

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): August 1, 2025 (August 1, 2025)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York
(State or other jurisdiction of incorporation)

000-19034
(Commission File Number)

13-3444607
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 August 1, 2025, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 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 August 1, 2025, Reporting Second 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: August 1, 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 Second Quarter 2025 Financial and Operating Results

- Second quarter 2025 revenues increased 4% to \$3.68 billion versus second quarter 2024
- Dupixent® global net sales (recorded by Sanofi) increased 22% to \$4.34 billion
- EYLEA HD® U.S. net sales increased 29% to \$393 million; total EYLEA HD and EYLEA® U.S. net sales decreased 25% to \$1.15 billion
- GAAP EPS increased 3% to \$12.81; non-GAAP EPS^(a) increased 12% to \$12.89
- FDA approved Lynozyfic™ (linvoseltamab) for relapsed or refractory multiple myeloma and Dupixent for bullous pemphigoid and chronic spontaneous urticaria (CSU)
- FDA accepted for priority review Libtayo® sBLA for adjuvant cutaneous squamous cell carcinoma (CSCC)
- In-licensed rights to late-stage dual GLP-1/GIP receptor agonist; reported interim 26-week data from Phase 2 COURAGE trial in obesity

Tarrytown, New York (August 1, 2025) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2025 and provided a business update.

"Regeneron had a strong quarter, marked by significant growth in U.S. sales of EYLEA HD and global sales of Dupixent and Libtayo along with multiple regulatory approvals," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "We have made significant progress in our oncology portfolio, including FDA approval for Lynozyfic for relapsed or refractory multiple myeloma, exciting emerging data from the lead-in cohorts of our pivotal programs in myeloma and lymphoma, as well as positive pivotal data supporting a potential upcoming FDA approval for Libtayo in adjuvant CSCC. Dupixent continues to be the world-leading treatment for diseases driven by type 2 inflammation, adding recent FDA approvals for bullous pemphigoid and chronic spontaneous urticaria, the seventh and eighth distinct indications for this important medicine. We are confident in the near- and long-term potential of our diverse pipeline and look forward to additional data and regulatory milestones later this year."

Financial Highlights

(\$ in millions, except per share data)

	Q2 2025	Q2 2024	% Change
Total revenues	\$ 3,676	\$ 3,547	4%
GAAP net income	\$ 1,392	\$ 1,432	(3%)
GAAP net income per share - diluted	\$ 12.81	\$ 12.41	3%
Non-GAAP net income ^(a)	\$ 1,424	\$ 1,351	5%
Non-GAAP net income per share - diluted ^(a)	\$ 12.89	\$ 11.56	12%

"We are pleased with our second quarter financial performance, which reflects strong momentum across our business, highlighted by 4% revenue growth and 12% non-GAAP earnings growth," said Christopher Fenimore, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "While we continue to prioritize internal investments, we also returned over \$2.3 billion of capital to shareholders through share repurchases and dividends and committed over \$7 billion to U.S. manufacturing investments, capital expenditures, and business development since the start of 2025, underscoring our commitment to deploy capital with the goal of driving 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 June 2025, the FDA approved Dupixent for the treatment of adults with bullous pemphigoid. Regulatory applications are under review in the European Union (EU) and Japan.
- In April 2025, the FDA approved Dupixent for the treatment of adults and adolescents aged 12 years and older with CSU who remain symptomatic despite antihistamine treatment. Regulatory applications were submitted to the FDA and in the EU for CSU in children aged 2 to 11 years.

EYLEA HD (afibercept) 8 mg

- The European Commission (EC) approved EYLEA 8 mg with extended dosing intervals of up to 6 months (24 weeks) for wet age-related macular degeneration (wAMD) and diabetic macular edema (DME).
- The Company now expects regulatory approvals to be delayed for its currently pending FDA applications for EYLEA HD (pre-filled syringe, every-four-week dosing, and for the treatment of macular edema following retinal vein occlusion), which have PDUFA dates in August 2025. The anticipated delay is related to observations from an FDA general site inspection at the filler for EYLEA HD in these regulatory applications, Catalent Indiana LLC (recently acquired by Novo Nordisk A/S). This inspection was completed in mid-July and was not specific to EYLEA HD. Novo has been in communication with the FDA and expects to submit its response next week. Based on the Company's review of the observations and Novo's proposed response to the FDA, along with the progress the Company has made with alternate third-party fillers, the Company anticipates an expeditious resolution of the filling issues for EYLEA HD.

