

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): April 29, 2025 (April 29, 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 April 29, 2025, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 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 April 29, 2025, Reporting First 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: April 29, 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 First Quarter 2025 Financial and Operating Results

- First quarter 2025 revenues of \$3.0 billion; GAAP diluted EPS of \$7.27 and non-GAAP diluted EPS^(a) of \$8.22
- First quarter 2025 Dupixent® global net sales (recorded by Sanofi) increased 19% to \$3.67 billion versus first quarter 2024
- First quarter 2025 EYLEA HD® U.S. net sales increased 54% to \$307 million versus first quarter 2024; total EYLEA HD and EYLEA® U.S. net sales decreased 26% to \$1.04 billion
- Dupixent approved for chronic spontaneous urticaria (CSU) in U.S.; approved for chronic obstructive pulmonary disease (COPD) in Japan
- FDA accepted for priority review EYLEA HD sBLA for both retinal vein occlusion (RVO) and for monthly dosing in approved indications; update provided on FDA review of EYLEA HD pre-filled syringe submission
- Lynozyfic™ (linvoseltamab) approved in EU for relapsed/refractory multiple myeloma
- Regulatory applications submitted for Libtayo® in adjuvant cutaneous squamous cell carcinoma (CSCC) in U.S. and EU
- Announced ongoing and planned investments in New York and North Carolina infrastructure and manufacturing expected to total more than \$7 billion

Tarrytown, New York (April 29, 2025) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2025 and provided a business update.

"Regeneron has one of the most exciting pipelines in the industry, with unmatched diversity, scientific distinction, and potential to help millions of patients," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "We are laser focused on fulfilling the promise of this pipeline by advancing our clinical programs, and expect several important data readouts this year. We are also working to ensure our four blockbuster medicines reach even more patients who could benefit, with year-to-date progress including regulatory approvals for Dupixent in CSU in the U.S. and COPD in Japan."

Financial Highlights

(\$ in millions, except per share data)

	Q1 2025	Q1 2024	% Change
Total revenues	\$ 3,029	\$ 3,145	(4 %)
GAAP net income	\$ 809	\$ 722	12 %
GAAP net income per share - diluted	\$ 7.27	\$ 6.27	16 %
Non-GAAP net income ^(a)	\$ 928	\$ 1,116	(17 %)
Non-GAAP net income per share - diluted ^(a)	\$ 8.22	\$ 9.55	(14 %)

"We have made meaningful progress across our pipeline so far in 2025, including four regulatory approvals, nine regulatory submissions, and are poised to report pivotal or proof-of-concept data across programs in immunology, oncology, hematology, internal medicine, and rare diseases later this year," said Christopher Fenimore, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We continue to deploy capital with the goal of maximizing long-term shareholder value, with a focus on internal investment in our research, development, and commercial capabilities, along with returning capital directly to our shareholders through opportunistic share repurchases and our dividend program, which we initiated earlier this year."

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 April 2025, the U.S. Food and Drug Administration (FDA) approved Dupixent for the treatment of adults and adolescents aged 12 years and older with CSU who remain symptomatic despite antihistamine treatment.
- In March 2025, Japan's Ministry of Health, Labour and Welfare (MHLW) approved Dupixent for the treatment of patients with COPD.
- The Company and Sanofi presented positive results from the pivotal Phase 2/3 trial in adults with moderate-to-severe bullous pemphigoid at the 2025 American Academy of Dermatology (AAD) Annual Meeting. In February 2025, the FDA accepted for priority review the supplemental Biologics License Application (sBLA) for Dupixent in bullous pemphigoid, with a target action date of June 20, 2025. A regulatory application has also been submitted in the European Union (EU).

