UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 28, 2025 (October 28, 2025)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of Principal Executive Offices, including zip code)

(914) 847-7000
Registrant's telephone number, including area code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 **Results of Operations and Financial Condition.**

On October 28, 2025, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2025. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information included or incorporated in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release, dated October 28, 2025, Reporting Third Quarter 2025 Financial and Operating Results.

104 Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 28, 2025 REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa
Name: Joseph J. LaRosa
Title: Executive Vice President, General Counsel and Secretary

REGENERON

Press Release

Regeneron Reports Third Quarter 2025 Financial and Operating Results

- *Third quarter 2025 revenues increased 1% to $3.75 billion versus third quarter 2024*
- *Dupixent® global net sales (recorded by Sanofi) increased 27% to $4.86 billion*
- *EYLEA HD® U.S. net sales increased 10% to $431 million; total EYLEA HD and EYLEA® U.S. net sales decreased 28% to $1.11 billion*
- *GAAP EPS of $13.62 and non-GAAP EPS[(a)] of $11.83; third quarter 2025 includes unfavorable $0.68 impact from acquired IPR&D charge*
- *FDA approved Libtayo® as the first and only immunotherapy for high-risk adjuvant cutaneous squamous cell carcinoma (CSCC); EMA's CHMP adopted positive opinion*
- *Positive Phase 3 results reported from trials in generalized myasthenia gravis, fibrodysplasia ossificans progressiva (FOP), and cat and birch allergies; updated positive data reported from pivotal trial in children with profound genetic hearing loss*

Tarrytown, New York (October 28, 2025) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2025 and provided a business update.

"Regeneron had a solid financial quarter and made progress across our late-stage portfolio by securing new FDA approvals for Libtayo, Evkeeza, and Lynozyfic, receiving positive CHMP opinions for Libtayo and Dupixent, and sharing promising data across our oncology, obesity, allergy, and rare disease portfolios," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "We were proud to receive one of the FDA's first Commissioner's National Priority Vouchers for DB-OTO for a rare form of congenital hearing loss. We also donated our Ebola treatment, Inmazeb, to countries most at risk of outbreaks, reflecting our commitment to ensuring patients in need are able to access our novel medicines."

Financial Highlights

($ in millions, except per share data)	Q3 2025	Q3 2024	% Change
Total revenues	$ 3,754	$ 3,721	1%
GAAP net income	$ 1,460	$ 1,341	9%
GAAP net income per share - diluted	$ 13.62	$ 11.54	18%
Non-GAAP net income[(a)]	$ 1,287	$ 1,462	(12%)
Non-GAAP net income per share - diluted[(a)]	$ 11.83	$ 12.46	(5%)

"We were pleased with our third quarter 2025 performance, which highlights the commercial strength of Dupixent, EYLEA HD, and Libtayo, and reinforces our momentum toward delivering solid financial performance for the year while advancing transformative therapies to patients around the world," said Christopher Fenimore, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "Our disciplined approach to capital allocation fuels innovation through targeted investments, all while delivering value to shareholders. In the first nine months of 2025, we reaffirmed our commitment to advancing U.S. innovation and manufacturing by investing nearly $5 billion in R&D and capital expenditures, predominantly within the United States. We also returned over $3 billion to shareholders via share repurchases and dividends, underscoring our commitment to long-term value creation."

Business Highlights

Key Pipeline Progress

Regeneron has approximately 45 product candidates in clinical development, including a number of marketed products for which it is investigating additional indications. Updates from the clinical pipeline include:

Dupixent (dupilumab)

- In September 2025, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of Dupixent in the European Union (EU) for the treatment of chronic spontaneous urticaria (CSU) in adults and adolescents aged 12 years and older who remain symptomatic despite antihistamine treatment. The European Commission (EC) is expected to announce a final decision in the coming months.

EYLEA HD (aflibercept) 8 mg

- In October 2025, the Company was notified by Catalent Indiana, LLC (Catalent), the manufacturing filler in the EYLEA HD Biologics License Application (BLA), that they received an official action indicated (OAI) letter from the FDA citing unresolved issues related to a July 2025 FDA general site inspection (not specific to EYLEA HD).