Oncology Programs

- In July 2025, the FDA granted accelerated approval for Lynozyfic (linvoseltamab) to treat adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Additionally, the EC granted conditional marketing approval of Lynozyfic to treat adults with relapsed or refractory multiple myeloma who have received at least three prior therapies.
- In July 2025, Lynozyfic was added to the National Comprehensive Cancer Network (NCCN) Guidelines for the treatment of multiple myeloma.
- The FDA accepted for priority review a supplemental Biologics License Application (sBLA) for Libtayo (cemiplimab) in adjuvant CSCC, with a target action date in October 2025.

- The Company announced detailed analyses from a Phase 3 trial of Libtayo in adjuvant CSCC. The results, presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in the *New England Journal of Medicine*, included additional data for the primary endpoint of disease-free survival (DFS) and the first presentation of key secondary endpoint outcomes.
- On July 30, 2025, the FDA issued a Complete Response Letter (CRL) for the BLA for odronextamab, a bispecific antibody targeting CD20 and CD3, in relapsed/refractory follicular lymphoma after two or more lines of systemic therapy, which was also impacted by the Catalent Indiana LLC site inspection (as described above).

Other Programs

- The Company announced interim 26-week results from the ongoing Phase 2 COURAGE trial investigating combinations of semaglutide and trevogrumab (myostatin antibody) with or without garetosmab (Activin A antibody) for the treatment of obesity. The trial demonstrated that approximately 35% of semaglutide-induced weight loss was due to loss of lean mass, and further demonstrated that combining semaglutide with trevogrumab with or without garetosmab preserved lean mass while increasing loss of fat mass. Final 26-week efficacy and safety results were consistent with the interim data and will be presented at the 61st Annual Meeting of the European Association for the Study of Diabetes (EASD) in September 2025.
- A Phase 3 study for REGN7508, an antibody to Factor XI (catalytic domain), was initiated to evaluate the prevention of venous thromboembolism after total knee replacement surgery. Initiation of additional Phase 3 studies is planned for later this year and the first half of 2026.
- The Company and Sanofi announced that a Phase 3 trial, AERIFY-1, for itepekimab, an antibody to IL-33, in adults who were former smokers with inadequately controlled chronic obstructive pulmonary disease (COPD) met the primary endpoint of significantly reducing moderate or severe acute exacerbations by 27% compared to placebo at week 52, a clinically meaningful benefit. A second Phase 3 trial, AERIFY-2, did not meet the same primary endpoint, although a benefit was seen earlier in the trial. The Company and Sanofi continue to evaluate the data to inform next steps for potential future COPD development.

Corporate and Business Development Updates

- In July 2025, the Company's license agreement with Hansoh Pharmaceuticals Group Company Limited to acquire development and commercial rights outside of mainland China, Hong Kong, and Macau for HS-20094 (a dual GLP-1/GIP receptor agonist currently in Phase 3 clinical development in China) became effective. In-licensing a late-stage GLP1/GIP agonist enables the Company to study combinations with its products and product candidates in order to address muscle loss and potentially other comorbidities of obesity, such as cardiovascular diseases, diabetes, and liver conditions.
- A jury verdict in the U.S. District Court for the District of Delaware found that Amgen Inc. violated antitrust and tort laws by creating an anticompetitive bundling scheme which was designed to exclude Praluent from the market.
- In June 2025, the Company announced the launch of a matching program for donations to Good Days, an independent national non-profit charitable organization, to support their Retinal Vascular and Neovascular Disease Fund. The Company has committed to matching donations up to a total of \$200 million at a one-to-one rate through the end of 2025, with the goal of enabling more patients to affordably access essential medicines that help protect their vision.
- The Company acquired an FDA Rare Pediatric Disease Priority Review Voucher from a third party for \$155 million.

