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changes to drug pricing regulations and requirements and Regeneron's drug pricing strategy, including in connection with Regeneron’s 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 the Company or other parties and pending or future litigation or patent office proceedings relating thereto (including without limitation patent litigation and other related proceedings relating to Regeneron’s Products), 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 September 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.

S&P Global
Market Intelligence

# Regeneron Pharmaceuticals, Inc.

# NasdaqGS:REGN

# FQ3 2026 Earnings Call Transcripts

## Friday, October 30, 2026 12:30 PM GMT

*[Proofread by REGN IR]*

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# Presentation

**Operator**

Welcome to the Regeneron Pharmaceuticals Third Quarter 2026 Earnings Conference Call. My name is Shannon, 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**
*Senior Vice President of Investor Relations & Strategic Analysis*

Thank you, Shannon. Good morning, good afternoon and good evening to everyone listening around the world. Thank you for your interest in Regeneron, and welcome to our third 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 third quarter performance drivers and highlight a few emerging pipeline programs. George will then detail our recent pipeline progress, followed by Marion, who will review our commercial performance. 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 September 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 S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

Thank you, Ryan, and welcome to everyone joining our call today. We're pleased to report another quarter of strong performance, driven by outstanding commercial execution and a large and diverse pipeline that is continuing to deliver on its promise. Total revenue grew 36% and non-GAAP earnings per share grew 70% compared to the third quarter of 2025. This marks our third consecutive quarter of double-digit growth on both the top and bottom lines.

Our commercial teams continue to execute at a very high level. Dupixent, EYLEA HD and Libtayo each set new all-time highs for quarterly net sales for the second quarter in a row. Dupixent global net sales in the third quarter, as reported by Sanofi, reached a record $6.5 billion, up 35% year-over-year at constant currency, which is truly remarkable for a medicine approaching 10 years on the market.

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In the U.S., where Dupixent is the leading biologic in 8 of its 9 FDA-approved indications, quarterly net sales grew 40% and exceeded $5 billion for the first time, primarily driven by robust demand across all indications as well as gross-to-net favorability as disclosed by Sanofi. EYLEA HD quarterly net sales in the U.S. reached a new all-time high of approximately $700 million, up 62% from a year ago and now represent nearly 2/3 of our U.S. retinal franchise.

Physician unit demand grew 20% sequentially, reflecting the value retinal specialists and their patients see in extended dosing intervals as well as last year's label enhancements, which added the retinal vein occlusion indication and greater dosing flexibility. We remain optimistic for approval of the prefilled syringe before the end of the year, and we expect it to drive even further adoption, if approved.

Libtayo is making important differences for patients with skin and lung cancers, and it continues to build clinical and commercial momentum. In the U.S., it is the leading immunotherapy in non-melanoma skin cancers and the second most prescribed immunotherapy in non-small cell lung cancer. Global net sales reached a record $550 million, up 51% in constant currency and U.S. net sales grew 81% to nearly $400 million.

Last week at ESMO, we presented longer-term data from our Phase III C-POST trial, showing an increase in overall survival benefit with adjuvant Libtayo in high-risk cutaneous squamous cell carcinoma, where it is the first and only approved immunotherapy. Libtayo is now on an annual run rate of approximately $2.2 billion and remains the foundation for our broader oncology strategy. Beyond our strong commercial execution, our pipeline is poised to deliver several potential blockbuster opportunities over the next several years.

Let me highlight new advances in 4 of our pipeline programs, which George will discuss in more detail along with other late-stage clinical programs, including Factor XI, Lynozyfic and olatorepatide.

In neuromuscular disease, we expect an FDA decision in November for cemdisiran in generalized myasthenia gravis. If approved, cemdisiran would be the first siRNA therapy for generalized myasthenia gravis and the only treatment that can offer quarterly subcutaneous dosing. Early in my career as a neurologist, I cared for many patients with this difficult-to-treat condition. So it is particularly gratifying to see us bring forward a potential new treatment option for them.

In metabolic disease, MASH affects millions of people and treatment options are limited. Our CIDEB program is a great example of our genetics-driven scientific process. Regeneron Genetics Center discovered that people with naturally occurring loss of function variants of the CIDEB gene have a markedly lower risk of fatty liver disease and cirrhosis which led us to develop a first-in-class siRNA that targets CIDEB. We are encouraged by the initial clinical data, which suggests best-in-disease potential, and we are rapidly advancing this program into registration-enabling studies.

I'd also like to highlight our program for postural orthostatic tachycardia syndrome or POTS. This is an increasingly recognized debilitating condition that affects many young people, often disrupting school, work and daily life with very few effective treatment options and no FDA-approved medicines. Recent estimates suggest that between 500,000 and several million people in the U.S. alone suffer from POTS. We believe the initial clinical data that George will highlight supports our antibody's potential to become the first FDA-approved treatment for this disease, and we plan to initiate a potentially pivotal study next year, pending regulatory feedback.

In oncology, we recently shared encouraging data for ubamatamab, our MUC16xCD3 bispecific antibody in advanced low-grade serous ovarian [cancer]. This is a rare and difficult-to-treat form of ovarian cancer that often affects younger women who urgently need better treatment options. We saw durable responses in heavily pretreated patients at rates well above those historically seen with available therapies.

