to identify potential opportunities for further collaboration, including for several of Regeneron's Dupixent follow-on programs.

EYLEA HD in the US continued to gain momentum with net product sales in the second quarter of nearly \$600 million, up 52% compared to the prior year. Importantly, this quarter marked the first time EYLEA HD net sales exceeded EYLEA, highlighting the continued strength of the conversion to our next-generation product.

Physician unit demand for EYLEA HD in the second quarter increased 24% sequentially, reflecting continued strong uptake following recent FDA label expansions and growing prescriber appreciation for EYLEA HD's differentiated profile and dosing flexibility.

We continue to work towards obtaining approval for yet another product enhancement for EYLEA HD, the EYLEA HD prefilled syringe. We expect launch of this new enhancement to drive even further adoption of EYLEA HD, and we are continuing to work closely with the FDA and multiple contract manufacturers with the goal of approval before the end of the year. All in all, EYLEA HD has performed extremely well, and we look forward to continuing to grow this product.

Libtayo maintained its strong growth trajectory in the second quarter. Global net product sales reached nearly \$500 million, up 29% compared to last year on a constant currency basis. Growth was driven by continued strong adoption in its approved non-melanoma skin cancer indications and further penetration in non-small cell lung cancer, where Libtayo now captures 20% of new-to-brand prescriptions in the US. Beyond its growing patient impact and commercial contribution, Libtayo remains the strategic backbone of our ongoing efforts to expand and strengthen our oncology portfolio.

Turning to the rest of the pipeline. I firmly believe that one of Regeneron's core strengths is that we do not rely on any single program or platform. Our pipeline is broad, diversified and highly productive. And while not every program will succeed, we are confident that it will create many [of] substantial value for patients and shareholders. With approximately 50 active clinical programs and many rapidly advancing preclinical candidates, we have one of the largest R&D portfolios in the entire industry.

George will have more details on our pipeline progress in his remarks, but I want to highlight a few important programs where we expect near-term regulatory and clinical milestones. We anticipate multiple milestones for our C5 complement programs, including an FDA decision in November for our new drug application for cemdisiran, an siRNA that targets C5 in generalized myasthenia gravis, which we believe has the potential to offer a differentiated profile for patients living with this serious autoimmune disease.

We also continue to make meaningful progress across several longer-term value drivers, including Factor XI for coagulation disorders, linvoseltamab for multiple myeloma and pre-malignant conditions and our obesity portfolio, where we expect multiple Phase III study initiations later this year.

Now to a few comments on capital allocation, where our framework remains consistent. First and foremost, we believe the highest return opportunities to continue [to come] from investing in our own science. At the same time, we remain active in evaluating external opportunities. We are casting a wide net across the universe of business development options with particular interest in areas where we can leverage Regeneron's differentiated expertise in genetics, antibody engineering, clinical development, manufacturing and product commercialization.

While we remain disciplined on valuation and strategic fit, we believe our financial strength, scientific capabilities, operational infrastructure and long-term perspective, position us well to capitalize on compelling opportunities as they emerge.

In closing, our ability to repeatedly discover, develop and deliver important medicines has been a defining strength of Regeneron for decades. This quarter's performance, together with the important milestones ahead, reinforces our confidence in the company's long-term outlook.

We have a thriving commercial business, a deep and diverse pipeline and a talented team committed to improving patients' lives through science. Together, these trends position us well to continue delivering meaningful innovation for patients and sustainable value for our shareholders.

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

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

Thanks, Len. Today, I'll focus on the key updates from our development pipeline. For a comprehensive summary of our mid- and late-stage pipeline, please refer to the Programs in Clinical Development section of our 10-Q.

I'll start with our complement-mediated disease franchise, beginning with cemdisiran, our C5 siRNA. Regulatory submissions for cemdisiran monotherapy in generalized myasthenia gravis or gMG, have been accepted for review by both the FDA and the EMA.

The FDA target action date is in November of this year, while the European Commission decision is anticipated in the second half of 2027. If approved, cemdisiran would represent a highly differentiated treatment option in gMG and be the first siRNA approved for this disease. We believe cemdisiran's efficacy, safety and convenient 4 times per year subcutaneous dosing profile, is highly differentiated from C5 antibodies and other modalities approved for gMG.

For cemdisiran, in combination with pozelimab, our C5 antibody, we continue to expect registrational data in paroxysmal nocturnal hemoglobinuria or PNH, in the fourth quarter of this year. Our Phase III lead-in cohort that compared this combination with ravulizumab, an FDA-approved antibody to C5 for the treatment of PNH, suggested that our combination could provide a more convenient monthly subcutaneous regimen that could also improve disease control based on LDL measures and support our hypothesis that complete complement blockade in this disease is required for sustained disease control.