Second Quarter 2025 Financial Results

Revenues

<i>(\$ in millions)</i>	Q2 2025	Q2 2024	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 393	\$ 304	29%
EYLEA - U.S.	754	1,231	(39%)
Total EYLEA HD and EYLEA - U.S.	1,147	1,535	(25%)
Libtayo - U.S.	248	182	36%
Libtayo - ROW*	129	115	12%
Total Libtayo - Global	377	297	27%
Praluent® - U.S.	66	56	18%
Evkeeza® - U.S.	41	31	32%
Total net product sales	1,631	1,919	(15%)
Collaboration revenue:			
Sanofi	1,444	1,146	26%
Bayer	415	375	11%
Other	2	3	(33%)
Other revenue	184	104	77%
Total revenues	\$ 3,676	\$ 3,547	4%

* Rest of world (ROW)

Net product sales of EYLEA HD increased in the second quarter of 2025, compared to the second quarter of 2024, due to higher sales volumes driven by increased demand.

Net product sales of EYLEA in the second quarter of 2025, compared to the second 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 second quarter of 2025, compared to the second quarter of 2024, due to an increase in the Company's share of profits from the commercialization of antibodies, which were \$1.282 billion and \$988 million in the second 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 second quarter of 2025, compared to the second quarter of 2024, due to an increase in royalties and share of profits earned in connection with license agreements, which were \$118 million and \$69 million for the second quarter of 2025 and 2024, respectively.

Operating Expenses

(\$ in millions)	GAAP			Non-GAAP ^(a)		
	Q2 2025	Q2 2024	% Change	Q2 2025	Q2 2024	% Change
Research and development (R&D)	\$ 1,422	\$ 1,200	19%	\$ 1,283	\$ 1,072	20%
Acquired in-process research and development (IPR&D)	\$ 10	\$ 24	(58%)	*	*	n/a
Selling, general, and administrative (SG&A)	\$ 634	\$ 759	(16%)	\$ 542	\$ 667	(19%)
Cost of goods sold (COGS)	\$ 276	\$ 258	7%	\$ 222	\$ 214	4%
Gross margin on net product sales ^(c)	83%	87%		86%	89%	
Cost of collaboration and contract manufacturing (COCM) ^(d)	\$ 255	\$ 222	15%	*	*	n/a
Other operating expense (income), net	\$ —	\$ 15	(100%)	*	\$ —	—%

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

- GAAP and non-GAAP R&D expenses increased in the second quarter of 2025, compared to the second quarter of 2024, driven by the advancement of the Company's mid- and late-stage clinical pipeline.
- GAAP and non-GAAP SG&A expenses decreased in the second quarter of 2025, compared to the second 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 second quarter of 2025, compared to the second quarter of 2024, partly due to ongoing investments to support the Company's manufacturing operations and higher inventory write-offs and reserves in the second quarter of 2025 compared to the second quarter of 2024.

Other Financial Information

GAAP other income (expense), net included the recognition of net unrealized gains on equity securities of \$250 million in the second quarter of 2025, compared to \$393 million in the second quarter of 2024.

In the second quarter of 2025, the Company's GAAP effective tax rate (ETR) was 8.4%, compared to 12.0% in the second quarter of 2024. The GAAP ETR decreased in the second quarter of 2025, compared to the second quarter of 2024, primarily due to the net change in uncertain tax positions, partly offset by lower tax benefits from less stock option exercises. During the second quarter of 2025, the release of liabilities for uncertain tax positions recognized upon the effective settlement of an IRS audit reduced the Company's GAAP ETR by 3.9%. In the second quarter of 2025, the non-GAAP ETR was 8.3%, compared to 10.8% in the second 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 second quarter of 2025, the Company repurchased shares of its common stock and recorded the cost of the shares, or \$1.070 billion, as Treasury Stock. As of June 30, 2025, \$2.814 billion remained available for share repurchases under the Company's share repurchase programs.

In July 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 September 3, 2025 to shareholders of record as of August 18, 2025.