EYLEA HD (aflibercept) 8 mg

- In April 2025, the FDA accepted for priority review an sBLA for both the treatment of macular edema following RVO, and broadening the dosing schedule to include every 4-week (monthly) dosing across approved indications. The FDA target action date is August 19, 2025, following the use of a priority review voucher.
- The FDA issued a Complete Response Letter (CRL) for the EYLEA HD pre-filled syringe on April 23, 2025. The Company held several teleconferences with the FDA to better understand the contents of the CRL, and believes the key outstanding issue relates to a question posed by the FDA to a third-party component supplier. This component supplier has expeditiously responded to FDA requests for information. The CRL did not identify any issues with the safety or efficacy of EYLEA HD, the usability of the device, proposed labelling, or pre-approval inspection findings.
- In April 2025, the FDA issued a CRL regarding the sBLA for the addition of extended dosing intervals. The FDA indicated that the submitted data did not support extended dosing intervals greater than every 16 weeks. The Company is evaluating the FDA's decision.
- The Company presented positive results from the Phase 3 QUASAR trial for the treatment of patients with macular edema following RVO, including those with central, branch, and hemiretinal vein occlusions, at the Angiogenesis, Exudation, and Degeneration (Angiogenesis) 2025 annual meeting.
- The Company announced positive three-year (156-week) results from an extension study of the Phase 3 PULSAR trial in patients with wet age-related macular degeneration (wAMD). Similar to the three-year results for the pivotal PHOTON trial in diabetic macular edema

(DME), the longer-term wAMD data demonstrated the vast majority of patients who entered the extension study sustained the visual gains and anatomic improvements achieved by the end of the second year, while also achieving substantially longer treatment intervals. The results were presented at the Angiogenesis 2025 annual meeting.

Oncology Programs

- The Company submitted an sBLA to the FDA and a regulatory application in the EU for Libtayo (cemiplimab) in adjuvant CSCC based upon data from a Phase 3 trial which demonstrated that adjuvant treatment with Libtayo was the first and only immunotherapy that led to a statistically significant and clinically meaningful improvement in the primary endpoint of disease-free survival (DFS) in patients with high-risk CSCC after surgery.
- The FDA accepted for review the resubmission of the BLA for odronextamab, a bispecific antibody targeting CD20 and CD3, in relapsed/refractory (R/R) follicular lymphoma, with a target action date of July 30, 2025.
- The FDA accepted for review the resubmission of the BLA for linvoseltamab, a bispecific antibody targeting BCMA and CD3, in R/R multiple myeloma, with a target action date of July 10, 2025.
- The European Commission (EC) granted conditional marketing approval of Lynozyfic (linvoseltamab) to treat adults with R/R multiple myeloma. The indication is specific to those who have received at least three prior therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and have demonstrated disease progression on the last therapy.
- Enrollment was completed in a Phase 3 confirmatory trial (LINKER-MM3) for linvoseltamab in R/R multiple myeloma.

Other Programs

- The Company presented updated data from the Phase 1/2 trial of DB-OTO, an AAV-based gene therapy, in children with profound genetic hearing loss due to variants of the otoferlin (OTOF) gene at the Association for Research in Otolaryngology's (ARO) 48th Annual MidWinter Meeting. The data showed that 11 out of 12 children treated demonstrated a notable response, with improved hearing at various decibel hearing levels. This included updated results from the first child dosed, who received treatment at 10 months of age and at 48 weeks post-treatment showed continued near-normal levels of hearing, as well as formal speech perception improvements between 48- and 72-weeks post-treatment.
- A Phase 3 study for itepekimab, an antibody to IL-33, in chronic rhinosinusitis with nasal polyposis (CRSwNP) was initiated.
- A Phase 2 study for REGN5381, an agonist antibody to NPR1, in uncontrolled hypertension was initiated.
- A Phase 2 study for REGN7544, an antagonist antibody to NPR1, in sepsis-induced hypotension was initiated.
- The FDA granted Orphan Drug designation for mibavademab, an agonist antibody to leptin receptor (LEPR), in generalized lipodystrophy; a Phase 3 study is ongoing.

Corporate Updates

- The Company reached resolution of its patent infringement litigation related to Biocon's EYLEA (aflibercept) Injection 2 mg biosimilar product. The settlement precludes Biocon from launching its biosimilar product in the United States until the second half of 2026. All intellectual property-related litigation with Biocon in the United States has been dismissed.
- The Company announced a 10-year agreement with FUJIFILM Diosynth Biotechnologies (Fujifilm) to manufacture and supply Regeneron's commercial bulk drug product at Fujifilm's

North Carolina campus. The agreement is anticipated to nearly double the Company's large-scale manufacturing capacity in the United States.

