

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, 2024 (August 1, 2024)

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, 2024, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 30, 2024. 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, 2024, Reporting Second Quarter 2024 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, 2024

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 2024 Financial and Operating Results

- Second quarter 2024 revenues increased 12% to \$3.55 billion versus second quarter 2023
- Second quarter 2024 Dupixent® global net sales (recorded by Sanofi) increased 27% to \$3.56 billion versus second quarter 2023
- Second quarter 2024 U.S. net sales for EYLEA® HD and EYLEA® increased 2% to \$1.53 billion versus second quarter 2023, including \$304 million from EYLEA HD
- Second quarter 2024 Libtayo® global net sales increased 42% to \$297 million versus second quarter 2023
- Second quarter 2024 GAAP diluted EPS increased 46% to \$12.41 and non-GAAP diluted EPS^(a) increased 13% to \$11.56 versus second quarter 2023; second quarter 2024 includes unfavorable \$0.18 impact from acquired IPR&D charge
- European Commission approved Dupixent as first-ever biologic therapy for uncontrolled chronic obstructive pulmonary disease (COPD) characterized by raised blood eosinophils

Tarrytown, New York (August 1, 2024) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2024 and provided a business update.

"Regeneron had a strong quarter, with total revenue up 12% driven by notable growth for EYLEA HD, Dupixent, and Libtayo," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "Importantly, Dupixent was granted its first regulatory approval for COPD by the European Commission, with FDA action anticipated in the third quarter, presenting an opportunity to help even more patients around the globe. As always, we remain focused on driving forward our diverse clinical pipeline, progressing late-stage trials for Dupixent in chronic spontaneous urticaria and other dermatologic indications; itepekimab, our IL-33 antibody in COPD; fianlimab, our LAG-3 antibody in metastatic melanoma; and Libtayo in adjuvant cutaneous squamous cell carcinoma. Finally, we were excited to advance several promising earlier-stage programs, including various antibody and GLP-1 combinations for obesity and our gene therapy DB-OTO for genetic hearing loss."

Financial Highlights

(\$ in millions, except per share data)

	Q2 2024	Q2 2023	% Change
Total revenues	\$ 3,547	\$ 3,158	12 %
GAAP net income	\$ 1,432	\$ 968	48 %
GAAP net income per share - diluted	\$ 12.41	\$ 8.50	46 %
Non-GAAP net income ^(a)	\$ 1,351	\$ 1,182	14 %
Non-GAAP net income per share - diluted ^(a)	\$ 11.56	\$ 10.24	13 %

"Our second quarter financial performance reflects continued strong momentum across our business, highlighted by double-digit revenue and earnings growth," said Christopher Fenimore, Senior Vice President, Finance and Chief Financial Officer of Regeneron. "In the second half of the year, we look forward to advancing our pipeline with several important clinical data readouts as well as continued commercial execution and prudent capital deployment to drive long-term value creation."

Business Highlights

Key Pipeline Progress

Regeneron has over 35 product candidates in clinical development, including a number of marketed products for which it is investigating additional indications. Updates from the clinical pipeline include:

EYLEA HD (afibercept) 8 mg

- In June 2024, a supplemental Biologics License Application (sBLA) with two-year data for wet age-related macular degeneration (wAMD) and diabetic macular edema (DME) was submitted to the U.S. Food and Drug Administration (FDA).

Dupixent (dupilumab)

- In May 2024, after requesting additional efficacy analyses, the FDA extended by three months the target action date of its priority review of the sBLA for Dupixent as an add-on maintenance treatment in certain adult patients with uncontrolled COPD, with a revised target action date of September 27, 2024. Regeneron and Sanofi remain confident that the additional analyses strongly support the approval of Dupixent in COPD with evidence of type 2 inflammation, and are committed to working with the FDA to bring Dupixent to patients living with uncontrolled COPD as quickly as possible.
- In June 2024, the European Commission (EC) approved Dupixent as an add-on maintenance treatment for adults with uncontrolled COPD characterized by raised blood eosinophils. The EC is the first regulatory authority in the world to have approved Dupixent for COPD patients. Additional submissions are under review with other regulatory authorities outside the United States, including in China and Japan.
- The Company and Sanofi presented at the 2024 American Thoracic Society International Conference positive data from the NOTUS Phase 3 trial evaluating Dupixent as an add-on maintenance treatment in adults with uncontrolled COPD on maximal standard-of-care inhaled therapy (nearly all on triple therapy) and evidence of type 2 inflammation. The NOTUS trial confirmed the positive results demonstrated in the Phase 3 BOREAS trial. The data from the NOTUS trial were also published in the *New England Journal of Medicine (NEJM)*.
- The FDA accepted for priority review the sBLA for Dupixent as an add-on maintenance treatment for adolescents aged 12 to 17 years with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP), with a target action date of September 15, 2024.
- The *NEJM* published results from a positive Phase 3 trial for Dupixent in children aged 1 to 11 years with eosinophilic esophagitis (EoE). The trial showed a greater proportion of those receiving weight-tiered higher dose Dupixent experienced significant improvements in many key disease measures of EoE, compared to placebo at week 16.