We are already enrolling a dedicated potentially registrational cohort and plan to start a confirmatory Phase III study next year. Each of these programs is supported by compelling clinical data, human genetic validation, or both. It is no accident that they span 4 distinct therapeutic areas and that each has first-in-class or best-in-disease potential. That reflects our disease-agnostic enterprise approach to R&D. Rather than confining ourselves to a few therapeutic areas, we apply our core technologies wherever the science leads us. These technology platforms, including our VelocImmune antibody and bispecific engines, Regeneron Genetics Center and siRNA and gene editing technologies that allow us to translate genetic discoveries like CIDEB into potential medicines.

Today, that approach supports approximately 50 clinical programs spanning immunology, oncology, ophthalmology, hematology, cardiovascular and metabolic diseases, neurology and rare diseases. Our commercial organization has been built the same way. Our teams already call on ophthalmologists, dermatologists, pulmonologists, allergists, gastroenterologists, ENT specialists, oncologists, cardiologists and hematologists. And if cemdisiran is approved, we will begin to call on neurologists as well. That means many of our pipeline medicines, including several of the programs I just mentioned, can launch into specialties where we already have deep relationships and expertise and can leverage our existing infrastructure and capabilities.

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Briefly on business development. Historically, we have been a net out-licensor of innovation with the most recent example being the expansion of our alliance with Sanofi. We are contributing to the alliance 4 next-generation long-acting antibodies, all invented at Regeneron, that target the same pathways that made Dupixent so successful. Regeneron will lead research and development and Sanofi will lead global commercialization now with greater transparency and increased participation by Regeneron. If approved, these medicines can also benefit from Dupixent's commercial leadership and the strong market access position it has established, an advantage neither company could capture on its own.

At the same time, our financial strength positions us to bring differentiated external innovation into Regeneron. We have done this effectively to date, primarily through early-stage research collaborations, including those that built our emerging genetic medicines pipeline across siRNA therapeutics, gene therapy and gene editing. We continue to evaluate a wide range of opportunities from early clinical programs and platforms to commercial stage products with a sharp focus on valuation and strategic fit.

In closing, this was an exceptional quarter by every measure. Our 3 core growth brands are performing at record levels, and our expanded alliance with Sanofi positions us to lead the next era of type 2 inflammation medicines. Our pipeline is poised to deliver additional potential blockbusters across a broad range of diseases, and our commercial organization is built to bring them to patients. Our future is bright, and we remain focused on translating our science into new medicines that can make a meaningful difference for patients and create long-term value for shareholders.

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

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

Thanks, Len. For my remarks today, I'll first provide further details on the 4 programs that Len highlighted, then cover other key updates from our pipeline. Beginning with our C5 program. Regulatory submissions are under review for cemdisiran, our C5 siRNA for generalized myasthenia gravis or gMG. An FDA decision is expected next month, and the European Commission decision is anticipated in the second half of 2027. If approved, cemdisiran will be the first and only siRNA therapy approved for gMG. It will be distinguished by a combination of rapid onset, consistent efficacy throughout the dosing interval, manageable safety and convenient subcutaneous dosing just 4 times per year.

Our C5 program also includes a co-formulation of cemdisiran with pozelimab, our C5 antibody that's already FDA approved for protein-losing enteropathy. Together, they are being evaluated as a combination therapy for paroxysmal nocturnal hemoglobinuria or PNH, where we expect to report pivotal results by the end of the year. Initial results from the lead-in cohort of the Phase III trial suggest that our novel combination approach could provide best-in-class control of intravascular hemolysis. Our C5 program further includes evaluating cemdisiran with and without pozelimab in geographic atrophy, or GA, via systemic administration.

We now expect to report interim 26-week data from an exploratory cohort of our ongoing Phase II/III study in early 2027, where we hope to see a trend towards slowing of lesion growth comparable to the approved agents at a similar time point. A potential advantage of our systemic approach is the ability to treat bilateral disease, which affects many patients, while avoiding the potentially devastating ocular safety events seen with certain FDA-approved agents that are delivered intravitreally. In addition, we are exploring our own intravitreal administration of pozelimab, which might also offer a safety advantage over currently approved therapies.

Moving to MASH. At the upcoming Liver Meeting in November, we will present first-in-human data for our siRNA for CIDEB. This target was discovered by our Regeneron Genetics Center, which identified CIDEB's unprecedented ability to protect against liver fat and liver disease through our large-scale human genetics database. In the initial data from 40 participants, a single dose was well tolerated and reduced liver fat by approximately 70% on average from baseline in just 12 weeks, bringing mean liver fat to near or below upper limit of normal at every dose level tested. This effect was durable through 24 weeks of follow-up and was accompanied by improvements in liver enzymes, consistent with reduced liver cell injury. These results not only clinically validate the CIDEB discovery from the Regeneron Genetics Center, but suggest that we have a breakthrough new approach that directly addresses a genetic driver of MASH and could benefit the millions of MASH patients underserved by current approaches.

We are working to rapidly advance to registrational trials and look forward to sharing more about this agent at our next Regeneron Roundtable investor event scheduled for November 10.