First Quarter 2025 Financial Results

Revenues

<i>(\$ in millions)</i>	Q1 2025	Q1 2024	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 307	\$ 200	54 %
EYLEA - U.S.	736	1,202	(39 %)
Total EYLEA HD and EYLEA - U.S.	1,043	1,402	(26 %)
Libtayo - U.S.	192	159	21 %
Libtayo - ROW**	93	105	(11 %)
Total Libtayo - Global	285	264	8 %
Praluent® - U.S.	57	70	(19 %)
Evkeeza® - U.S.	31	24	29 %
Inmazoleb® - ROW	—	1	(100 %)
Total net product sales	1,416	1,761	(20 %)
Collaboration revenue:			
Sanofi	1,183	910	30 %
Bayer	344	356	(3 %)
Other	4	1	*
Other revenue	82	117	(30 %)
Total revenues	\$ 3,029	\$ 3,145	(4 %)

* Percentage not meaningful

** Rest of world (ROW)

Net product sales of EYLEA HD increased in the first quarter of 2025, compared to the first quarter of 2024, primarily due to higher sales volumes.

Net product sales of EYLEA in the first quarter of 2025, compared to the first quarter of 2024, were negatively impacted by (i) lower volume as a result of continued competitive pressures (as described below), 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.

In addition, total EYLEA and EYLEA HD net product sales were negatively impacted by lower wholesaler inventory levels at the end of the first quarter of 2025 compared to the end of the fourth quarter of 2024. Total EYLEA and EYLEA HD net product sales decreased 30% on a sequential basis; however, physician unit demand decreased sequentially by 11%.

EYLEA net product sales have been, and are likely to continue to be, negatively impacted by increased competition from other anti-VEGF products, including biosimilars, as well as the transition of patients from EYLEA to EYLEA HD. In addition, if independent not-for-profit patient assistance funds that provide copay assistance are unable to support eligible patients, this will likely have a continued negative impact on patient affordability resulting in lower utilization of higher-cost anti-VEGF agents.

Sanofi collaboration revenue increased in the first quarter of 2025, compared to the first quarter of 2024, due to an increase in the Company's share of profits from the commercialization of antibodies, which were \$1.018 billion and \$804 million in the first 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.

Operating Expenses

(\$ in millions)	GAAP			Non-GAAP ^(a)		
	Q1 2025	Q1 2024	% Change	Q1 2025	Q1 2024	% Change
Research and development (R&D)	\$ 1,327	\$ 1,248	6 %	\$ 1,186	\$ 1,122	6 %
Acquired in-process research and development (IPR&D)	\$ 12	\$ 7	71 %	*	*	n/a
Selling, general, and administrative (SG&A)	\$ 633	\$ 689	(8 %)	\$ 537	\$ 584	(8 %)
Cost of goods sold (COGS)	\$ 266	\$ 240	11 %	\$ 217	\$ 196	11 %
Gross margin on net product sales ^(c)	81%	86%		85%	89%	
Cost of collaboration and contract manufacturing (COCM)	\$ 199	\$ 193	3 %	*	*	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 first quarter of 2025, compared to the first quarter of 2024, driven by the advancement of the Company's clinical pipeline and higher personnel-related costs.
- GAAP and non-GAAP gross margin on net product sales was adversely impacted by higher inventory write-offs and reserves in the first quarter of 2025 compared to the first quarter of 2024.

Other Financial Information

GAAP other income (expense), net included the recognition of net unrealized gains on equity securities of \$140 million in the first quarter of 2025, compared to \$196 million of net unrealized losses in the first quarter of 2024.

In the first quarter of 2025, the Company's GAAP effective tax rate (ETR) was 10.6%, compared to (3.0%) in the first quarter of 2024. The GAAP ETR increased in the first quarter of 2025, compared to the first quarter of 2024, due to lower tax benefits from less stock option exercises. In the first quarter of 2025, the non-GAAP ETR was 11.6%, compared to 6.1% in the first 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

In February 2025, the Company's board of directors authorized a new share repurchase program to repurchase up to an additional \$3.0 billion of the Company's common stock. During the first quarter of 2025, the Company repurchased shares of its common stock and recorded the cost of the shares, or \$1.052 billion, as Treasury Stock. As of March 31, 2025, an aggregate

of \$3.874 billion remained available for share repurchases under the Company's share repurchase programs.