As a reminder, the registrational study is evaluating non-inferiority of our C5 combination versus eculizumab, the other C5 antibody that is FDA approved for the treatment of PNH, using co-primary endpoints of intravascular hemolysis control as well as transfusion avoidance.

In ophthalmology, our C5 approach in geographic atrophy, or GA, remains on track to read out 26-week data from our exploratory cohort in the fourth quarter of 2026, which will help inform our pivotal strategy. As a reminder, we are evaluating systemic administration of cemdisiran with or without pozelimab with the goal of slowing the rate of GA lesion growth and associated declines in visual acuity while avoiding the ocular safety issues that have been observed with certain FDA-approved therapies.

We are also evaluating intravitreal pozelimab in GA to provide optionality and are actively developing co-formulations of this with other agents such as aflibercept to address comorbid retinal disease settings. In immunology and inflammation, to follow on, on Dupixent's success, we continue to advance a series of next-generation fully human antibodies and bispecifics designed to build on Dupixent by extending duration, enhancing target coverage and potentially improving efficacy.

We have enrolled initial healthy subjects in our first-in-human trial for a long-acting IL-13 antibody and expect to begin dosing patients with atopic dermatitis later this quarter with plans to execute an expedited path to starting registration-enabling studies potentially by the end of next year or early 2028.

Our initial clinical data indicate that this antibody has a prolonged half-life that has the potential to extend the dosing interval well beyond those achieved with currently approved products in this category. First-in-human studies of our other next-generation long-acting antibodies

are planned with next-generation Dupixent, or Supi-Dupi, expected to be clinic ready by early 2027 and additional candidates, including our IL-4/IL-13 bispecific next year.

Briefly on to oncology. Ubatamab, our MUC16xCD3 bispecific continues to demonstrate promising monotherapy activity in low-grade serous ovarian cancer, a subset of advanced ovarian cancers, and we plan to present detailed data in this setting at a medical meeting this fall.

We also continue to advance pivotal studies for Lynozyfic, our BCMAxCD3 bispecific in multiple myeloma and pre-malignant conditions, including a newly initiated pivotal study in high-risk smoldering multiple myeloma. We expect results next year from the LINKER-MM3 study, our confirmatory trial of Lynozyfic monotherapy versus standard of care in patients who have received at least one but no more than 4 lines of therapy.

In 2028, we expect minimal residual disease or MRD negativity results from our first-line study in transplant ineligible myeloma patients as well as our Lynozyfic-carfilzomib combination study in myeloma patients who have received one or more prior lines of therapy.

At the American Society of Clinical Oncology, or the ASCO meeting, we presented first results from the Phase I/II LINKER-AL2 trial of Lynozyfic monotherapy in patients with second-line plus systemic light chain or AL amyloidosis.

Normalization of free light chain occurred by day 15 across all doses and 100% of patients achieved a hematologic complete response at the highest dose tested. The majority of patients with renal or cardiac involvement demonstrated improvement in organ function despite short follow-up. The Phase II portion of the study which has registrational intent is now ongoing. A Phase III study in first-line light chain amyloidosis is planned to start early next year.

Moving to anticoagulation. We are on track to initiate the remaining Phase III studies from our comprehensive Factor XI program this year, featuring cenvacibart, our catalytic antibody formerly known as REGN7508 and amrecibart, our A2 antibody formerly known as REGN9933. Pivotal results from our studies in venous thromboembolism or VTE prevention following total knee replacement surgery are expected in the first half of 2027.

Also in 2027, we anticipate results from the Phase II ROXI-ATLAS study, which evaluates both Factor XI antibodies against apixaban in stroke prevention in patients with atrial fibrillation or SPAF, which is expected to provide us with important insights into bleeding risks after three months of observation.

We have also begun enrolling patients in our Phase III SPAF trial, ROXI-INCLINE, that will evaluate both of our antibodies against placebo in patients who are not candidates for conventional anticoagulant therapy. We remain excited about our program and favor antibodies as opposed to a small molecule approach as we believe antibodies enable greater and more specific inhibition of Factor XI, leading to improved antithrombotic activity without increased bleeding risk or other off-target safety issues.

Turning to obesity. Olatorepatide, our dual GLP-GIP receptor agonist in-licensed from Hansoh continues to advance. Data from Hansoh's Phase III study of olatorepatide in Chinese patients with obesity, which top-lined in March, will be presented as a late breaker at the European Society for the Study of Diabetes Conference, or EASD in October.

Acknowledging the inherent limitations of cross-trial comparisons, olatorepatide generated weight loss that was comparable to the weight loss observed in a similar study of tirzepatide in China, while demonstrating a favorable gastrointestinal tolerability profile, including meaningfully lower rates of diarrhea, nausea and vomiting. We remain on track to commence Phase III studies later this year in patients with obesity as well as patients with obesity and type 2 diabetes.