Moving to postural orthostatic tachycardia syndrome or POTS. This disease appears to be driven by chronic pathological depletion of intravascular volume. Current treatments include salt and fluid administration, which provide only short-term relief. There are no FDA-approved therapies and off-label treatments are generally unsatisfactory. At the American Autonomic Society Congress in November, we will be reporting initial results from our Phase II study. After a single treatment with high-dose baloncibart, we saw

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improvements in the 2 key endpoints for this disease, tachycardia and orthostatic symptoms sustained over 4 weeks from a single dose. These improvements appear to be associated with durable restoration of intravascular volume.

We are planning to initiate a potentially registrational study in the first half of next year, pending regulatory feedback, and we believe this could be a game-changing treatment for a debilitating disease with significant unmet need.

Next, turning to ubamatamab, our MUC16xCD3 bispecific antibody in development for ovarian cancer, which was featured in a late-breaking plenary session at the International Gynecological Cancer Society meeting. The data presented there, along with additional data indicate that ubamatamab monotherapy has an approximately 70% objective response rate with prolonged progression-free survival in women with advanced low-grade serous ovarian cancer with an acceptable safety profile and no biomarker selection required. To put this in context, chemotherapy and endocrine therapy have historically delivered response rates below 15% in this setting and the only approved therapy achieved a 44% response rate, but only in the roughly 30% of patients with low-grade serous ovarian cancers with tumors carrying a specific biomarker. Based on these encouraging early results for ubamatamab, we are enrolling a potentially registrational cohort and plan to start a confirmatory Phase III trial in mid-2027.

Turning now to our larger late-stage programs and starting with Lynozyfic, our BCMAxCD3 bispecific. We believe Lynozyfic is differentiated not only by the efficacy demonstrated in late-line multiple myeloma, but also by our development strategy, which creates important new opportunities in first- and second-line settings and even in premalignant disease with pivotal readouts beginning next year.

In 2027, we expect initial results from our confirmatory trial of Lynozyfic monotherapy versus standard of care in patients with multiple myeloma who received at least one prior line of therapy. In 2028, we expect initial results from our first-line study in transplant ineligible patients as well as from our Lynozyfic-carfilzomib combination study in patients who received at least one prior line of therapy.

We are also enrolling potentially registrational cohort in second-line light chain amyloidosis and plan to start a Phase III study in first-line light chain amyloidosis by early 2027. In addition, we are actively enrolling a Phase III trial in high-risk smoldering myeloma. We also have a differentiated development strategy for odronextamab, our CD20xCD3 bispecific. We have a regulatory application under FDA review for relapsed/refractory diffuse large B-cell lymphoma with a February 2027 target action date. Importantly, we expect results in 2028 from our fully enrolled Phase III study of odronextamab monotherapy in first-line follicular lymphoma, which could provide these patients who have high unmet need with the first bispecific and chemo-free immunotherapy option.

Moving to anticoagulation. For Factor XI inhibition, we continue to favor our antibody approach over small molecules because antibodies may enable more potent and specific inhibition with the potential to improve anti-thrombotic activity without increasing bleeding risk or introducing off-target safety issues. Our program features cenvacibart, our catalytic domain antibody and amrecibart, our A2 domain antibody.

I'm pleased to report that all but one of the planned Phase III studies are now enrolling patients. These studies span venous thromboembolism prevention after total knee replacement, stroke prevention in patients with atrial fibrillation, cancer-associated thrombosis, peripheral artery disease and most recently, venous thromboembolism prevention in patients with peripherally inserted central catheters. The one remaining Phase III study yet to initiate in secondary stroke prevention is expected to begin enrollment by year-end. We expect pivotal results from our knee replacement program starting next year with other pivotal studies expected to read out in 2028 and beyond.

Turning to olatorepatide, our dual GLP-1 GIP receptor agonist in-licensed from Hansoh. Recently, Hansoh presented encouraging efficacy, safety and tolerability data from their Phase III trial in patients with obesity in China at the European Association for the Study of Diabetes Conference. We look forward to starting our global Phase III program, which is differentiated by our ability to co-formulate olatorepatide with Praluent, our PCSK9 antibody. We believe this could provide an important new treatment option for the many patients with obesity and type 2 diabetes who comorbidly also suffer from hypercholesterolemia and increased cardiovascular risk, and we plan to begin registrational studies of this combination next year.

As Len discussed, we recently announced an expansion of our alliance with Sanofi. Building on the success of Dupixent and the validation of the IL-4 and IL-13 pathways as central drivers of type 2 inflammation, the alliance is advancing Regeneron's 4 fully human VelocImmune-derived long-acting antibodies and bispecifics. These candidates are designed to preserve Dupixent-like efficacy and safety while enabling substantially less frequent dosing. All 4 candidates avoid the heavy engineering that tends to compromise biopharmaceutical properties or raise the risk of antidrug antibodies.

Our candidates, which are fully human and nonengineered, also share important molecular properties. So learnings from one should carry over to the others and potentially support an expedited development. Our first-in-human trial for our lead IL-13 antibody, which

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has a target dosing interval of every 3 to 6 months is currently enrolling with patients with atopic dermatitis with registrational trials expected to begin in late 2027 and 2028. Three additional programs, a long-acting IL-4/13 bispecific, a long-acting antibody to IL-4 receptor alpha and an IL-4 ligand antibody are expected to enter the clinic next year.