  Yesterday, the FDA issued a Complete Response Letter (CRL) for the pre-filled syringe supplemental BLA (sBLA). The sole approvability issue cited in the CRL relates to unresolved inspection findings at Catalent. The Company is planning to submit by January 2026 an application to include a new pre-filled syringe manufacturing filler in the EYLEA HD BLA.

  There is also an sBLA under review by the FDA for EYLEA HD every-four-week dosing and for the treatment of macular edema following retinal vein occlusion (RVO), which has a target action date in late November 2025. In addition, the Company has submitted an application to include an additional vial filler, with an FDA decision regarding this new vial filler expected by late December 2025.

Libtayo (cemiplimab)

- In October 2025, the FDA approved an sBLA for Libtayo as an adjuvant treatment for adults with CSCC at high risk of recurrence after surgery and radiation, making Libtayo the first and only immunotherapy approved in this setting. The EMA's CHMP also adopted a positive opinion for the adjuvant treatment of CSCC, and the EC is expected to announce a final decision in the coming months.
- In September 2025, Japan's Ministry of Health, Labour and Welfare (MHLW) approved Libtayo for an additional indication, as a monotherapy and in combination with chemotherapy

for the treatment of adult patients with unresectable advanced or relapsed non-small cell lung cancer (NSCLC).
- In September 2025, the Company announced five-year follow-up results on overall survival from a Phase 3 trial, which evaluated Libtayo plus platinum-based chemotherapy versus chemotherapy alone as a first-line treatment for adults with locally advanced or metastatic NSCLC. The data demonstrate a more than double five-year overall survival rate of 19.4%, compared to 8.8% with chemotherapy alone, and was presented at the IASLC 2025 World Conference on Lung Cancer.

Other Programs
- In August 2025, the Company announced that the primary and key secondary endpoints were met in a Phase 3 trial of cemdisiran (siRNA therapy), as both a monotherapy and in combination with pozelimab (C5 antibody), in adults with generalized myasthenia gravis. Cemdisiran monotherapy was numerically better than the combination treatment across these endpoints, showing a statistically significant 2.3-point placebo-adjusted improvement in Myasthenia Gravis Activities of Daily Living (MG-ADL) total score. A U.S. regulatory submission for cemdisiran monotherapy is planned for the first quarter of 2026, pending discussions with the FDA.
- In October 2025, updated data from the pivotal trial of DB-OTO, an AAV-based gene therapy, in children with profound genetic hearing loss due to variants of the otoferlin (OTOF) gene were published in the *New England Journal of Medicine* and presented at the annual American Academy of Otolaryngology-Head and Neck Surgery meeting. These latest results from the CHORD trial show 11 out of 12 participants have experienced clinically meaningful hearing improvements. A U.S. regulatory submission for DB-OTO is planned for the fourth quarter of 2025.
- In October 2025, the FDA selected DB-OTO to receive one of the Commissioner's National Priority Vouchers, a pilot program intended to reduce the review time for certain drug and biologic applications to just one to two months.
- In September 2025, the Company announced the primary endpoint was met in a Phase 3 trial of garetosmab in adults with FOP, showing a 90% or greater reduction in new bone lesions (heterotopic ossification, or HO lesions) compared to placebo at 56 weeks, and a greater than 99% reduction in the total volume of new HO lesions. A U.S. regulatory submission for garetosmab is planned for the fourth quarter of 2025.
- In September 2025, the FDA approved Evkeeza® (evinacumab) for the treatment of homozygous familial hypercholesterolemia (HoFH), extending the already approved indication to include children from age 1 to less than 5 years old.
- In September 2025, the Company announced results from the Phase 3 trials evaluating its allergen-blocking antibodies in adults with moderate-to-severe cat allergies (REGN1908 and REGN1909) or birch allergies (REGN5713 and REGN5715). Both trials met their respective primary and key secondary endpoints, with single doses of the allergen-specific antibody blockers significantly reducing allergy symptoms compared to placebo at day 8. Additional Phase 3 development is planned to begin by the end of the year.