In addition to the olatorepatide monotherapy program, we also continue to advance our combination of ola and Praluent, our PCSK9 antibody to address patients with obesity or type 2 diabetes that have comorbid hypercholesterolemia. Also at EASD, we will present 52-week results from the COURAGE study, including accompanying MRI findings in a subset of patients.

Adding trevogrumab to semaglutide did not drive additional weight loss but did show encouraging skeletal muscle mass preservation versus semaglutide alone. These findings reinforce our belief that preventing muscle mass loss may become increasingly important as obesity treatment evolves, particularly in older patients with sarcopenic obesity.

In rare disease, we expect an FDA decision in August for garetosmab, our Activin A blocking antibody in fibrodysplasia ossificans progressiva or FOP. If approved, garetosmab would be the first treatment shown to reduce the number of new abnormal bone formation lesions as well as clinician-assessed flare-ups in FOP patients.

From our earlier-stage pipeline, we are planning to present at medical meetings this fall, some promising clinical data from our pipeline of siRNAs for metabolic dysfunction-associated steatohepatitis or MASH, and for our NPR1 antagonist antibody, [baloncibart] for the treatment of postural orthostatic tachycardia syndrome or POTS.

Finally, we continue to work with the US government and international health organization to deliver potential new treatments for the devastating recent Ebola virus epidemic that is driving the current outbreak in the Democratic Republic of the Congo.

Regeneron developed antibodies are now being tested in nonhuman primates with early data showing they can prevent mortality when administered even after clinical symptoms have already appeared. We are talking with the international health organizations to see whether we will be able to once again help with the current Ebola outbreak as we have in previous outbreaks. In summary, we remain focused on rapidly advancing our broad diverse pipeline, which we firmly believe has the potential to change the practice of medicine across many diseases with high unmet need.

And with that, I'll turn it over to Marion.

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

Thanks, George. Our second quarter results reflect strong commercial execution across our portfolio, delivering meaningful growth from our market-leading brands in multiple therapeutic categories. Starting with our retinal franchise. In the second quarter, EYLEA HD and EYLEA delivered just over \$1 billion in combined US net sales, up 7% quarter-over-quarter.

We also achieved an important milestone in the second quarter with more than 100 million doses of EYLEA HD and EYLEA administered to patients since EYLEA's launch in 2011. Second quarter EYLEA HD net sales in the US were \$596 million, representing a 52% year-over-year increase and 27% growth quarter-over-quarter. These results reflect strong physician demand, which grew 24% from the prior quarter.

EYLEA HD has the broadest label and greatest dosing flexibility of any anti-VEGF medicine following last year's label enhancements to include retinal vein occlusion and additional dosing options that range from every four weeks through to every 20 weeks. EYLEA HD now comprises approximately 60% of US franchise net sales compared to 34% in the second quarter of last year.

Within the innovative branded category, EYLEA HD and EYLEA captured 57% share in the second quarter, and EYLEA HD was the only innovative brand that achieved quarter-over-quarter share growth. Physicians increasingly recognize EYLEA HD for its efficacy, safety and durability profile.

Initial uptake of EYLEA HD in RVO has been strong, driven by its differentiated label and clinical data. EYLEA HD is the only product that offers every eight week dosing in this indication and was the only product to demonstrate numerical improvement in visual acuity in clinical studies compared to EYLEA, the prior gold standard in RVO.

EYLEA US net sales in the second quarter were \$412 million, representing a 45% year-over-year decline and a 13% decline quarter-over-quarter, primarily driven by ongoing conversion to EYLEA HD and competitive dynamics.

Looking to the second half of 2026 for EYLEA, we expect sequential quarterly demand declines in the low to mid-teens due to the factors mentioned as well as additional competition primarily from multiple aflibercept 2-milligram biosimilar launches.

With an EYLEA HD label that now includes wet AMD, DME, DR and RVO as well as the broadest dosing interval in the category, retina specialists increasingly recognize EYLEA HD as the next standard of care in the anti-VEGF category. We expect this will drive sequential demand for EYLEA HD in the low to mid-teens in the third and fourth quarters of 2026.

Turning to Dupixent, which continues to deliver significant benefit to patients globally with more than 1.5 million patients actively treated worldwide, Dupixent has had a tremendous impact across its nine approved indications and is the number 1 biologic medicine prescribed by dermatologists, pulmonologists, allergists and ENTs.

Second quarter net sales were \$6 billion, reflecting 38% growth on a constant currency basis. In the US, sales grew 42% year-over-year to \$4.6 billion, primarily driven by continued growth across our blockbuster indications and uptake in recent launches. In addition, as reported by Sanofi this morning, a favorable gross to net adjustment also boosted US net sales in the quarter.

Dupixent continues to drive strong growth across blockbuster indications, including atopic dermatitis, asthma, nasal polyps and eosinophilic esophagitis, supported by its clinical efficacy and safety profile. Uptake is also growing in our new indications of COPD, chronic spontaneous urticaria, bullous pemphigoid and allergic fungal rhinosinusitis.