Relevant to these programs, I want to end by reminding you that we have previously shared early clinical results for our BCMAxCD3 bispecific in combination with Dupixent in severe food allergy. These results strongly supported our hypothesis that food allergies could potentially be cured by rapidly and completely depleting plasma cells, which produce immunoglobulins, including the allergy-causing IgEs and then continuously suppressing the return of IgE antibodies by blocking IL-4 and IL-13. While the BCMAxCD3 eliminates plasma cells producing all classes of immunoglobulins, we have invented a new bispecific antibody that selectively eliminates only the IgE producing and allergy-causing plasma cells.

We plan to build on our groundbreaking results combining our BCMA bispecific with Dupixent by expeditiously pursuing this more targeted approach with clinical studies of this new bispecific antibody to start in the first half of 2027.

In summary, we have strong momentum across our broad and diverse pipeline that we believe that has the potential to change the practice of medicine across many diseases with high unmet need.

With that, let me turn it over to Marion.

**Marion E. McCourt**
*Executive Vice President of Commercial*

Thank you, George. Our third quarter results reflect strong commercial execution across our portfolio with our largest brands achieving new all-time highs in net sales. Our team is also focused on recent and upcoming launches with Pasatru now approved in the U.S. for ultra-rare FOP, and we are preparing for the November PDUFA for cemdisiran in generalized myasthenia gravis.

Starting with Dupixent, which continues to deliver transformative benefits to patients across 9 type 2 inflammatory diseases with more than 1.5 million patients currently treated worldwide. In the U.S., Dupixent remains the most prescribed branded biologic among dermatologists, pulmonologists, allergists and ENTs. Third quarter worldwide net sales exceeded $6.5 billion, reflecting 35% growth on a constant currency basis. U.S. net sales grew 40% year-over-year to $5.1 billion, driven by continued growth across all indications and age groups as well as favorable gross to net adjustments as reported by Sanofi.

Dupixent is the leading biologic across our blockbuster indications of atopic dermatitis, asthma, nasal polyps and eosinophilic esophagitis, reported by its best-in-class clinical efficacy and safety profile. Uptake is also strong in our more recently launched indications of COPD, prurigo nodularis, chronic spontaneous urticaria, bullous pemphigoid and allergic fungal rhinositis with continued growth in new-to-brand prescriptions.

With significant opportunity for future growth across all 9 indications, Dupixent is well positioned over both the near and long term. Additionally, we are excited about the recently announced expansion of the Regeneron Sanofi alliance and to continue building on the strong foundation we've laid together with Dupixent.

Turning to our retinal franchise. In the third quarter, combined EYLEA HD and EYLEA U.S. net sales were $1.1 billion, down 1% compared to last year, with EYLEA HD now comprising nearly 2/3 of the franchise net sales. Third quarter EYLEA HD net sales in the U.S. were $699 million, up 62% versus prior year. These results demonstrate strong physician unit demand, which grew 20% from the second quarter. This growth is driven by the ongoing benefit of recent label enhancements, which have increased adoption and broadened use of EYLEA HD across the spectrum of retinal practices. Physicians increasingly recognize EYLEA HD as the best-in-class product in the anti-VEGF category based on its efficacy, safety and durability.

EYLEA U.S. net sales were $400 million for the quarter, a 41% decrease versus the prior year. Sequential physician unit demand declined by a high single-digit percentage compared to the second quarter, with this decline partially offset by favorable gross to net adjustments. Both EYLEA HD and EYLEA benefited modestly from the timing of end-of-quarter shipments. Looking ahead to the fourth quarter, we expect continued EYLEA HD momentum with sequential physician unit demand growth of approximately 10%, partially offset by ongoing pricing pressure, resulting in full year net sales growth of over 50% compared with 2025.

For EYLEA, we expect a sequential demand decline in the low to mid-teens in the fourth quarter. Overall, the franchise remains in a strong position despite increasing competition from additional aflibercept 2-milligram biosimilar launches, and we look forward to potential FDA approval of the EYLEA HD prefilled syringe to help sustain EYLEA HD momentum in 2027 and beyond.

Turning to Libtayo, which delivered worldwide net sales of $550 million, up 51% year-over-year on a constant currency basis. In the U.S. net sales were $396 million, up 81%. In non-melanoma skin cancer, Libtayo continues its strong trajectory as the leading

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immunotherapy. In the U.S., the recent approval in adjuvant CSCC is helping to drive growth and is changing the treatment paradigm. Libtayo remains the only NCCN Category 1 Preferred immunotherapy option for eligible patients and ongoing formulary wins are driving increased usage.

In non-small cell lung cancer, Libtayo remains the second most prescribed immunotherapy as physicians increasingly recognize its strong clinical profile. We continue to build on Libtayo's strong momentum by enhancing the patient experience through extended dosing and shorter infusion times across all approved indications. We recently received a positive CHMP opinion for every 6-week dosing for Libtayo, along with an infusion time as short as 15 minutes. An sBLA for this updated dosing regimen is under review with the FDA with a decision expected by March 2027.

We expect continued growth for Libtayo as we gain incremental share in lung cancer and drive uptake in adjuvant CSCC. On to Lynozyfic in multiple myeloma, physician feedback on the currently approved late-line setting remains positive based on Lynozyfic's differentiated efficacy and safety profiles, lower hospitalization requirements and convenient dosing. Despite its strong profile, we expect Lynozyfic growth to remain modest as we work to advance into earlier lines of therapy.