2025 Financial Guidance^(b)

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

	2025 Guidance	
	Prior	Updated
GAAP R&D	\$5.560–\$5.795 billion	\$5.660–\$5.790 billion
Non-GAAP R&D ^(a)	\$5.000–\$5.200 billion	\$5.100–\$5.200 billion
GAAP SG&A	\$2.910–\$3.095 billion	\$2.810–\$2.940 billion
Non-GAAP SG&A ^(a)	\$2.550–\$2.700 billion	\$2.450–\$2.550 billion
GAAP gross margin on net product sales	83%–84%	Approximately 83%
Non-GAAP gross margin on net product sales ^(a)	86%–87%	Approximately 86%
COCM*	\$1.000–\$1.150 billion	\$1.000–\$1.050 billion
Capital expenditures*	\$850–\$950 million	\$880–\$950 million
GAAP effective tax rate	9%–11%	11%–13%
Non-GAAP effective tax rate ^(a)	11%–13%	Unchanged

* 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	\$ 5,660	\$ 5,790
Stock-based compensation expense	560	590
Non-GAAP R&D	\$ 5,100	\$ 5,200
GAAP SG&A	\$ 2,810	\$ 2,940
Stock-based compensation expense	360	390
Non-GAAP SG&A	\$ 2,450	\$ 2,550
GAAP gross margin on net product sales	83%	83%
Intangible asset amortization expense	2%	2%
Stock-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	86%	86%
GAAP ETR	11%	13%
Income tax effect of GAAP to non-GAAP reconciling items	<1%	<1%
Non-GAAP ETR	11%	13%

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- (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) 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.
- (c) 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.
- (d) Corresponding reimbursements from collaborators and others for manufacturing product is recorded within revenues.
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Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its second quarter 2025 financial and operating results on Friday, August 1, 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[®] (afibercept) Injection 8 mg, EYLEA[®] (afibercept) 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 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 June 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)

	June 30, 2025	December 31, 2024
Assets:		
Cash and marketable securities	\$ 17,527.8	\$ 17,912.6
Accounts receivable, net	5,610.0	6,211.9
Inventories	3,205.6	3,087.3
Property, plant, and equipment, net	4,840.7	4,599.7
Intangible assets, net	1,351.7	1,148.6
Deferred tax assets	3,572.2	3,314.1
Other assets	2,111.2	1,485.2
Total assets	\$ 38,219.2	\$ 37,759.4
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 4,887.0	\$ 4,888.0
Finance lease liabilities	720.0	720.0
Deferred revenue	688.2	813.4
Long-term debt	1,985.1	1,984.4
Stockholders' equity	29,938.9	29,353.6
Total liabilities and stockholders' equity	\$ 38,219.2	\$ 37,759.4

TABLE 2

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
Net product sales	\$ 1,631.0	\$ 1,918.6	\$ 3,046.6	\$ 3,679.9
Collaboration revenue	1,860.7	1,524.0	3,391.9	2,790.8
Other revenue	183.9	104.5	265.8	221.4
	<u>3,675.6</u>	<u>3,547.1</u>	<u>6,704.3</u>	<u>6,692.1</u>
Expenses:				
Research and development	1,421.7	1,200.0	2,749.1	2,448.4
Acquired in-process research and development	10.0	23.9	22.3	31.0
Selling, general, and administrative	634.2	758.8	1,267.2	1,447.8
Cost of goods sold	275.6	257.8	541.1	498.2
Cost of collaboration and contract manufacturing	254.6	222.4	453.4	415.8
Other operating expense (income), net	—	14.6	—	29.9
	<u>2,596.1</u>	<u>2,477.5</u>	<u>5,033.1</u>	<u>4,871.1</u>
Income from operations	1,079.5	1,069.6	1,671.2	1,821.0
Other income (expense):				
Other income (expense), net	442.8	573.3	764.8	538.7
Interest expense	(3.6)	(14.8)	(12.3)	(30.9)
	<u>439.2</u>	<u>558.5</u>	<u>752.5</u>	<u>507.8</u>
Income before income taxes	1,518.7	1,628.1	2,423.7	2,328.8
Income tax expense	127.1	195.8	223.4	174.5
Net income	<u>\$ 1,391.6</u>	<u>\$ 1,432.3</u>	<u>\$ 2,200.3</u>	<u>\$ 2,154.3</u>
Net income per share - basic	\$ 13.24	\$ 13.25	\$ 20.78	\$ 19.95
Net income per share - diluted	\$ 12.81	\$ 12.41	\$ 20.02	\$ 18.68
Weighted average shares outstanding - basic	105.1	108.1	105.9	108.0
Weighted average shares outstanding - diluted	108.6	115.4	109.9	115.3