With significant opportunity to improve the lives of even more patients, Dupixent is well positioned for sustained growth over the near and long term across approved indications. In the second half of the year, we expect year-over-year global net sales growth to remain strong, but to moderate relative to the first half of 2026 as we annualize recent indication launches and face stronger prior year comparisons.

Turning to Libtayo, which delivered worldwide net sales of \$489 million, up 29% year-over-year on a constant currency basis. In the US, sales grew 38% year-over-year to \$343 million with growth across both non-melanoma skin cancers and non-small cell lung cancer.

The recent launch in adjuvant cutaneous squamous cell carcinoma has generated positive feedback on this paradigm-changing treatment and has been accompanied by increasing use across all approved CSCC settings.

In first-line non-small cell lung cancer, Libtayo is now firmly established as the second most prescribed immunotherapy treatment in the US, where Libtayo's share of new patient starts has doubled since early 2025 to 20% as physicians increasingly recognize its strong clinical profile. We expect continued growth for Libtayo in the second half of 2026 as we strive to gain incremental share in lung cancer and drive uptake across all approved stages of CSCC.

On to Lynozyfic, which is now in its third full quarter on the market, physician feedback in this late-line treatment setting is positive based on Lynozyfic's differentiated efficacy and safety profile, lower hospitalization requirements and convenient dosing. Despite its strong profile, we expect Lynozyfic growth to remain modest in this small late-line setting as we work to advance into earlier lines of therapy.

Turning to rare disease, where Regeneron is expanding our portfolio of life-changing medicines for patients with significant unmet medical need. Our homozygous familial hypercholesterolemia medicine, Evkeeza, delivered net sales of \$53 million in the second quarter, representing 29% year-over-year growth. I'm also delighted to inform you that first patients have been dosed with Otarmeni, the first and only gene therapy for children born with genetic hearing loss and our early launch efforts continue.

We are looking forward to adding garetosmab to our rare disease portfolio with a potential FDA approval in August for FOP. FOP is a serious life-threatening disease where garetosmab would be the first treatment shown to reduce the number of new abnormal bone formation lesions as well as clinician-assessed flare-ups in FOP patients.

We are also excited about the potential FDA approval of cemdisiran in generalized myasthenia gravis later this year. We see significant opportunity in a large and growing category based on cemdisiran's clinical profile demonstrated in its pivotal study, including rapid, deep and sustained clinical benefit, favorable safety profile and convenient quarterly subcutaneous dosing.

In closing, our second quarter results reflect focused commercial execution across therapeutic areas. We continue to drive growth for our in-line brands and are preparing for upcoming launches. We remain well positioned to deliver meaningful benefit to patients worldwide across many different diseases.

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

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

Thank you, Marion. My comments today for Regeneron's financial results and outlook will be on a non-GAAP basis, unless otherwise noted. Regeneron delivered a strong second quarter, highlighted by continued momentum across our key growth drivers and disciplined execution across the business.

Second quarter total revenue increased 17% from the prior year to \$4.3 billion, driven by higher Sanofi collaboration revenue, reflecting the continued strength of Dupixent, as well as strong growth for EYLEA HD in the US and Libtayo globally.

Second quarter diluted net income per share grew 11% to \$14.29 on net income of \$1.5 billion. This included a \$0.99 negative impact from acquired in-process research and development expense, reflecting upfront and opt-in payments associated with collaboration and licensing agreements.

Beginning with the Sanofi collaboration, second quarter total Sanofi collaboration revenue reached an all-time high of \$2.2 billion, of which \$2 billion related to our share of collaboration profits. Regeneron share of profits grew 59% versus the prior year, driven by Dupixent growth and improving collaboration margins.

We've now fully repaid the Sanofi development balance, which was approximately \$3.1 billion when the Sanofi antibody collaboration agreement was amended as part of the 2022 Libtayo transaction. That amendment accelerated repayment of the balance, which further reduced our share of collaboration profits as it was paid down.

The repayment lowered our reported Sanofi collaboration revenue by approximately \$930 million in 2025 and \$530 million in the first half of this year. Given full repayment of the Sanofi development balance starting in the third quarter, we expect Sanofi collaboration revenue to step up as we record our full share of collaboration profits.

Moving to Bayer. Second quarter net sales of EYLEA 8 mg and EYLEA outside the US, were \$667 million, inclusive of \$366 million of EYLEA 8 mg sales. Total Bayer collaboration revenue was \$276 million, of which \$227 million related to our share of net profits outside the US.

Other revenue in the second quarter increased 5% to \$193 million, of which royalty income from Ilaris combined with our share of profits from ARCALYST totaled \$157 million, an increase of 44% versus the prior year.