We are also building Regeneron's rare disease portfolio, serving patients with significant unmet need. Evkeeza continues to grow in its sixth year on the market with U.S. net sales of $55 million, up 28% versus the prior year. We have also expanded our portfolio with the recent launches of Otarmeni for genetic hearing loss and Pasatru for FOP. Initial progress for both brands is promising, and we look forward to helping patients suffering from these devastating diseases.

Finally, in neurology, we're preparing for the potential launch of cemdisiran in generalized myasthenia gravis, which has a November PDUFA date. We see significant commercial opportunity for cemdisiran based on 3 key factors: its novel siRNA modality, rapid onset and durable efficacy without the waning treatment effect observed with many other approved therapies and convenient 4 times per year subcutaneous dosing.

In closing, our third quarter results reflect strong commercial capability across therapeutic areas. We've built an effective commercial infrastructure that enables us to execute across both in-line brands and new launches. As Len mentioned earlier, our commercialization platform currently spans nearly every relevant specialty, and this market experience positions us well for the many potential new products from our pipeline, whether a common or rare disease medicine, specialty or internal medicine prescriber, medical or pharmacy benefit product, we are confident in the capabilities of our commercial organization in both the near and longer term.

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

**Christopher R. Fenimore**
*Executive VP of Finance & CFO*

Thank you, Marion. My comments today on Regeneron's financial results and outlook will be on a non-GAAP basis, unless otherwise noted. Regeneron delivered a strong third quarter, once again reaching double-digit growth on both the top and bottom line, driven by sustained momentum across our key growth drivers and solid execution throughout the business. Third quarter total revenue increased 36% from the prior year to $5.1 billion, driven primarily by higher Sanofi collaboration revenue, along with strong growth from both Libtayo and EYLEA HD.

Third quarter diluted net income per share grew 70% to $20.07 on net income of $2.2 billion. Beginning with the Sanofi collaboration, third quarter collaboration revenues reached an all-time high of $2.7 billion, including $2.6 billion from our share of collaboration profits. Our share of profits increased 77% versus the prior year, primarily driven by continued Dupixent net sales growth and the repayment of the Sanofi development balance, which was completed in the second quarter.

Consequently, in the third quarter, we recorded our full share of collaboration profits for the first time. Under the recently amended antibody collaboration, Regeneron and Sanofi will share equally the development and commercialization costs of 4 next-generation antibodies. Since R&D costs will be co-funded as they are incurred, there will be no R&D development balance. Global profits from these antibodies will also be shared 50-50, while the existing economic terms for Dupixent and Kevzara remain unchanged.

Regeneron expects to record the full $1 billion upfront payment as Sanofi collaboration revenue in the fourth quarter with any future milestone payments recognized in full in the period achieved.

Moving to Bayer. Third quarter net sales of EYLEA 8 mg and EYLEA outside the U.S. were $643 million, inclusive of $384 million of EYLEA 8 mg sales. Total Bayer collaboration revenue was $267 million, of which $212 million related to our share of net profits outside the U.S. Other revenues in the third quarter increased 57% year-over-year to $310 million, including $253 million from our share of ARCALYST profits and Ilaris royalties. Third quarter Ilaris royalty revenue included an approximately $60 million

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cumulative catch-up adjustment, reflecting the application of the highest royalty tier on year-to-date sales. This cumulative catch-up will not recur in the fourth quarter.

Now to our operating expenses. Third quarter R&D expense was $1.7 billion, driven by continued advancement of our broad clinical pipeline as well as the timing of related clinical manufacturing. Third quarter SG&A was $588 million, an increase of 9% year-over-year, reflecting investments across our commercial organization and broader business. Our third quarter effective tax rate was 15%. The year-over-year increase was primarily due to shift in the geographic mix of our pretax income driven by higher Sanofi collaboration revenue.

Regeneron generated $2.9 billion of free cash flow through the first 9 months of 2026 and ended the quarter with $16.2 billion of cash and marketable securities net of debt. In the first 9 months of 2026, we deployed nearly $3 billion across share repurchases, business development and dividends. This included $2.3 billion to repurchase 3.2 million shares. We expect full year share repurchases to total approximately $3 billion. And as of September 30, we had $2.2 billion remaining under our repurchase authorization.

Moving to guidance. We made modest refinements to our 2026 financial guidance as we enter the last quarter of the year. A full summary of our guidance can be found in our earnings press release published earlier this morning. As we look to 2027, Len and George discussed the meaningful progress we are making across our innovative pipeline. We expect to advance multiple large registrational programs in myeloma, anticoagulation, obesity and emerging mid-stage opportunities with significant revenue potential, such as our programs in POTS and MASH. This year alone, we are on pace to initiate more than 15 Phase III trials. We believe these investments can create substantial long-term value. To support this progress, we currently expect 2027 R&D expense to increase by a mid-teens percentage compared with 2026.

Regarding our 2027 effective tax rate, we expect approximately 100 to 200 basis points of upward pressure relative to 2026, consistent with our prior long-term tax rate commentary.