Oncology Programs

- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending conditional marketing authorization of

odronextamab, a bispecific antibody targeting CD20 and CD3, to treat adults with relapsed/refractory (R/R) follicular lymphoma (FL) or R/R diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy. The EC is expected to announce a final decision in the coming months.

- In June 2024, the 14-month median follow-up data from the pivotal Phase 1/2 trial of linvoseltamab, a bispecific antibody targeting BCMA and CD3, in patients with R/R multiple myeloma were presented at the European Hematology Association (EHA) Congress 2024 and published in the *Journal of Clinical Oncology*. These longer-term results show a deepening of responses following the 11-month median follow-up data previously presented in April 2024.
- A Phase 2 study for fianlimab, an antibody to LAG-3, in combination with Libtayo (cemiplimab) for perioperative non-small cell lung cancer (NSCLC) was initiated. A Phase 2/3 study for fianlimab, in combination with Libtayo, for perioperative melanoma was also initiated.
- The Company announced positive updated results from an ongoing Phase 1/2 trial evaluating REGN7075, a costimulatory bispecific antibody targeting EGFR and CD28, in combination with Libtayo in patients with advanced solid tumors. Data from the dose-escalation portion of the trial showed the investigational combination led to anti-tumor responses in certain patients with microsatellite stable colorectal cancer. The results were shared during an oral presentation at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting.

Other Programs

- In June 2024, the FDA approved Kevzara® (sarilumab) for the treatment of patients weighing 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA), a form of arthritis that impacts multiple joints at a time.
- A Phase 2 study in obesity was initiated for trevogrumab, an antibody to myostatin (GDF8), in combination with semaglutide with and without garetosmab, an antibody to Activin A.
- A Phase 2 study for REGN7508, an antibody to Factor XI, was initiated in patients with thrombosis.
- The Company presented updated data from the Phase 1/2 trial of DB-OTO, an AAV-based gene therapy, at the American Society of Gene and Cell Therapy (ASGCT) annual conference and announced that DB-OTO improved hearing to normal levels in one child and that initial hearing improvements were observed in a second child. In addition, the FDA recently granted DB-OTO Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of congenital auditory neuropathy secondary to biallelic mutations of the otoferlin gene.

Second Quarter 2024 Financial Results

Revenues

<i>(\$ in millions)</i>	Q2 2024	Q2 2023	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 304	\$ —	*
EYLEA - U.S.	1,231	1,500	(18 %)
Total EYLEA HD and EYLEA - U.S.	1,535	1,500	2 %
Libtayo - Global	297	210	41 %
Praluent - U.S.	56	41	37 %
Evkeeza® - U.S.	31	19	63 %
Inmazed® - Global	—	2	(100 %)
Total net product sales	1,919	1,772	8 %
Collaboration revenue:			
Sanofi	1,146	944	21 %
Bayer	375	377	(1 %)
Other	3	(4)	*
Other revenue	104	69	51 %
Total revenues	\$ 3,547	\$ 3,158	12 %

* Percentage not meaningful

Total EYLEA HD and EYLEA net product sales in the U.S. increased 2% in the second quarter of 2024 compared to the second quarter of 2023. EYLEA HD was approved by the FDA in August 2023 and EYLEA HD net product sales in the second quarter of 2024 were driven by the transition of patients from other anti-VEGF products, including EYLEA, to EYLEA HD, as well as new patients naïve to anti-VEGF therapy. Net product sales of EYLEA decreased in the second quarter of 2024, compared to the second quarter of 2023, primarily due to (i) the aforementioned approval and transition of certain patients to EYLEA HD, and (ii) other market dynamics that resulted in lower volumes and a lower net selling price.