Now to our operating expenses. R&D expense was \$1.5 billion in the second quarter, reflecting continued investment to support Regeneron's innovative pipeline, which has approximately 50 product candidates, including mid- and late-stage programs across hem/onc, anticoagulation and complement-mediated diseases.

Second quarter SG&A was \$574 million, reflecting investments to support our commercial portfolio, including continued growth of EYLEA HD and Libtayo as well as ongoing launch activities across our broader product portfolio.

Non-GAAP gross margin on net product sales was 87% in the second quarter. Our GAAP gross margin was 78%, which similar to the first quarter was negatively impacted by unabsorbed manufacturing costs related to the temporary interruption in bulk manufacturing production at our Limerick, Ireland facility. Production at this facility resumed to normal levels as of the end of the second quarter.

Regeneron generated \$1.4 billion of free cash flow through the first half of 2026 and ended the second quarter with \$15.1 billion of cash and marketable securities net of debt. During the first half of the year, we deployed approximately \$2.5 billion to share repurchases, business development and dividends.

Within that, we repurchased \$1.2 billion of our shares in the second quarter alone, bringing total repurchases to approximately \$2 billion for the first half, resulting in a net reduction of 2.4 million shares outstanding since the end of 2025.

As of June 30, we had \$2.5 billion of share repurchase authorization remaining, and we continue to be opportunistic buyers of our stock. Finally, we made modest refinements to our 2026 financial guidance as we enter the second half of the year. A full summary of our guidance can be found in our earnings press release published earlier this morning.

In conclusion, Regeneron's strong second quarter results position us well to continue investing in our differentiated pipeline, delivering important medicines to patients and prudently deploying capital to drive long-term value for shareholders.

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

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

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Chris Raymond, Raymond James.

Chris Raymond - Raymond James - Analyst

Hey, thanks for taking my questions. Just on cash management. So you guys have about \$18 billion on hand now. And with the Sanofi obligation sort of rolling off, I guess it seems that will be accelerating pretty meaningfully.

Hearing what you guys have said about R&D and share repurchases and other uses of cash, even with pretty robust investment, that outlook is pretty sizable. Len, I'm wondering if you could maybe square that dynamic with some of the aversion to M&A that you've expressed in the past as a primary use of cash. Thanks.

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

Thanks for the question. I don't think I expressed an aversion to M&A. I think I expressed an aversion to overpaying in M&A settings. And we have been involved in many of these interested transactions, and we have seen people pay far more than we think the value would justify. We deploy a lot of our R&D money, and I think we'll talk more about that later in the year when Chris gives some guidelines.

But if you look at what we spend on R&D, both internally and externally, we're really kind of in line with what other people spend, but we tilt more towards the internal R&D. We are not allergic to any external opportunity.

We look at them all, but we are pretty disciplined in trying to create value with these transactions. So no aversion whatsoever. We could do small, we can do large, but we want them to make sense and make money for our shareholders over the long term.

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

Thanks, Len. Michelle, go to the next question, please.

Operator

Chris Schott, JPMorgan.

Taylor Hanley - JPMorgan - Analyst

Hey, this is Taylor Hanley on for Chris Schott from JPMorgan. Thanks for taking our question. We were just wondering, given some of the recent updates in the broader I&I space, can you talk a bit more about your latest thoughts on expanding the Sanofi collaboration to include additional assets? And then also what steps you could take to accelerate the development of those assets? Thank you.

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

Right. Thanks for the question. I think as you heard from Sanofi today, they talked about the productivity of our alliance, and we agree with that, that this has been perhaps one of the, if not the most productive alliance in the history of our industry with Dupixent driving remarkable returns for both Sanofi and Regeneron.

We do have some follow-on opportunities to Dupixent, as George mentioned in his talk, including our IL-13 long-acting antibody, which we now confirmed with some very early PK data, our Supi-Dupi, and we have several others that are related to the Dupixent portfolio.

We have had productive early discussions. Belén, the new CEO and I have talked multiple times. We are looking to see what might make sense and what kind of transaction might make sense for the two companies to get together on further assets where some of those assets might be best honed in the Dupixent portfolio. We'll keep you posted on those discussions as they progress.

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

And when you asked about development and expediting it, we should just remind you that we have led the most innovative development program, probably in the history of the industry in terms of with Dupixent, getting it approved for nine different indications, including many of them, the first approved biologic in many of these indications.

Obviously, we know this field. We created this field better than anyone else. And just as we've been very innovative with the first-in-class Dupixent, you can imagine that we'll be just as, if not more innovative going forward.

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

Thanks Len and George. Michelle, next question please.

Operator

Tyler Van Buren, TD Cowen.