Finally, turning to the new BARDA agreement for Inmazeb. Beginning in late 2027, we expect to supply additional treatment doses to the U.S. government through 2031. Therefore, we do not anticipate recording any revenue in the fourth quarter of 2026 for Inmazeb. In conclusion, we delivered another outstanding quarter and remain well positioned to invest in our differentiated pipeline, deliver important medicines to patients and create durable long-term value for shareholders.

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

**Ryan Crowe**
*Senior Vice President of Investor Relations & Strategic Analysis*

Thanks Chris, this concludes our prepared remarks. We will now open up the call for Q&A.
[Operator Instructions]

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# Question and Answer

**Operator**

[Operator Instructions]

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

**Elizabeth Daniels Webster**
*Goldman Sachs Group, Inc., Research Division*

This is Elizabeth Webster on for Salveen. Just ahead of AASLD, could you further frame the clinical data from CIDEB we've seen to date in the context of the competitive landscape and expand upon where Regeneron would position this asset? And in your view, what are the key aspects of differentiation? Also noting you will speak about this at the roundtable, but any color you can share now would be appreciated.

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

Well, the other approaches to MASH and reducing liver fat are all somewhat indirect in that they are not directly addressing the fundamental genetic pathway that's underlying or driving this disease. They work, for example, by trying to decrease body weight, for example, semaglutide, a GLP, which lowers body weight, which then indirectly lowers liver fat.

Similarly, the product for Madrigal works by a separate mechanism as well. This is the first pathway that directly involves a genetically validated target that is central to protecting the liver against multiple liver diseases, including liver fat generated diseases. Reflecting the genetics and the specificity and importance of this pathway, the liver fat reductions that one is seeing here are unprecedented in the rapidity of onset and the depth of the liver fat reductions. As we said, they're on the order of 70% achieved in just a few weeks. And this is with a single dose lasting for a very long period of time. These are really game-changing results and of course, highly supported with the genetics.

So of course, we've reproduced now the genetic effects on liver fat. This gives us even more confidence that we're going to reproduce the genetic effects on benefits in terms of liver disease. So this is really game-changing, unprecedented. There's nothing like this before for this disease. And I think it's reflective of our approach to using large-scale human genetics to actually define the underlying mechanism of disease and not just come up with drugs that sort of accidentally or by chance also benefit a disease of interest, but actually defining the underlying genetic pathway causing the disease, directly targeting with one of our signature platforms, in this case, the siRNA approach and producing unprecedented results in these early-stage data.

**Ryan Crowe**
*Senior Vice President of Investor Relations & Strategic Analysis*

Thanks, George. And we certainly look forward to highlighting that in a couple of weeks at our roundtable event on November 10.

**Operator**

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

**Brian Corey Abrahams**
*RBC Capital Markets, Research Division*

Wonder if you could talk a little bit more about the cemdisiran prelaunch activities, just kind of some of the learnings there as you prepare for the launch now that you're closer to the approval and a potential label? And just how you're thinking about the initial target audience and uptake?

**Marion E. McCourt**
*Executive Vice President of Commercial*

Sure. Very happy to make comments. So we certainly have a very talented neurology team at Regeneron. Very pleased with the caliber of experience that the team has in neurology with other programs, and now we're really excited to bring that to Regeneron. As we mentioned, PDUFA date in November, very exciting. So launch activities, preparation are well underway. I'm not going to say a lot about launch strategy, but delighted to talk about it in the future. But certainly assure everyone that we are launch ready. We look

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forward to the label and certainly bringing cemdisiran into the marketplace is a really important enhancement for patients who need this treatment.

**Operator**

Our next question comes from the line of Akash Tewari with Jefferies.

**Akash Tewari**
*Jefferies LLC, Research Division*

I noticed that your Sanofi collaboration allows you to add another early-stage Sanofi asset. Can we revisit STAT6? If the STAT6 oral start to deliver efficacy, not better, but let's just say similar to Dupixent, would that be an asset that your team would be interested in adding to the ongoing collaboration with Sanofi?

**Leonard S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

Yes, so, look, the alliance is open to doing anything and everything that makes sense to build on our expertise. I think the oral agents are an interesting class, but they're a long way from giving the efficacy and safety that Dupixent pathway blockers would give. You're talking -- as you further get away from the membrane and downstream, you always have to deal with other potential activities. And frankly, when you get into longer dosing intervals, a daily pill doesn't afford much of an advantage in convenience and maybe even have to take it more than once compared to something that you might take once a quarter or once every 6 months.

So the bottom line is, I think the alliance is open. We have a very good relationship now with Sanofi. I think we're back on a very strong track. Belén Garijo has been really clear cut in helping us frame that we want to continue to build on Dupixent for a long time.

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

Yes. I think we should add that certainly, there may be room for multiple treatment options and ways at dealing with the patients with so much high unmet need out there. But certainly, as Len said, an injectable that can be given 2 or 4 times a year will certainly be an incredibly attractive option for so many patients, whereas, of course, there may also be room for an oral pending, of course, dealing with the efficacy and, of course, safety issues that Len raised.

**Operator**

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

**Tyler Martin Van Buren**
*TD Cowen, Research Division*

Congratulations on a very, very impressive quarter. So is it fair to say that Regeneron will become even more aggressive on the business development front than it was a year ago, given the long-term new product revenue incentive stretching up to $30 billion to $40 billion? And what stage of development is the ideal time to acquire external assets in your view? Is it post Phase II, so you can have a hand in operating the Phase III? Or is it post Phase III when you're closer to commercialization?