Corporate Updates
- In September and October 2025, the Company reached resolution of its patent infringement litigation related to the Sandoz, Formycon, and Celltrion EYLEA (aflibercept) Injection 2 mg biosimilar products. The settlements preclude Sandoz, Formycon, and Celltrion from launching their biosimilar products in the United States until the fourth quarter of 2026. All intellectual property-related litigation with Sandoz, Formycon, and Celltrion in the United States has been dismissed.

Third Quarter 2025 Financial Results

Revenues

($ in millions)	Q3 2025	Q3 2024	% Change
Net product sales:			
EYLEA HD - U.S.	$ 431	$ 392	10%
EYLEA - U.S.	681	1,145	(41%)
Total EYLEA HD and EYLEA - U.S.	1,112	1,537	(28%)
Libtayo - U.S.	219	195	12%
Libtayo - ROW*	146	94	55%
Total Libtayo - Global	365	289	26%
Praluent® - U.S.	67	53	26%
Evkeeza - U.S.	43	32	34%
Other products - Global	1	35	(97%)
Total net product sales	1,588	1,946	(18%)
Collaboration revenue:			
Sanofi	1,617	1,263	28%
Bayer	345	391	(12%)
Other	6	6	—%
Other revenue	198	114	74%
Total revenues	$ 3,754	$ 3,720	1%

* Rest of world (ROW)

Net product sales of EYLEA HD increased in the third quarter of 2025, compared to the third quarter of 2024, due to higher sales volumes driven by increased demand, partly offset by a lower net selling price.

Net product sales of EYLEA in the third quarter of 2025, compared to the third quarter of 2024, were negatively impacted by (i) lower sales volumes as a result of continued competitive pressures, loss in market share to compounded bevacizumab due to patient affordability constraints, and the continued transition of patients to EYLEA HD, and (ii) a lower net selling price.

Sanofi collaboration revenue increased in the third quarter of 2025, compared to the third quarter of 2024, due to an increase in the Company's share of profits from the commercialization of antibodies, which were $1.46 billion and $1.09 billion in the third quarter of 2025 and 2024, respectively. The change in the Company's share of profits from commercialization of antibodies was driven by higher profits associated with an increase in Dupixent sales.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue increased in the third quarter of 2025, compared to the third quarter of 2024, due to an increase in royalties and share of profits earned in connection with license agreements, which were $165 million and $91 million for the third quarter of 2025 and 2024, respectively.

Operating Expenses

($ in millions)	GAAP Q3 2025	GAAP Q3 2024	GAAP % Change	Non-GAAP[a] Q3 2025	Non-GAAP[a] Q3 2024	Non-GAAP[a] % Change
Research and development (R&D)	$ 1,475	$ 1,272	16%	$ 1,350	$ 1,146	18%
Acquired in-process research and development (IPR&D)	$ 83	$ 56	48%	*	*	n/a
Selling, general, and administrative (SG&A)	$ 658	$ 714	(8%)	$ 541	$ 613	(12%)
Cost of goods sold (COGS)	$ 281	$ 262	7%	$ 227	$ 217	5%
Gross margin on net product sales[b]	82%	87%		86%	89%	
Cost of collaboration and contract manufacturing (COCM)[c]	$ 241	$ 229	5%	*	*	n/a
Other operating (income) expense, net	$ (10)	$ 8	**	*	$ —	**

* GAAP and non-GAAP amounts are equivalent as no non-GAAP adjustments have been recorded

** Percentage not meaningful

- GAAP and non-GAAP R&D expenses increased in the third quarter of 2025, compared to the third quarter of 2024, driven by the advancement of the Company's late-stage clinical pipeline.
- Acquired IPR&D expenses for the third quarter of 2025 included an $80 million up-front payment in connection with the Company's license agreement with Hansoh Pharmaceuticals Group Company Limited. Acquired IPR&D expenses for the third quarter of 2024 included a $45 million development milestone in connection with the Company's collaboration agreement with Sonoma Biotherapeutics, Inc.
- GAAP and non-GAAP SG&A expenses decreased in the third quarter of 2025, compared to the third quarter of 2024, primarily due to lower charitable contributions to an independent not-for-profit patient assistance organization.
- GAAP and non-GAAP gross margin on net product sales decreased in the third quarter of 2025, compared to the third quarter of 2024, partly due to ongoing investments to support the Company's manufacturing operations. In addition, GAAP gross margin on net product sales decreased due to higher amortization expense associated with the Company's Libtayo intangible asset.