Sanofi collaboration revenue increased in the second quarter of 2024, compared to the second quarter of 2023, due to the Company's share of profits from commercialization of antibodies, which were \$988 million in the second quarter of 2024, compared to \$751 million in the second quarter of 2023. 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)		
	Q2 2024	Q2 2023	% Change	Q2 2024	Q2 2023	% Change
Research and development (R&D)	\$ 1,200	\$ 1,085	11 %	\$ 1,072	\$ 974	10 %
Acquired in-process research and development (IPR&D)	\$ 24	\$ —	**	*	*	n/a
Selling, general, and administrative (SG&A)	\$ 759	\$ 652	16 %	\$ 667	\$ 562	19 %
Cost of goods sold (COGS)	\$ 258	\$ 192	34 %	\$ 214	\$ 163	31 %
Cost of collaboration and contract manufacturing (COCM)	\$ 222	\$ 213	4 %	*	*	n/a
Other operating expense (income), net	\$ 15	\$ (1)	**	\$ —	*	**

* 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 second quarter of 2024, compared to the second quarter of 2023, driven by the advancement of the Company's late-stage oncology programs, and higher headcount and headcount-related costs.
- Acquired IPR&D for the second quarter of 2024 included up-front payments, as well as a premium on equity securities purchased, in connection with collaboration and licensing agreements.
- GAAP and non-GAAP SG&A expenses increased in the second quarter of 2024, compared to the second quarter of 2023, due to higher commercialization-related expenses to support the Company's launch of EYLEA HD and higher headcount and headcount-related costs partly related to the Company's international commercial expansion.
- GAAP and non-GAAP COGS increased in the second quarter of 2024, compared to the second quarter of 2023, primarily due to higher start-up costs for the Company's Rensselaer, New York fill/finish facility.
- GAAP other operating expense (income), net, for the second quarter of 2024 reflects a charge related to the increase in the estimated fair value of the contingent consideration liability recognized in connection with the Company's 2023 acquisition of Decibel Therapeutics, Inc.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized gains on equity securities of \$393 million in the second quarter of 2024, compared to \$31 million of net unrealized losses in the second quarter of 2023. GAAP and Non-GAAP other income (expense) also included interest income of \$179 million in the second quarter of 2024, compared to \$118 million in the second quarter of 2023.

In the second quarter of 2024, the Company's GAAP effective tax rate (ETR) was 12.0%, compared to 10.6% in the second quarter of 2023. The GAAP ETR increased in the second quarter of 2024, compared to the second quarter of 2023, due to the remeasurement of existing uncertain tax positions, offset by a higher benefit from stock-based compensation. In the second quarter of 2024, the non-GAAP ETR was 10.8%, compared to 12.2% in the second quarter of 2023.

GAAP net income per diluted share was \$12.41 in the second quarter of 2024, compared to \$8.50 in the second quarter of 2023. Non-GAAP net income per diluted share was \$11.56 in the second quarter of 2024, compared to \$10.24 in the second quarter of 2023. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

In April 2024, 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 second quarter of 2024, the Company repurchased shares of its common stock and recorded the cost of the shares, or \$601 million, as Treasury Stock. As of June 30, 2024, an aggregate of \$3.6 billion remained available for share repurchases under the Company's share repurchase programs.

2024 Financial Guidance^(c)

The Company's full year 2024 financial guidance consists of the following components:

	2024 Guidance	
	Prior	Updated
GAAP R&D	\$4.920–\$5.170 billion	\$5.020–\$5.170 billion
Non-GAAP R&D ^(a)	\$4.400–\$4.600 billion	\$4.500–\$4.600 billion
GAAP SG&A	\$2.940–\$3.090 billion	\$2.920–\$3.060 billion
Non-GAAP SG&A ^(a)	\$2.550–\$2.650 billion	Unchanged
GAAP gross margin on net product sales ^(d)	86%–88%	Approximately 86%
Non-GAAP gross margin on net product sales ^{(a)(d)}	89%–91%	Approximately 89%
COCM ^{(e)*}	\$850–\$910 million	Unchanged
Capital expenditures*	\$780–\$880 million	\$750–\$820 million
GAAP effective tax rate	7%–9%	8%–9%
Non-GAAP effective tax rate ^(a)	10%–12%	10%–11%

* 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 2024 GAAP to non-GAAP financial guidance is included below:

(\$ in millions)	Projected Range	
	Low	High
GAAP R&D	\$ 5,020	\$ 5,170
Stock-based compensation expense	510	540
Acquisition and integration costs	10	30
Non-GAAP R&D	\$ 4,500	\$ 4,600
GAAP SG&A	\$ 2,920	\$ 3,060
Stock-based compensation expense	330	350
Acquisition and integration costs	40	60
Non-GAAP SG&A	\$ 2,550	\$ 2,650
GAAP gross margin on net product sales	Approximately 86%	Approximately 86%
Stock-based compensation expense	1%	1%
Intangible asset amortization expense	1%	1%
Acquisition and integration costs	<1%	<1%
Non-GAAP gross margin on net product sales	Approximately 89%	Approximately 89%
GAAP ETR	8%	9%
Income tax effect of GAAP to non-GAAP reconciling items	2%	2%
Non-GAAP ETR	10%	11%

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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, total revenues excluding Ronapreve™^(b), 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 flows, 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, such non-GAAP measures 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 casirivimab and imdevimab antibody cocktail for COVID-19 is known as REGEN-COV in the United States and Ronapreve in other countries. Roche records net product sales of Ronapreve outside the United States.
- (c) The Company's 2024 financial guidance does not assume the completion of any business development transactions not completed as of the date of this press release.
- (d) 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.
- (e) Corresponding reimbursements from collaborators and others for manufacturing of commercial supplies 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 2024 financial and operating results on Thursday, August 1, 2024, 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 Pharmaceuticals, Inc.

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, the nature, timing, and possible success and therapeutic applications of 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") 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), odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, NTLA-2001, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), 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; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; 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 of Regeneron's Products from third-party payers, including private payer 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 payers and new policies and procedures adopted by such payers; 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 (such as the COVID-19 pandemic) on Regeneron's business; and 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), other 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), 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, 2023 and its Form 10-Q for the quarterly period ended June 30, 2024. 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, 2024	December 31, 2023
Assets:		
Cash and marketable securities	\$ 17,531.4	\$ 16,241.3
Accounts receivable, net	5,717.1	5,667.3
Inventories	2,873.6	2,580.5
Property, plant, and equipment, net	4,305.9	4,146.4
Intangible assets, net	1,102.2	1,038.6
Deferred tax assets	2,880.9	2,575.4
Other assets	1,675.7	830.7
Total assets	\$ 36,086.8	\$ 33,080.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 4,385.8	\$ 3,818.6
Finance lease liabilities	720.0	720.0
Deferred revenue	791.6	585.6
Long-term debt	1,983.6	1,982.9
Stockholders' equity	28,205.8	25,973.1
Total liabilities and stockholders' equity	\$ 36,086.8	\$ 33,080.2

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,	
	2024	2023	2024	2023
Revenues:				
Net product sales	\$ 1,918.6	\$ 1,772.1	\$ 3,679.9	\$ 3,440.1
Collaboration revenue	1,524.0	1,316.7	2,790.8	2,694.8
Other revenue	104.5	69.3	221.4	185.3
	<u>3,547.1</u>	<u>3,158.1</u>	<u>6,692.1</u>	<u>6,320.2</u>
Expenses:				
Research and development	1,200.0	1,085.3	2,448.4	2,186.5
Acquired in-process research and development	23.9	—	31.0	56.1
Selling, general, and administrative	758.8	652.0	1,447.8	1,253.1
Cost of goods sold	257.8	192.4	498.2	400.8
Cost of collaboration and contract manufacturing	222.4	212.5	415.8	461.6
Other operating expense (income), net	14.6	(0.6)	29.9	(1.1)
	<u>2,477.5</u>	<u>2,141.6</u>	<u>4,871.1</u>	<u>4,357.0</u>
Income from operations	1,069.6	1,016.5	1,821.0	1,963.2
Other income (expense):				
Other income (expense), net	573.3	85.3	538.7	14.6
Interest expense	(14.8)	(18.9)	(30.9)	(36.9)
	<u>558.5</u>	<u>66.4</u>	<u>507.8</u>	<u>(22.3)</u>
Income before income taxes	1,628.1	1,082.9	2,328.8	1,940.9
Income tax expense	195.8	114.5	174.5	154.7
Net income	<u>\$ 1,432.3</u>	<u>\$ 968.4</u>	<u>\$ 2,154.3</u>	<u>\$ 1,786.2</u>
Net income per share - basic	\$ 13.25	\$ 9.05	\$ 19.95	\$ 16.69
Net income per share - diluted	\$ 12.41	\$ 8.50	\$ 18.68	\$ 15.68
Weighted average shares outstanding - basic	108.1	107.0	108.0	107.0
Weighted average shares outstanding - diluted	115.4	113.9	115.3	113.9