In April 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 June 6, 2025 to shareholders of record as of May 20, 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	Unchanged
Non-GAAP R&D ^(a)	\$5.000–\$5.200 billion	Unchanged
GAAP SG&A	\$2.910–\$3.095 billion	Unchanged
Non-GAAP SG&A ^(a)	\$2.550–\$2.700 billion	Unchanged
GAAP gross margin on net product sales	84%–85%	83%–84%
Non-GAAP gross margin on net product sales ^(a)	87%–88%	86%–87%
COCM ^{(d)*}	\$1.000–\$1.150 billion	Unchanged
Capital expenditures*	\$850–\$975 million	\$850–\$950 million
GAAP effective tax rate	9%–11%	Unchanged
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	\$ 5,560	\$ 5,795
Stock-based compensation expense	560	590
Acquisition and integration costs	—	5
Non-GAAP R&D	\$ 5,000	\$ 5,200
GAAP SG&A	\$ 2,910	\$ 3,095
Stock-based compensation expense	360	390
Acquisition and integration costs	—	5
Non-GAAP SG&A	\$ 2,550	\$ 2,700
GAAP gross margin on net product sales	83%	84%
Intangible asset amortization expense	2%	2%
Stock-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	86%	87%
GAAP ETR	9%	11%
Income tax effect of GAAP to non-GAAP reconciling items	2%	2%
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 first quarter 2025 financial and operating results on Tuesday, April 29, 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), itepekimab, fianlimab, garetosmab, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), REGN5713-5715, nexiguran ziclumeran (nex-z, NTLA-2001), REGN1908-1909, mibavademab, 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 March 31, 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)

	March 31, 2025	December 31, 2024
Assets:		
Cash and marketable securities	\$ 17,625.7	\$ 17,912.6
Accounts receivable, net	5,561.0	6,211.9
Inventories	3,192.4	3,087.3
Property, plant, and equipment, net	4,694.2	4,599.7
Intangible assets, net	1,167.0	1,148.6
Deferred tax assets	3,442.9	3,314.1
Other assets	1,862.0	1,485.2
Total assets	\$ 37,545.2	\$ 37,759.4
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 4,621.7	\$ 4,888.0
Finance lease liabilities	720.0	720.0
Deferred revenue	831.1	813.4
Long-term debt	1,984.8	1,984.4
Stockholders' equity	29,387.6	29,353.6
Total liabilities and stockholders' equity	\$ 37,545.2	\$ 37,759.4

TABLE 2

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

	Three Months Ended March 31,	
	2025	2024
Revenues:		
Net product sales	\$ 1,415.6	\$ 1,761.3
Collaboration revenue	1,531.2	1,266.8
Other revenue	81.9	116.9
	<u>3,028.7</u>	<u>3,145.0</u>
Expenses:		
Research and development	1,327.4	1,248.4
Acquired in-process research and development	12.3	7.1
Selling, general, and administrative	633.0	689.0
Cost of goods sold	265.5	240.4
Cost of collaboration and contract manufacturing	198.8	193.4
Other operating expense (income), net	—	15.3
	<u>2,437.0</u>	<u>2,393.6</u>
Income from operations	591.7	751.4
Other income (expense):		
Other income (expense), net	322.0	(34.6)
Interest expense	(8.7)	(16.1)
	<u>313.3</u>	<u>(50.7)</u>
Income before income taxes	905.0	700.7
Income tax expense (benefit)	96.3	(21.3)
Net income	\$ 808.7	\$ 722.0
Net income per share - basic	\$ 7.58	\$ 6.70
Net income per share - diluted	\$ 7.27	\$ 6.27
Weighted average shares outstanding - basic	106.7	107.8
Weighted average shares outstanding - diluted	111.2	115.1