Other Financial Information

GAAP other income (expense), net included the recognition of net gains on marketable and other securities of $578 million in the third quarter of 2025, compared to $135 million in the third quarter of 2024.

In the third quarter of 2025, the Company's GAAP effective tax rate (ETR) was 17.2%, compared to 10.2% in the third quarter of 2024. The GAAP ETR increased in the third quarter of 2025, compared to the third quarter of 2024, primarily due to the impact of the enactment of the "One Big Beautiful Bill Act" or "OBBBA," including a $45 million charge related to the re-measurement of the Company's U.S. net deferred tax assets, as well as lower tax benefits from less stock option exercises. In the third quarter of 2025, the non-GAAP ETR was 13.1%, compared to 10.7% in the third quarter of 2024.

A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

Capital Allocation

During the third quarter of 2025, the Company repurchased shares of its common stock and recorded the cost of the shares, or $663 million, as Treasury Stock. As of September 30, 2025, $2.156 billion remained available for share repurchases under the Company's share repurchase programs.

In October 2025, the Company's board of directors declared a cash dividend of $0.88 per share on the Company's common stock and Class A stock, payable on December 5, 2025 to shareholders of record as of November 20, 2025.

2025 Financial Guidance*

The Company's full year 2025 financial guidance consists of the following components:

	2025 Guidance	
	Prior	**Updated**
GAAP R&D	$5.660–$5.790 billion	$5.680–$5.750 billion
Non-GAAP R&D[(a)]	$5.100–$5.200 billion	$5.150–$5.200 billion
GAAP SG&A**	$2.810–$2.940 billion	$2.775–$2.845 billion
Non-GAAP SG&A[(a)]**	$2.450–$2.550 billion	$2.400–$2.450 billion
GAAP gross margin on net product sales	Approximately 83%	Approximately 82%
Non-GAAP gross margin on net product sales[(a)]	Approximately 86%	Unchanged
COCM***	$1.000–$1.050 billion	$950 million–$1.000 billion
Capital expenditures***	$880–$950 million	$850–$890 million
GAAP effective tax rate	11%–13%	Approximately 14%
Non-GAAP effective tax rate[(a)]	11%–13%	Approximately 12%

* The Company's 2025 financial guidance does not assume the completion of any business development transactions not completed as of the date of this press release

** The Company's 2025 financial guidance includes potential matching program donations to Good Days, an independent national non-profit charitable organization, to support Good Days' Retinal Vascular and Neovascular Disease Fund

*** GAAP and non-GAAP amounts are equivalent as no non-GAAP adjustments have been or are expected to be recorded

A reconciliation of full year 2025 GAAP to non-GAAP financial guidance is included below:

($ in millions)	Projected Range	
	Low	**High**
GAAP R&D	$ 5,680	$ 5,750
Stock-based compensation expense	530	550
Non-GAAP R&D[(a)]	$ 5,150	$ 5,200
GAAP SG&A	$ 2,775	$ 2,845
Stock-based compensation expense	350	370
Litigation settlements	25	25
Non-GAAP SG&A[(a)]	$ 2,400	$ 2,450
GAAP gross margin on net product sales	82%	82%
Intangible asset amortization expense	2%	2%
Stock-based compensation expense	1%	1%
Other	< 1%	< 1%
Non-GAAP gross margin on net product sales[(a)]	86%	86%
GAAP ETR	14%	14%
Income tax effect of GAAP to non-GAAP reconciling items	1%	1%
Income tax expense: Charge related to enactment of OBBBA	1%	1%
Non-GAAP ETR[(a)]	12%	12%

(a) This press release uses non-GAAP R&D, non-GAAP SG&A, non-GAAP COGS, non-GAAP gross margin on net product sales, non-GAAP other operating (income) expense, net, non-GAAP other income (expense), net, non-GAAP ETR, non-GAAP net income, non-GAAP net income per share, and free cash flow, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP). These non-GAAP financial measures are computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate from period to period based on factors that are not within the Company's control (such as the Company's stock price on the dates share-based grants are issued or changes in the fair value of the Company's investments in equity securities) or items that are not associated with normal, recurring operations (such as acquisition and integration costs). Management uses these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. With respect to free cash flow, the Company believes that this non-GAAP measure provides a further measure of the Company's ability to generate cash flows from its operations. Additionally, the non-GAAP measures presented are intended to provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by the Company should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.