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,	
	2024	2023	2024	2023
GAAP R&D	\$ 1,200.0	\$ 1,085.3	\$ 2,448.4	\$ 2,186.5
Stock-based compensation expense	122.4	109.1	245.4	248.6
Acquisition and integration costs	5.3	2.6	9.1	4.2
Non-GAAP R&D	<u>\$ 1,072.3</u>	<u>\$ 973.6</u>	<u>\$ 2,193.9</u>	<u>\$ 1,933.7</u>
GAAP SG&A	\$ 758.8	\$ 652.0	\$ 1,447.8	\$ 1,253.1
Stock-based compensation expense	82.6	73.3	168.8	150.1
Acquisition and integration costs	9.7	16.5	28.5	26.1
Non-GAAP SG&A	<u>\$ 666.5</u>	<u>\$ 562.2</u>	<u>\$ 1,250.5</u>	<u>\$ 1,076.9</u>
GAAP COGS	\$ 257.8	\$ 192.4	\$ 498.2	\$ 400.8
Stock-based compensation expense	18.2	19.6	39.1	42.0
Acquisition and integration costs	0.8	0.5	1.2	0.5
Intangible asset amortization expense	25.1	19.8	48.3	38.3
Charges related to REGEN-COV	—	(10.0)	—	(10.0)
Non-GAAP COGS	<u>\$ 213.7</u>	<u>\$ 162.5</u>	<u>\$ 409.6</u>	<u>\$ 330.0</u>
GAAP other operating expense (income), net	\$ 14.6	\$ (0.6)	\$ 29.9	\$ (1.1)
Change in fair value of contingent consideration	14.6	—	29.9	—
Non-GAAP other operating expense (income), net	<u>\$ —</u>	<u>\$ (0.6)</u>	<u>\$ —</u>	<u>\$ (1.1)</u>
GAAP other income (expense), net	\$ 558.5	\$ 66.4	\$ 507.8	\$ (22.3)
(Gains) losses on investments, net	(392.6)	30.9	(196.5)	197.5
Non-GAAP other income (expense), net	<u>\$ 165.9</u>	<u>\$ 97.3</u>	<u>\$ 311.3</u>	<u>\$ 175.2</u>
GAAP net income	\$ 1,432.3	\$ 968.4	\$ 2,154.3	\$ 1,786.2
Total of GAAP to non-GAAP reconciling items above	(113.9)	262.3	373.8	697.3
Income tax effect of GAAP to non-GAAP reconciling items	32.8	(49.1)	(61.0)	(134.4)
Non-GAAP net income	<u>\$ 1,351.2</u>	<u>\$ 1,181.6</u>	<u>\$ 2,467.1</u>	<u>\$ 2,349.1</u>
Non-GAAP net income per share - basic	\$ 12.50	\$ 11.04	\$ 22.84	\$ 21.95
Non-GAAP net income per share - diluted	\$ 11.56	\$ 10.24	\$ 21.09	\$ 20.32
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	108.1	107.0	108.0	107.0
Non-GAAP net income per share - diluted	116.9	115.4	117.0	115.6

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
<i>Revenue reconciliation:</i>				
Total revenues	\$ 3,547.1	\$ 3,158.1	\$ 6,692.1	\$ 6,320.2
Global gross profit payment from Roche in connection with sales of Ronapreve	0.4	—	0.9	222.2
Other	—	(3.8)	—	(3.8)
Total revenues excluding Ronapreve	<u>\$ 3,546.7</u>	<u>\$ 3,161.9</u>	<u>\$ 6,691.2</u>	<u>\$ 6,101.8</u>
<i>Effective tax rate reconciliation:</i>				
GAAP ETR	12.0%	10.6%	7.5%	8.0%
Income tax effect of GAAP to non-GAAP reconciling items	(1.2%)	1.6%	1.2%	3.0%
Non-GAAP ETR	<u>10.8%</u>	<u>12.2%</u>	<u>8.7%</u>	<u>11.0%</u>
			Six Months Ended June 30,	
			2024	2023
<i>Free cash flow reconciliation:</i>				
Net cash provided by operating activities		\$ 1,866.5	\$ 2,390.0	
Capital expenditures		(314.4)	(291.2)	
Free cash flow		<u>\$ 1,552.1</u>	<u>\$ 2,098.8</u>	