TABLE 3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
GAAP R&D	\$ 1,421.7	\$ 1,200.0	\$ 2,749.1	\$ 2,448.4
Stock-based compensation expense	139.0	122.4	280.0	245.4
Acquisition and integration costs	—	5.3	—	9.1
Non-GAAP R&D	<u>\$ 1,282.7</u>	<u>\$ 1,072.3</u>	<u>\$ 2,469.1</u>	<u>\$ 2,193.9</u>
GAAP SG&A	\$ 634.2	\$ 758.8	\$ 1,267.2	\$ 1,447.8
Stock-based compensation expense	91.8	82.6	187.0	168.8
Acquisition and integration costs	—	9.7	0.8	28.5
Non-GAAP SG&A	<u>\$ 542.4</u>	<u>\$ 666.5</u>	<u>\$ 1,079.4</u>	<u>\$ 1,250.5</u>
GAAP COGS	\$ 275.6	\$ 257.8	\$ 541.1	\$ 498.2
Stock-based compensation expense	20.9	18.2	40.4	39.1
Acquisition and integration costs	—	0.8	—	1.2
Intangible asset amortization expense	32.4	25.1	61.1	48.3
Non-GAAP COGS	<u>\$ 222.3</u>	<u>\$ 213.7</u>	<u>\$ 439.6</u>	<u>\$ 409.6</u>
GAAP other operating expense (income), net	\$ —	\$ 14.6	\$ —	\$ 29.9
Change in fair value of contingent consideration	—	14.6	—	29.9
Non-GAAP other operating expense (income), net	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
GAAP other income (expense), net	\$ 439.2	\$ 558.5	\$ 752.5	\$ 507.8
Gains on investments, net	(250.0)	(392.6)	(389.9)	(196.5)
Non-GAAP other income (expense), net	<u>\$ 189.2</u>	<u>\$ 165.9</u>	<u>\$ 362.6</u>	<u>\$ 311.3</u>
GAAP net income	\$ 1,391.6	\$ 1,432.3	\$ 2,200.3	\$ 2,154.3
Total of GAAP to non-GAAP reconciling items above	34.1	(113.9)	179.4	373.8
Income tax effect of GAAP to non-GAAP reconciling items	(2.1)	32.8	(27.7)	(61.0)
Non-GAAP net income	<u>\$ 1,423.6</u>	<u>\$ 1,351.2</u>	<u>\$ 2,352.0</u>	<u>\$ 2,467.1</u>
Non-GAAP net income per share - basic	\$ 13.55	\$ 12.50	\$ 22.21	\$ 22.84
Non-GAAP net income per share - diluted	\$ 12.89	\$ 11.56	\$ 21.06	\$ 21.09
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	105.1	108.1	105.9	108.0
Non-GAAP net income per share - diluted	110.4	116.9	111.7	117.0

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
<i>Effective tax rate reconciliation:</i>				
GAAP ETR	8.4%	12.0%	9.2%	7.5%
Income tax effect of GAAP to non-GAAP reconciling items	(0.1%)	(1.2%)	0.4%	1.2%
Non-GAAP ETR	8.3%	10.8%	9.6%	8.7%
<i>Gross margin on net product sales reconciliation:</i>				
GAAP gross margin on net product sales	83%	87%	82%	86%
Intangible asset amortization expense	2%	1%	2%	2%
Stock-based compensation expense	1%	1%	2%	1%
Non-GAAP gross margin on net product sales	86%	89%	86%	89%