Tyler Van Buren - Cowen and Company LLC - Analyst

Great, good morning. Congratulations on the tremendous quarterly performance. So can you provide additional details on the ongoing EYLEA HD prefilled syringe review with hopeful approval by year-end now? And when you say working with multiple contract manufacturers, does that mean there is now a third CMO in the mix? And if so, why did you feel the need to add another? Or is it still just the two? And is the second one most likely to receive approval by the end of the year? Thank you.

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

Yes. Thanks, Tyler. Look, I think a lot of things have been changing at the FDA. People have been changing. Leadership has changed. We had thought that we would get some action, perhaps an approval by the end of the second quarter.

That obviously didn't happen. But we have now had renewed discussions. We are looking at every -- leaving no stone unturned, multiple, and that means more than two are in the mix. We could always use backups if we succeed on one, three, one and two, two and three or three and so forth. But we're doing everything we can. We've had some good conversations recently. We know what the path is. We could see this ending by the end of the year or sooner.

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

Michelle, next question, please.

Operator

Cory Kasimov, Evercore ISI.

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

Cory. Before you begin, I neglected to point out, if you think about EYLEA HD and how it's progressed, we had a great product. The product itself really made a difference to patients in terms of durability, the doctors really appreciate it. But we felt that we could bring on additional enhancements to really make the product even more attractive to patients and their doctors.

Those enhancements included getting the Q4 monthly indication in the label. It included getting the RVO indication with a favorable -- and the only one with a favorable interval and getting the long-term durability intervals in the label.

Those three enhancements have really driven EYLEA HD, and it's really the only product in the branded space that has had this remarkable growth recently. We think that can continue, but we do believe if we can add another enhancement, it would go even set another leg up. But everybody should understand that the product is doing great. Just look at the numbers, look at the growth, look at how the other products in the space are doing, it's really doing very, very well.

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

Okay. Let's move on, Josh, are you still on the line from Evercore?

Unidentified Participant

Still here. From the market research you've done in myasthenia gravis, what percent of the market is currently served by IV C5 therapies? And do you expect a robust switch market to develop once cemdisiran reaches the market before the end of the year? Thank you.

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

You're welcome. Josh, so we very much look forward to the potential approval of cemdisiran and bringing our product into the marketplace for gMG patients, very important market. Certainly, therapies is in market today, but we do believe our clinical profile, our safety profile, convenience of dosing will be very meaningful.

We have experts working on the commercialization launch strategy. We know the market well through them. We've had an amazing ability to attract talent to the organization for this launch. Specifics on launch strategy, market size opportunity we'll hold till later times. But just assure everybody, they would look forward to the launch, and we're preparing for it actively. And obviously, as we mentioned today, potential approval from FDA in November.

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

Yeah. Just to amplify tiny bit on what Marion said, to address some part of your question. Look, the switch population is an obvious what some might say in the business, one of the lower-hanging fruits in this space. But we're not going to only focus on that because if you look at the FcRn approach and our data in terms of convenience potentially being given very infrequently to be able to have a continuous effect on myasthenia gravis patients in their ability to function. I think this can compete in all segments. But of course, there are some easier versus harder parts of the market.

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

Okay. Thanks, Marion and Len. Let's move to the next question, please, Michelle.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Good morning. Thanks for taking my question. You'll be presenting data from one of your siRNA programs in MASH this year. Could you just speak to the expected differentiation of this asset versus approved targeted agents such as Rezdifra and then maybe put the commercial opportunity in context for us, especially with the uptake of GLPs in this category as well.

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

Right. All other agents in this field are not really directly addressing the mechanism of MASH itself. They're working indirectly by decrease, for example, food intake through the GLPs and other mechanisms. What I want to remind you is due to the investment we made in the Regeneron Genetics Center, we have actually redefined the field, reinvented – we discovered actual genetic mechanisms that are protective for the actual basis of this disease.

And the genetics would suggest that if you could come up with a medicine that could mimic the genetics like we've done in other areas, then we could directly impact the actual mechanism of this disease and perhaps reverse it more quickly and more deeply than other indirect approaches, which are not directly working on the mechanism itself, but working directly, as I said, by decreasing food intake and so forth.

So these would be results using the first agents that are directly addressing the mechanism of action of this disease as defined genetically. So we will be very excited to see based on this potential, how these agents will have performed in these clinical studies.

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

Thanks, George. Exciting data to come. Next question, please, Michelle.

Operator

Alexandria Hammond, Wolfe.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Hey, guys. Thanks for taking my question. So on pozelimab cemdisiran in PNH, we're expecting that readout later this year. So can you kind of help us think about the incremental data points beyond LDH control, maybe transfusion avoidance that you need to see to kind of support a best-in-class label claim? And assuming a clean readout, what does the regulatory and commercial path look like from here and time line? Thank you.

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

Well, we strongly believe that improved control of intravascular hemolysis is the most relevant and validated endpoint because it directly reflects the C5 mechanism of action. And it's directly related to preventing what are the most devastating consequences of this disease, which is thrombosis and clotting and so forth. And that is what we're really looking for.