TABLE 3

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

	Three Months Ended March 31,	
	2025	2024
GAAP R&D	\$ 1,327.4	\$ 1,248.4
Stock-based compensation expense	141.0	123.0
Acquisition and integration costs	—	3.8
Non-GAAP R&D	<u>\$ 1,186.4</u>	<u>\$ 1,121.6</u>
GAAP SG&A	\$ 633.0	\$ 689.0
Stock-based compensation expense	95.2	86.2
Acquisition and integration costs	0.8	18.8
Non-GAAP SG&A	<u>\$ 537.0</u>	<u>\$ 584.0</u>
GAAP COGS	\$ 265.5	\$ 240.4
Stock-based compensation expense	19.5	20.9
Acquisition and integration costs	—	0.4
Intangible asset amortization expense	28.7	23.2
Non-GAAP COGS	<u>\$ 217.3</u>	<u>\$ 195.9</u>
GAAP other operating expense (income), net	\$ —	\$ 15.3
Change in fair value of contingent consideration	—	15.3
Non-GAAP other operating expense (income), net	<u>\$ —</u>	<u>\$ —</u>
GAAP other income (expense), net	\$ 313.3	\$ (50.7)
(Gains) losses on investments, net	(139.9)	196.1
Non-GAAP other income (expense), net	<u>\$ 173.4</u>	<u>\$ 145.4</u>
GAAP net income	\$ 808.7	\$ 722.0
Total of GAAP to non-GAAP reconciling items above	145.3	487.7
Income tax effect of GAAP to non-GAAP reconciling items	(25.6)	(93.8)
Non-GAAP net income	<u>\$ 928.4</u>	<u>\$ 1,115.9</u>
Non-GAAP net income per share - basic	\$ 8.70	\$ 10.35
Non-GAAP net income per share - diluted	\$ 8.22	\$ 9.55
<i>Shares used in calculating:</i>		
Non-GAAP net income per share - basic	106.7	107.8
Non-GAAP net income per share - diluted	113.0	116.8

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

	Three Months Ended March 31,	
	2025	2024
<i>Effective tax rate reconciliation:</i>		
GAAP ETR	10.6%	(3.0%)
Income tax effect of GAAP to non-GAAP reconciling items	1.0%	9.1%
Non-GAAP ETR	11.6%	6.1%
<i>Gross margin on net product sales reconciliation:</i>		
GAAP gross margin on net product sales	81%	86%
Intangible asset amortization expense	2%	2%
Stock-based compensation expense	2%	1%
Non-GAAP gross margin on net product sales	85%	89%
<i>Free cash flow reconciliation:</i>		
Net cash provided by operating activities	\$ 1,045.1	\$ 1,512.5
Capital expenditures	(229.3)	(133.9)
Free cash flow	\$ 815.8	\$ 1,378.6

TABLE 4

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

	Three Months Ended March 31,	
	2025	2024
<i>Sanofi collaboration revenue:</i>		
Regeneron's share of profits in connection with commercialization of antibodies	\$ 1,018.2	\$ 804.0
Reimbursement for manufacturing of commercial supplies	165.0	105.8
Total Sanofi collaboration revenue	1,183.2	909.8
<i>Bayer collaboration revenue:</i>		
Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States	317.3	333.9
Reimbursement for manufacturing of commercial supplies	26.6	22.1
Total Bayer collaboration revenue	343.9	356.0
Other collaboration revenue	4.1	1.0
Total collaboration revenue	\$ 1,531.2	\$ 1,266.8

TABLE 5

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

	Three Months Ended March 31,						% Change (Total Sales)
	2025			2024			
	U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA HD ^(a)	\$ 306.8	\$ 146.4	\$ 453.2	\$ 200.0	\$ 15.2	\$ 215.2	111 %
EYLEA ^(a)	\$ 736.0	\$ 711.4	\$ 1,447.4	\$ 1,201.6	\$ 834.2	\$ 2,035.8	(29 %)
Total EYLEA HD and EYLEA	\$ 1,042.8	\$ 857.8	\$ 1,900.6	\$ 1,401.6	\$ 849.4	\$ 2,251.0	(16 %)
Dupixent ^(b)	\$ 2,629.4	\$ 1,036.2	\$ 3,665.6	\$ 2,218.0	\$ 858.8	\$ 3,076.8	19 %
Libtayo ^(c)	\$ 192.5	\$ 92.6	\$ 285.1	\$ 159.2	\$ 104.7	\$ 263.9	8 %
Praluent ^(d)	\$ 56.8	\$ 136.5	\$ 193.3	\$ 70.0	\$ 131.3	\$ 201.3	(4 %)
Kevzara ^(b)	\$ 72.8	\$ 43.6	\$ 116.4	\$ 50.0	\$ 44.1	\$ 94.1	24 %
Other products ^(e)	\$ 31.1	\$ 23.5	\$ 54.6	\$ 25.3	\$ 18.9	\$ 44.2	24 %

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 "First 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.