(b) Gross margin on net product sales represents gross profit expressed as a percentage of total net product sales recorded by the Company. Gross profit is calculated as net product sales less cost of goods sold.

(c) Corresponding reimbursements from collaborators and others for manufacturing product is recorded within revenues.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its third quarter 2025 financial and operating results on Tuesday, October 28, 2025, at 8:30 AM Eastern Time. Participants may access the conference call live via webcast, or register in advance and participate via telephone, on the "Investors and Media" page of Regeneron's website at www.regeneron.com. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the Company's website for at least 30 days.

About Regeneron

Regeneron is a leading biotechnology company that invents, develops, and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most of which were homegrown in Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using its proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. Regeneron is shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling Regeneron to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook, or X.

Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, competing drugs and product candidates 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") (including biosimilar versions of Regeneron's Products); 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), other clinical programs discussed in this press release, Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; the likelihood and timing of achieving any of the anticipated milestones described in this press release; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including those listed above and/or otherwise discussed in this press release; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the availability and extent of reimbursement or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's drug pricing strategy; other changes in laws, regulations, and policies affecting the healthcare industry; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance, including GAAP and non-GAAP R&D, GAAP and non-GAAP SG&A, GAAP and non-GAAP gross margin on net product sales, COCM, capital expenditures, and GAAP and non-GAAP ETR; 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 fiscal year ended

December 31, 2024 and its Form 10-Q for the quarterly period ended September 30, 2025. 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

Non-GAAP Financial Measures

This press release and/or the financial results attached to this press release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of such non-GAAP financial measures.

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TABLE 1

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In millions)

	September 30, 2025	December 31, 2024
Assets:		
Cash and marketable securities	$ 18,729.3	$ 17,912.6
Accounts receivable, net	5,687.1	6,211.9
Inventories	3,254.4	3,087.3
Property, plant, and equipment, net	5,002.3	4,599.7
Intangible assets, net	1,380.9	1,148.6
Deferred tax assets	3,846.7	3,314.1
Other assets	2,268.7	1,485.2
Total assets	$ 40,169.4	$ 37,759.4
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 5,741.3	$ 4,888.0
Finance lease liabilities	720.0	720.0
Deferred revenue	764.8	813.4
Long-term debt	1,985.5	1,984.4
Stockholders' equity	30,957.8	29,353.6
Total liabilities and stockholders' equity	$ 40,169.4	$ 37,759.4

TABLE 2

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In millions, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues:				
Net product sales	$ 1,587.7	$ 1,946.4	$ 4,634.3	$ 5,626.3
Collaboration revenue	1,968.4	1,660.1	5,360.3	4,450.9
Other revenue	198.2	114.2	464.0	335.6
	3,754.3	3,720.7	10,458.6	10,412.8
Expenses:				
Research and development	1,475.0	1,271.5	4,224.1	3,719.9
Acquired in-process research and development	83.1	56.2	105.4	87.2
Selling, general, and administrative	657.8	714.4	1,925.0	2,162.2
Cost of goods sold	281.0	262.3	822.1	760.5
Cost of collaboration and contract manufacturing	240.6	228.8	694.0	644.6
Other operating (income) expense, net	(10.0)	8.0	(10.0)	37.9
	2,727.5	2,541.2	7,760.6	7,412.3
Income from operations	1,026.8	1,179.5	2,698.0	3,000.5
Other income (expense):				
Other income (expense), net	755.8	327.3	1,520.6	866.0
Interest expense	(19.3)	(13.8)	(31.6)	(44.7)
	736.5	313.5	1,489.0	821.3
Income before income taxes	1,763.3	1,493.0	4,187.0	3,821.8
Income tax expense	303.3	152.4	526.7	326.9
Net income	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Net income per share - basic	$ 14.09	$ 12.40	$ 34.83	$ 32.36
Net income per share - diluted	$ 13.62	$ 11.54	$ 33.61	$ 30.23
Weighted average shares outstanding - basic	103.6	108.1	105.1	108.0
Weighted average shares outstanding - diluted	107.2	116.2	108.9	115.6