We think that, that would most strongly demonstrate whether this product is really differentiated and perhaps superior to existing therapies in addition to providing a much more convenient dosing regimen. So that's what we're really focused on here. And we think that, that is what everybody should focus on because it directly addresses the C5 mechanism of action and it's related to what are the devastating consequences of this disease.

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

Thank you, George. Let's go to the next question, please.

Operator

Tazeen Ahmad, Bank of America.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Hi, good morning. Thanks for taking my question. I wanted to get your thoughts on cemdisiran and how you're thinking about the launch trajectory in gMG. So you would be entering a market that has quite a few options. So can you just give us your thoughts about what you

think doctors, in particular, could respond to as a differentiating factor relative to, let's say, the market leader, which is VYVGART right now? Thanks.

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

Yeah. So certainly, as we launch into the market, we study it carefully and the competitive dynamic. As I mentioned with cemdisiran, we're very excited about the potential launch in November in the US marketplace, certainly working towards that.

In terms of the overall uptake, it's probably early to predict, but I would point to some of the characteristics of cemdisiran that are really exciting, not only to Regeneron, but to the key opinion leaders and physicians who've been involved in the clinical trials, and that is the efficacy, the safety, the convenience of dosing. And those elements certainly have the opportunity to create differentiation that will be meaningful in that market.

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

Just to add that from a clinical point of view, I don't feel it's optimal to chase symptoms, it's much better to have a steady improvement where you're not cycling on and off. And some of the -- clearly in the FcRns, you see this cycling even though you can even give repeat cycles now, you still are seeing evidence of loss of control.

And we think that the unpredictable nature of all that compared to giving something every quarter by a simple injection is really going to be changing the practice and the way patients think about it. Convenience does matter, we know that.

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

Yeah. As Len said, it's important that a significant proportion of the FcRn treated patients do lose efficacy over time and have to be switched to another therapy. We think that we have obviously an optimal option for patients and physicians to consider.

We think that we have the best efficacy cross study shown in the field. But as Len said, we have consistent efficacy over time. We have convenience. But we should also not dismiss that one of the concerns with all the treatments here is the impact on complete complement inhibition and also immunosuppression with FcRns.

And we have to remind you, and this is something that we have to remain to demonstrate. But what we have demonstrated, which is very clear and for the first time is that we are achieving best-in-class efficacy in cross-study comparisons while doing this using this siRNA approach without complete complement inhibition, which is really stunning.

And that may, over time, represent another benefit to patients that we'll have to demonstrate probably using real-world evidence and so forth over time. But I think this is a very, very exciting and very differentiated profile that has the opportunity not only to capture by switch a lot of the C5 class, but also all the patients who over time begin to lose efficacy using the FcRn approaches.

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

Okay. Thank you. Next question, please, Michelle.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - Bank of Montreal - Analyst

Hi, guys. Thank you so much for taking my question. And I want to follow up on your partnership with Sanofi. It's been a very successful partnership for Dupixent. As you think about the next phase of the relationship, what are the key elements you want to preserve from the original collaboration? And where do you see opportunities to improve the structure going forward? Thank you.

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

It's a very astute question, Evan. I'll answer in more general terms, than will satisfy you because these are ongoing negotiations. But what we want to do is capture the joint learned capabilities and experience in developing and commercializing Dupixent. And that -- those learnings are substantial. And together, if we're able to reach an agreement, they would, I think, drive success of these follow-on products.

I think as Belén may have mentioned in her Q&A today, we need to make some adjustments when we were a first partner with Sanofi. George probably remembers, but it was got to be a couple of decades ago, we were quite a different company.

And so the rules of the game were a little bit different. And so we have to, I think, get together and be open-minded, and I think Belén is to have a relationship that reflects where the companies are now. So I'm cautiously optimistic that we can get there.

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

But I think importantly, the companies have complementary as well as overlapping strengths and so forth. And I think that the proposed deal opportunities will take advantage of both the complementary but also overlapping strength of both companies.

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

Thank you, guys. Next question, please, Michelle.

Operator

Gregory Renza, Truist Securities.

Gregory Renza - Truist Securities - Analyst

Great. Good morning, guys. Congrats on a nice quarter. Thanks for taking my question. I just wanted to follow up on the obesity programs and certainly that path. You commented certainly on this evolving GLP landscape here. Just given the maturing landscape, what is the realistic time line for the [GLP/GIP] plus Praluent combination? And how should we be thinking about that potential and differentiation to carve enough share here? Thank you very much.

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

Well, as we've announced, we're going to be initiating the Phase III program over the next few months, and we're continuing to advance the combination. The way that we're looking at it, and I think the way we've termed it is everybody is trying to compete by getting a few more percentage points of weight loss and so forth. Whereas what we're trying to do is provide a fundamentally substantially different profile.