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
<i>Sanofi collaboration revenue:</i>				
Regeneron's share of profits in connection with commercialization of antibodies	\$ 988.3	\$ 751.1	\$ 1,792.3	\$ 1,387.6
Reimbursement for manufacturing of commercial supplies	157.3	192.6	263.1	354.5
Total Sanofi collaboration revenue	1,145.6	943.7	2,055.4	1,742.1
<i>Bayer collaboration revenue:</i>				
Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States	353.0	349.5	686.9	681.1
Reimbursement for manufacturing of ex-U.S. commercial supplies	22.1	27.2	44.2	52.5
Total Bayer collaboration revenue	375.1	376.7	731.1	733.6
<i>Other collaboration revenue:</i>				
Global gross profit payment from Roche in connection with sales of Ronapreve	0.4	—	0.9	222.2
Other	2.9	(3.7)	3.4	(3.1)
Total collaboration revenue	\$ 1,524.0	\$ 1,316.7	\$ 2,790.8	\$ 2,694.8

TABLE 5

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

	Three Months Ended June 30,						% Change (Total Sales)
	2024			2023			
	U.S.	ROW ^(g)	Total	U.S.	ROW	Total	
EYLEA HD and EYLEA ^(a)	\$ 1,534.7	\$ 907.8	\$ 2,442.5	\$ 1,500.1	\$ 886.3	\$ 2,386.4	2 %
Dupixent ^(b)	\$ 2,610.2	\$ 946.2	\$ 3,556.4	\$ 2,105.2	\$ 684.2	\$ 2,789.4	27 %
Libtayo ^(c)	\$ 182.4	\$ 115.0	\$ 297.4	\$ 130.2	\$ 79.8	\$ 210.0	42 %
Praluent ^(d)	\$ 56.1	\$ 135.8	\$ 191.9	\$ 40.5	\$ 99.8	\$ 140.3	37 %
Kevzara ^(b)	\$ 65.1	\$ 44.6	\$ 109.7	\$ 56.9	\$ 42.6	\$ 99.5	10 %
REGEN-COV ^(e)	\$ —	\$ 1.1	\$ 1.1	\$ —	\$ —	\$ —	*
Other products ^(f)	\$ 30.9	\$ 20.8	\$ 51.7	\$ 22.5	\$ 16.9	\$ 39.4	31 %

	Six Months Ended June 30,						% Change (Total Sales)
	2024			2023			
	U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA HD and EYLEA ^(a)	\$ 2,936.3	\$ 1,757.2	\$ 4,693.5	\$ 2,933.9	\$ 1,733.4	\$ 4,667.3	1 %
Dupixent ^(b)	\$ 4,828.2	\$ 1,805.0	\$ 6,633.2	\$ 4,003.3	\$ 1,271.1	\$ 5,274.4	26 %
Libtayo ^(c)	\$ 341.6	\$ 219.7	\$ 561.3	\$ 239.9	\$ 152.7	\$ 392.6	43 %
Praluent ^(d)	\$ 126.1	\$ 267.1	\$ 393.2	\$ 80.7	\$ 205.5	\$ 286.2	37 %
Kevzara ^(b)	\$ 115.1	\$ 88.7	\$ 203.8	\$ 96.1	\$ 81.9	\$ 178.0	14 %
REGEN-COV ^(e)	\$ —	\$ 2.3	\$ 2.3	\$ —	\$ 613.2	\$ 613.2	(100 %)
Other products ^(f)	\$ 56.2	\$ 38.5	\$ 94.7	\$ 40.6	\$ 33.4	\$ 74.0	28 %

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.

* Percentage not meaningful

^(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. Prior to July 1, 2022, Sanofi recorded net product sales of Libtayo outside the United States. Included in this line item for the six months ended June 30, 2023 is approximately \$6 million of first quarter 2023 net product sales recorded by Sanofi in connection with sales in certain markets outside the United States (Sanofi recorded net product sales in such markets during a transition period).

^(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) Roche records net product sales outside the United States and the Company records its share of gross profits from sales based on a pre-specified formula, which is recorded within Collaboration revenue.

^(f) Included in this line item are products which are sold by the Company and others. Refer to "Second Quarter 2024 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; net product sales of ARCALYST were \$79 million for the first quarter of 2024.

^(g) Rest of world (ROW)