TABLE 3

REGENERON PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION (Unaudited)
(In millions, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
GAAP R&D	$ 1,475.0	$ 1,271.5	$ 4,224.1	$ 3,719.9
Stock-based compensation expense	125.1	123.7	405.1	369.1
Acquisition and integration costs	—	2.0	—	11.1
Non-GAAP R&D	$ 1,349.9	$ 1,145.8	$ 3,819.0	$ 3,339.7
GAAP SG&A	$ 657.8	$ 714.4	$ 1,925.0	$ 2,162.2
Stock-based compensation expense	92.0	83.1	279.0	251.9
Acquisition and integration costs	—	8.2	0.8	36.7
Litigation settlements	25.0	10.0	25.0	10.0
Non-GAAP SG&A	$ 540.8	$ 613.1	$ 1,620.2	$ 1,863.6
GAAP COGS	$ 281.0	$ 262.3	$ 822.1	$ 760.5
Stock-based compensation expense	19.9	18.3	60.3	57.4
Acquisition and integration costs	—	0.5	—	1.7
Intangible asset amortization expense	33.7	26.1	94.8	74.4
Non-GAAP COGS	$ 227.4	$ 217.4	$ 667.0	$ 627.0
GAAP other operating (income) expense, net	$ (10.0)	$ 8.0	$ (10.0)	$ 37.9
Change in fair value of contingent consideration	—	8.0	—	37.9
Non-GAAP other operating (income) expense, net	$ (10.0)	$ —	$ (10.0)	$ —
GAAP other income (expense), net	$ 736.5	$ 313.5	$ 1,489.0	$ 821.3
Gains on marketable and other securities, net	(577.7)	(134.7)	(967.6)	(331.2)
Non-GAAP other income (expense), net	$ 158.8	$ 178.8	$ 521.4	$ 490.1
GAAP net income	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Total of GAAP to non-GAAP reconciling items above	(282.0)	145.2	(102.6)	519.0
Income tax effect of GAAP to non-GAAP reconciling items	64.7	(23.4)	37.0	(84.4)
Income tax expense: Charge related to enactment of OBBBA	44.5	—	44.5	—
Non-GAAP net income	$ 1,287.2	$ 1,462.4	$ 3,639.2	$ 3,929.5
Non-GAAP net income per share - basic	$ 12.42	$ 13.53	$ 34.63	$ 36.38
Non-GAAP net income per share - diluted	$ 11.83	$ 12.46	$ 32.87	$ 33.53
Shares used in calculating:				
Non-GAAP net income per share - basic	103.6	108.1	105.1	108.0
Non-GAAP net income per share - diluted	108.8	117.4	110.7	117.2

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION (Unaudited) ***(continued)***

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Effective tax rate reconciliation:				
GAAP ETR	17.2%	10.2%	12.6%	8.6%
Income tax effect of GAAP to non-GAAP reconciling items	(2.4%)	0.5%	(0.8%)	0.9%
Income tax expense: Charge related to enactment of OBBBA	(1.7%)	—%	(0.9%)	—%
Non-GAAP ETR	13.1%	10.7%	10.9%	9.5%
Gross margin on net product sales reconciliation:				
GAAP gross margin on net product sales	82%	87%	82%	86%
Intangible asset amortization expense	2%	1%	2%	2%
Stock-based compensation expense	2%	1%	2%	1%
Non-GAAP gross margin on net product sales	86%	89%	86%	89%

	Nine Months Ended September 30,	
	2025	**2024**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 3,808.2	$ 3,157.7
Capital expenditures	(649.7)	(556.3)
Free cash flow	$ 3,158.5	$ 2,601.4