**Leonard S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

Yes. So Tyler, that's a great question. We do appreciate the 2 verys in your introductory remarks. I think our record show you've only given us one very in the past. So thank you for that. In terms of business development, look, we look at the overall spend and investment, if you will, on research and development. And when you add up what other companies spend on external innovation and internal innovation and what we spend on internal and external innovation, these numbers, we're not out of line at all. It's just that we have this incredibly productive research effort that George detailed a little bit and that is producing things where some of the things we haven't even talked about and aren't in the clinic yet are still even more exciting than you can imagine.

So we are open to any and all opportunities at all stages. But as I said in my remarks, we're focused on the science. Does it really make sense? We love platforms if we can get platforms, but we have the firepower to do an advanced product or an early stage. So we are sort of agnostic. We don't really manage our BD that, hey, we need to fill a Phase II slot or Phase III slot. We're looking for things that can make a difference to patients and build and interact better with and be better with us than they might be by themselves.

**George D. Yancopoulos**

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*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

I think to add to what Len just said, I think that every company looks internally and externally and tries to evaluate which are the best opportunities for them to take on. And unfortunately, for most companies, they end up deciding that they have to look outside for the best opportunities compared to what's coming through the pipeline.

As Len just described, most of the time, when we compare almost all external opportunities to what we have coming internally from our R&D engine, we choose to focus to spend our resources on the internal opportunities when we compare them to what we get from the outside. If you evaluate the track history of the industry in-licensing outside opportunities, I think you would realize that our track record tends to outperform the industry standards for in-licensing by far.

**Operator**

Our next question comes from the line of [ Joon Lee ] with UBS.

**Unknown Analyst**

Congrats on a very strong quarter. You have 4 very promising next-gen dupi's based on patent filings. Do you need just one to succeed? Or do you have different plans for different antibodies for different indications?

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

That's a great question. I think that one of the reasons that we have these 4 assets is that we can actually imagine, as you say, that some might be better tailored for one setting versus another setting. And so our development plan is certainly anticipating that possibility.

**Operator**

Our next question comes from the line of Tazeen Ahmad with Bank of America.

**Tazeen Ahmad**
*BofA Securities, Research Division*

I just wanted to get your updated view on the competitive landscape in AD, especially as it relates to next-gen assets. You've talked about the importance of having long-acting treatment. Do you think that's going to be sufficient to be competitive in the long run, just given that others might also try to have similar dosing frequencies? Or do you think showing improved efficacy over dupi is also going to be needed?

**Leonard S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

I'll let Marion comment on the commercial side, but showing efficacy over dupi reminds me of the number of people that have tried to show efficacy over EYLEA over the last 15 years. Very difficult to do, and I think the same will be true for our CIDEB and other things that George talked about because when you get to the heart of a problem, it's tough to really improve on mechanism. That said, I think while others might be able to do long-acting as we are, there's room for multiple entries in this space, but very few will have the experience, the leverage, the capabilities that Sanofi and Regeneron have put together with their experience with dupi. I don't know, Marion, if you'd like to.

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

Well, let me just add one point to the competition. So -- and I think it's a really, really important point. In order to achieve long-acting, if you look at the competition, they're using heavily human engineered versions of previously existing old antibodies that were generated decades ago. And when history shows, if you look across the industry, human engineering generally results in more problems than advances in terms of issues, for example, with antidrug antibodies and so forth.

So our approaches, remember, depend on a very natural system, all derived naturally from our almost magical genetically engineered mouse that's fully humanized that delivers these requiring almost no human intervention and engineering. So history shows based on our own track record that our naturally derived antibodies tend to outperform heavily engineered antibodies. So while others are trying to do what we're doing, we'll have to see how these heavily engineered versions will compare to what we've historically delivered and tend to perform very well in patients. Go ahead, Marion.

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**Marion E. McCourt**
*Executive Vice President of Commercial*

So from commercialization, it's the platform that George and Len described on the differentiation of our science, which results in efficacy, safety and potential advancements on dosing frequency. But today, it starts with Dupixent. We're across 9 indications, age groups, geographies. Dupixent time and time again has shown itself to be the product with best efficacy across type 2 diseases. Remarkable safety and tremendous results for patients. So from a commercialization standpoint, we look forward to these next programs. As George described, it all starts with the differentiation of our science.

**Operator**

Our next question comes from the line of Ellie Merle with Barclays.

**Eliana Rachel Merle**
*Barclays Bank PLC, Research Division*

Congrats on the quarter. On the MASH program, interesting on the 70% liver fat reduction, and we certainly agree that MASH is a very large opportunity. Curious your perspective on the antifibrotic mechanism that you might be seeing here? And how are you thinking about this in the context of the FGF21 class? I guess from your look at the genetics, do these point to a mechanistic rationale in F4 cirrhosis? Or would you be focused more on the F2, F3 fibrosis setting?

And then you alluded to moving into registrational studies here. I know there's been an evolving discussion at the FDA on noninvasive markers versus histologic endpoints. Just curious your perspective and strategy here in thinking about the target patient population and potential next steps.