	Six Months Ended June 30,	
	2025	2024
<i>Free cash flow reconciliation:</i>		
Net cash provided by operating activities	\$ 2,189.5	\$ 1,866.5
Capital expenditures	(448.3)	(314.4)
Free cash flow	\$ 1,741.2	\$ 1,552.1

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
<i>Sanofi collaboration revenue:</i>				
Regeneron's share of profits in connection with commercialization of antibodies	\$ 1,282.1	\$ 988.3	\$ 2,300.2	\$ 1,792.3
Reimbursement for manufacturing of commercial supplies	161.5	157.3	326.6	263.1
Total Sanofi collaboration revenue	<u>1,443.6</u>	<u>1,145.6</u>	<u>2,626.8</u>	<u>2,055.4</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States	383.4	353.0	700.7	686.9
Reimbursement for manufacturing of commercial supplies	31.6	22.1	58.2	44.2
Total Bayer collaboration revenue	<u>415.0</u>	<u>375.1</u>	<u>758.9</u>	<u>731.1</u>
Other collaboration revenue	2.1	3.3	6.2	4.3
Total collaboration revenue	<u>\$ 1,860.7</u>	<u>\$ 1,524.0</u>	<u>\$ 3,391.9</u>	<u>\$ 2,790.8</u>

TABLE 5

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

	Three Months Ended June 30,						% Change (Total Sales)
	2025			2024			
	U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA HD ^(a)	\$ 393.2	\$ 241.7	\$ 634.9	\$ 304.2	\$ 59.1	\$ 363.3	75%
EYLEA ^(a)	\$ 754.3	\$ 736.0	\$ 1,490.3	\$ 1,230.5	\$ 848.7	\$ 2,079.2	(28%)
Total EYLEA HD and EYLEA	\$ 1,147.5	\$ 977.7	\$ 2,125.2	\$ 1,534.7	\$ 907.8	\$ 2,442.5	(13%)
Dupixent ^(b)	\$ 3,205.0	\$ 1,139.6	\$ 4,344.6	\$ 2,610.2	\$ 946.2	\$ 3,556.4	22%
Libtayo ^(c)	\$ 247.8	\$ 128.7	\$ 376.5	\$ 182.4	\$ 115.0	\$ 297.4	27%
Praluent ^(d)	\$ 65.8	\$ 156.2	\$ 222.0	\$ 56.1	\$ 135.8	\$ 191.9	16%
Kevzara ^(b)	\$ 95.7	\$ 56.5	\$ 152.2	\$ 65.1	\$ 44.6	\$ 109.7	39%
Other products ^(e)	\$ 42.1	\$ 30.0	\$ 72.1	\$ 30.9	\$ 21.9	\$ 52.8	37%

	Six Months Ended June 30,						% Change (Total Sales)
	2025			2024			
	U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA HD ^(a)	\$ 700.0	\$ 388.1	\$ 1,088.1	\$ 504.2	\$ 74.3	\$ 578.5	88%
EYLEA ^(a)	\$ 1,490.3	\$ 1,447.4	\$ 2,937.7	\$ 2,432.1	\$ 1,682.9	\$ 4,115.0	(29%)
Total EYLEA HD and EYLEA	\$ 2,190.3	\$ 1,835.5	\$ 4,025.8	\$ 2,936.3	\$ 1,757.2	\$ 4,693.5	(14%)
Dupixent ^(b)	\$ 5,834.4	\$ 2,175.8	\$ 8,010.2	\$ 4,828.2	\$ 1,805.0	\$ 6,633.2	21%
Libtayo ^(c)	\$ 440.3	\$ 221.3	\$ 661.6	\$ 341.6	\$ 219.7	\$ 561.3	18%
Praluent ^(d)	\$ 122.6	\$ 292.7	\$ 415.3	\$ 126.1	\$ 267.1	\$ 393.2	6%
Kevzara ^(b)	\$ 168.5	\$ 100.1	\$ 268.6	\$ 115.1	\$ 88.7	\$ 203.8	32%
Other products ^(e)	\$ 73.2	\$ 53.5	\$ 126.7	\$ 56.2	\$ 40.8	\$ 97.0	31%

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 "Second Quarter 2025 Financial Results" section above for a complete 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.