So imagine if somebody had invented a GLP that could also lower your bad cholesterol by 50% to 60% and substantially, in addition, further you reduce your risk of cardiovascular disease. Well, that's what we're offering and our program is advancing quickly in this area.

In addition, providing co-treatments that counter some of the negative aspects of GLP-induced weight loss such as muscle loss would be once again a fundamentally different profile and we're moving those programs along and we'll be releasing more data from those programs and so forth.

So we think it's very different to not just be going after a few more points of weight loss, but substantially enhancing the profile that you get along with it, whether you're addressing a related comorbidity that many of these patients also suffer from, which is cardiovascular disease or a side effect that causes and is being recognized as causing increasing problems, especially for sarcopenic patients, that is patients who are already starting with low muscle mass.

Those are the sort of things that we're actually going for. But we also, as we discussed, at least in cross-study comparisons, the GLP that we're working on might have indeed favorable profile on its own as well. I should also remind you that we have a very additional deep and slightly earlier-stage pipeline using many other approaches as well that we're very excited about, but we don't have time to discuss right now.

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

Thank you. We have time for two more questions, please. Michelle?

Operator

Carter Gould, Cantor.

Carter Gould - Cantor Fitzgerald LP - Analyst

Great. Good morning. Thanks for taking my question. I think this probably falls on George here. On the back of the fianlimab setbacks and costim progress, which has been relatively pace, I was wondering if you kind of use that as an opportunity to step back and reassess your solid tumor portfolio. It clearly was less of a point of focus on the call today. And maybe just how you see that going forward and if that's still going to warrant the same sort of spend and attention and effort that had in the past couple of years.

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

Yeah. Well, obviously, cancer is a challenge. I mean, the United States put out a war on cancer in the 1960s. I don't know if you realize it, but back in the 1960s, they did a survey and 90% of the US population thought that based on the war on cancer, cancer would be cured. 90% of the US thought cancer would be cured by the year 2000. Clearly, we celebrate incremental advances in the field. I mean, getting a few more months here and there.

We think that, obviously, fianlimab demonstrated that it was an active agent. Numerically, it did add about five months in PFS. And as you saw, we just missed on our primary endpoint. We have a lot of programs, many programs, both in solid and liquid tumors. We continue to be very excited about them and moving them forward.

And if anything, we are going to continue to advance and continue to take more shots in many different ways, both in monotherapies and combinations using a lot of our unique and first-in-class agents against this very tough and devastating disease, and we hope to be delivering successes going forward. But as we all know, it's a challenging field, but we need progress, and we're not going to stop focusing on it.

Operator

Geoff Meacham, Citi.

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

Great. Thanks, guys, for the question. Just overall, maybe a bigger picture on ophthalmology. Just trying to get a sense for you guys' strategy, obviously, beyond VEGF, how do you think about kind of the investments and strategy looking at complement and glaucoma and others? Is this like a vertical that we should expect you guys to add a lot of resources to in terms of R&D investments? Or is it really hem/onc is the primary focus and I&I? Thank you.

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

No. We have a huge, huge investment belief in our ophthalmology portfolio. As I like to put it, we're hoping to deliver the sort of successes and differentiated advances that we did with EYLEA for AMD and all those associated diseases and bring those elsewhere as I like saying we want to deliver the EYLEA for glaucoma. We want to deliver the EYLEA for thyroid eye disease. And as you just said, for geographic atrophy and related diseases, we want to deliver those sorts of successes.

We think that there's still so much opportunity in all of these areas. But since we're furthest advanced right now in geographic atrophy, we know the field needs safer agents. The field needs longer-acting agents. The field needs to address the fact that many of these patients suffer from comorbid diseases. There are many patients with GA who also have wet AMD. Who need to be simultaneously treated with multiple injections to try to control both sides of the disease. And obviously, we know the devastating consequences that are possible with some of the current complement treatments for this disease.

So we think that there's many, many, many ways that we can really help patients out here because there is a crying need, just like as I said, just like in cancer, we have so much unmet need, and we're going to continue to focus on that. We're going to continue to focus on eye. We're going to continue to focus in all the many areas in I&I. And that's -- as Len started the show today, he highlighted the thing that distinguishes us is we don't take one shot.

We don't focus on one thing. Why? Because many times, the one thing doesn't work out. But when you look over the years at the many shots that we've taken, so many of them have delivered so much benefit to so many patients that have literally changed the practice of medicine. That's what we continue to do. We don't just focus on eye or on one disease in eye. We don't just focus on one indication in immunology. We don't just focus on one setting in cancer. We focus on everything, and that's why we have the deepest and broadest and I think most exciting pipeline in the history of the industry.

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

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

Operator

Thank you for your participation. This does conclude the call. You may now disconnect.

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