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

It was a little hard to hear you, and there was a lot of questions in there. But the bottom line, and you can read our published data on the genetics. In terms of this pathway seems to protect against multiple aspects of liver disease, including that driven by fat, but by other mechanisms as well, with the effects represented in all facets of the resulting subsequent liver disease.

So we feel that this mechanism may be getting at the heart and driving of many aspects of the liver disease that the world would like to be preventing. And no other pathway has shown this sort of genetic protection profile. So that's what makes it so exciting, together with the fact that the early clinical data actually are mirroring what we see genetically, which is giving us even more confidence in the genetics.

In terms of registrational trials, as we said, we are moving aggressively forward in this program, and we'll be talking more at the November 10 roundtable where we can give you a lot more details.

**Operator**

Our next question comes from the line of Gregory Renza with Truist Securities.

**Gregory James Renza**
*Truist Securities, Inc., Research Division*

Congrats on a tremendous quarter. Len, you certainly touched on along with the team, the advantageous breadth of your presence across specialties, therapeutic areas. Just my question is, at what stage do you see that versatility perhaps presenting a challenge or even a risk to the execution and the depth that you want Regeneron to have? And maybe relatedly, as you talk about olatorepatide and opening up a 3,000-patient trial, to what extent are you and the team willing to make an investment in the vast obesity space and the resources that are in demand for winning there?

**Leonard S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

Very good question, Greg. It seems as though you may have been sitting in on some of our internal discussions. This is something that concerns us a lot. How do we make sure that our best-in-class opportunities and drugs get adequately developed, compete well both in the development as well as commercialization. I can tell you, we are very focused on that, but our experience matters. As I think we try to get across, we have developed drugs for eye diseases, for cancer, for endocrinology, for ENT, for gastroenterology, for allergists and so forth, pulmonologists. And we have this experience of working with the specialists that we need to.

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We have a great diverse group that George leads internally. I think we can do it. It doesn't mean we're going to be perfect, but we are going to strive to. Anything we take on, we're going to wholeheartedly we need. And I think we do now have the experience that it's going to take. George, do you want to add to that?

**George D. Yancopoulos**
*Co-Founder, President, Chief Scientific Officer & Co-Chairman*

Yes. I remind you, not only are we working with all these specialists across these areas, in many, if not most of those cases, we have the world's leading biologic that's utilized by these specialists. And the reason why is a combination of the fact that we are providing what we believe is best-in-class, often first-in-class medicines for our commercial team to then explain and deliver to these various specialists.

So when you talk about, for example, obesity, we don't want to just compete with just another obesity agent where we're maybe fighting that we might have 1% or 2% more, more weight loss or something like that. We want to deliver once again something that's truly differentiated. And that's what we're striving to do. For example, a weight loss agent that not only causes similar weight loss to all the other weight loss agents, but also by a completely different mechanism of action, dramatically lowers your lipids and your cardiovascular risk.

We also have other approaches that we're combining with our obesity agent to prevent the profound loss of muscle that's caused by many of these obesity agents and on and on. So if we're entering a space, our goal is not to just compete commercially with a me-too, but to give our commercial group an agent that really makes a difference for patients, which they can then convey to the specialists that we're already dealing with who have already seen our ability to deliver game-changing best-in-class medicines to their patients.

**Ryan Crowe**
*Senior Vice President of Investor Relations & Strategic Analysis*

Okay. I think we have time for 2 more questions, Shannon.

**Operator**

Our next question comes from the line of Evan Seigerman with BMO Capital Markets.

**Evan David Seigerman**
*BMO Capital Markets Equity Research*

So the expanded Sanofi alliance adds, I think, 4 next-gen antibodies focused on type 2 inflammation. What is the unmet need you're trying to solve that Dupixent cannot? And should we think about these programs primarily as franchise expansion, life cycle protection or ultimately replacement products?

**Leonard S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

Good questions, Evan. I don't think this is a format where we really want to unveil our strategy. I think the alliance has some very interesting ideas, and I think you'll hear about them over time. Sorry to put that off, but I do think there's a better format for us to discuss this with Sanofi.

**Operator**

Our last question comes from the line of Alexandria Hammond with Wolfe Research.

**Alexandria Janet Hammond**
*Wolfe Research, LLC*

So on PNH, the ACCESS-1 cohort extension data versus Ultomiris showed some really strong data. If you continue to replicate those efficacy results in the upcoming readout against Soliris, what are your expectations on patients switching in the near term and steady state? I guess are there any nuances to this patient population? We've heard them being characterized as sticky.

**Leonard S. Schleifer**
*Co-Founder, President, CEO & Co-Chairman*

Marion, do you want to take that?

**Marion E. McCourt**

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*Executive Vice President of Commercial*

Happy to. So I do think that the early clinical results have been very, very exciting and very compelling. But to the point, we'll have to see additional clinical data differentiation. But certainly, we will look forward to bringing this particular product and indication into the marketplace.

**Ryan Crowe**
*Senior Vice President of Investor Relations & Strategic Analysis*

Okay. Thanks, Marion, and thank you to everyone who dialed in for today's call. We apologize to those remaining in the Q&A queue who did not have a chance to ask their questions today. As always, the Investor Relations team is available to answer any questions that may remain. Thank you once again, and have a great day.

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

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