TABLE 4

REGENERON PHARMACEUTICALS, INC.
COLLABORATION REVENUE (Unaudited)
(In millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Sanofi collaboration revenue:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 1,455.5	$ 1,088.3	$ 3,755.7	$ 2,880.6
Reimbursement for manufacturing of commercial supplies	161.5	175.1	488.1	438.2
Total Sanofi collaboration revenue	1,617.0	1,263.4	4,243.8	3,318.8
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States	311.9	367.6	1,012.6	1,054.5
Reimbursement for manufacturing of commercial supplies	32.9	23.2	91.1	67.4
Total Bayer collaboration revenue	344.8	390.8	1,103.7	1,121.9
Other collaboration revenue	6.6	5.9	12.8	10.2
Total collaboration revenue	$ 1,968.4	$ 1,660.1	$ 5,360.3	$ 4,450.9

TABLE 5

REGENERON PHARMACEUTICALS, INC.
NET PRODUCT SALES OF REGENERON-DISCOVERED PRODUCTS (Unaudited)
(In millions)

	Three Months Ended September 30,						
	2025			2024			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA HD[a]	$ 430.6	$ 232.4	$ 663.0	$ 392.3	$ 75.2	$ 467.5	42%
EYLEA[a]	$ 680.6	$ 621.4	$ 1,302.0	$ 1,144.6	$ 856.5	$ 2,001.1	(35%)
Total EYLEA HD and EYLEA	$ 1,111.2	$ 853.8	$ 1,965.0	$ 1,536.9	$ 931.7	$ 2,468.6	(20%)
Dupixent[b]	$ 3,618.8	$ 1,238.2	$ 4,857.0	$ 2,824.7	$ 992.5	$ 3,817.2	27%
Libtayo[c]	$ 219.1	$ 146.1	$ 365.2	$ 194.5	$ 94.1	$ 288.6	27%
Praluent[d]	$ 67.7	$ 148.0	$ 215.7	$ 52.9	$ 138.5	$ 191.4	13%
Kevzara[b]	$ 102.9	$ 51.1	$ 154.0	$ 72.7	$ 47.4	$ 120.1	28%
Other products[e]	$ 43.9	$ 28.0	$ 71.9	$ 68.2	$ 24.4	$ 92.6	(22%)

	Nine Months Ended September 30,						
	2025			2024			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA HD[a]	$ 1,130.6	$ 620.5	$ 1,751.1	$ 896.5	$ 149.5	$ 1,046.0	67%
EYLEA[a]	$ 2,170.9	$ 2,068.8	$ 4,239.7	$ 3,576.7	$ 2,539.4	$ 6,116.1	(31%)
Total EYLEA HD and EYLEA	$ 3,301.5	$ 2,689.3	$ 5,990.8	$ 4,473.2	$ 2,688.9	$ 7,162.1	(16%)
Dupixent[b]	$ 9,453.2	$ 3,414.0	$ 12,867.2	$ 7,652.9	$ 2,797.5	$ 10,450.4	23%
Libtayo[c]	$ 659.4	$ 367.4	$ 1,026.8	$ 536.1	$ 313.8	$ 849.9	21%
Praluent[d]	$ 190.3	$ 440.7	$ 631.0	$ 179.0	$ 405.6	$ 584.6	8%
Kevzara[b]	$ 271.4	$ 151.2	$ 422.6	$ 187.8	$ 136.1	$ 323.9	30%
Other products[e]	$ 117.1	$ 81.5	$ 198.6	$ 124.4	$ 65.2	$ 189.6	5%

Note: The table above includes net product sales of Regeneron-discovered products. Such net product sales are recorded by the Company or others, as further described in the footnotes below.

[a] The Company records net product sales of EYLEA HD and EYLEA in the United States, and Bayer records net product sales outside the United States. The Company records its share of profits in connection with sales outside the United States within Collaboration revenue.

[b] Sanofi records global net product sales of Dupixent and Kevzara, and the Company records its share of profits in connection with global sales of such products within Collaboration revenue

[c] The Company records global net product sales of Libtayo and pays Sanofi a royalty on such sales

[d] The Company records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales, which is recorded within Other revenue.

[e] Included in this line item are products which are sold by the Company and others. Refer to "Third Quarter 2025 Financial Results" section above for a listing of net product sales recorded by the Company. Not included in this line item are net product sales of ARCALYST®, which are recorded by Kiniksa.