

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): May 2, 2024 (May 2, 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 May 2, 2024, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 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 May 2, 2024, Reporting First 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: May 2, 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 First Quarter 2024 Financial and Operating Results

- First quarter 2024 revenues decreased 1% to \$3.15 billion versus first quarter 2023; excluding Ronapreve^{TM(a)(b)}, revenues increased 7%
- First quarter 2024 Dupixent[®] global net sales (recorded by Sanofi) increased 24% to \$3.08 billion versus first quarter 2023
- First quarter 2024 U.S. net sales for EYLEA[®] HD and EYLEA[®] were \$1.40 billion, including \$200 million from EYLEA HD
- First quarter 2024 Libtayo[®] global net sales increased 45% to \$264 million versus first quarter 2023
- First quarter 2024 GAAP diluted EPS of \$6.27 and non-GAAP diluted EPS^(a) of \$9.55
- New \$3.0 billion share repurchase program authorized in April 2024

Tarrytown, New York (May 2, 2024) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2024 and provided a business update.

"The Regeneron team has already made substantial progress this year, delivering our approved medicines to more patients around the globe, advancing our pipeline consisting of dozens of clinical-stage programs, and relentlessly pursuing cutting-edge science," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "We had a strong quarter of EYLEA HD uptake, and we are well positioned to continue our leadership in retinal diseases. Dupixent continues to grow at a remarkable pace seven years into its launch and is currently treating over 850,000 patients across a variety of diseases characterized by type 2 inflammation. Our promising oncology franchise is strengthening, driven by strong global growth in Libtayo sales and potential regulatory approvals later this year for linvoseltamab in relapsed/refractory multiple myeloma."

Financial Highlights

(\$ in millions, except per share data)

	Q1 2024	Q1 2023	% Change
Total revenues	\$ 3,145	\$ 3,162	(1 %)
Total revenues excluding Ronapreve ^{(a)(b)}	\$ 3,145	\$ 2,940	7 %
GAAP net income	\$ 722	\$ 818	(12 %)
GAAP net income per share - diluted	\$ 6.27	\$ 7.17	(13 %)
Non-GAAP net income ^(a)	\$ 1,116	\$ 1,168	(4 %)
Non-GAAP net income per share - diluted ^(a)	\$ 9.55	\$ 10.09	(5 %)

"We are off to a strong start in 2024 as reflected in our solid first quarter financial results and the progress we have made across our growing pipeline," said Christopher Fenimore, Senior Vice President, Finance and Chief Financial Officer of Regeneron. "While investing in innovation remains our top capital allocation priority, the recent authorization by Regeneron's board of directors of a new \$3.0 billion share repurchase program provides us with additional flexibility to continue returning capital to shareholders over time."

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 January 2024, the European Commission (EC) and Japan's Ministry of Health, Labour and Welfare (MHLW) each approved EYLEA 8 mg (known as EYLEA HD in the United States) for the treatment of patients with wet age-related macular degeneration (wAMD) and diabetic macular edema (DME).
- In January 2024, the United States Centers for Medicare & Medicaid Services (CMS) assigned a permanent and product-specific J-code (J0177) for EYLEA HD, which became effective on April 1, 2024. J-codes simplify and streamline the billing and reimbursement processes for Medicare Part B treatments, allowing for efficient claims processing.

Dupilixent (dupilumab)

- The U.S. Food and Drug Administration (FDA) accepted for priority review the supplemental Biologics License Application (sBLA) for Dupilixent as an add-on maintenance treatment in adult patients with uncontrolled chronic obstructive pulmonary disease (COPD) and evidence of type 2 inflammation. A regulatory application is also under review in the European Union (EU) and Japan.
- A Phase 3 study for Dupilixent in asthma for children aged 2 to 5 years was initiated.
- In February 2024, the MHLW in Japan approved Dupilixent for the treatment of chronic spontaneous urticaria (CSU) in adults and children aged 12 years and older whose disease is not adequately controlled with existing therapy. A regulatory application has also been submitted in the EU.

Oncology Programs

- The FDA accepted the BLA seeking accelerated approval for linvoseltamab, a bispecific antibody targeting BCMA and CD3, to treat adult patients with relapsed/refractory (R/R) multiple myeloma that has progressed after at least three prior therapies, and the BLA was granted priority review with a target action date of August 22, 2024. A Phase 3 confirmatory trial is currently enrolling patients. A regulatory application is also under review in the EU.
- In April 2024, the Company presented positive pivotal data from the Phase 1/2 trial of linvoseltamab in patients with R/R multiple myeloma at the American Association for Cancer Research (AACR) Annual Meeting 2024. The linvoseltamab data reinforced previously shared findings and included a 71% objective response rate (ORR), with 46% of patients achieving a complete response (CR) or better.
- In March 2024, the FDA issued Complete Response Letters (CRLs) for the BLA for odronextamab, a bispecific antibody targeting CD20 and CD3, in R/R follicular lymphoma (FL) and R/R diffuse large B-cell lymphoma (DLBCL). The only approvability issue cited in the CRLs is related to the enrollment status of the confirmatory trials. The CRLs (one for R/R FL and one for R/R DLBCL) did not identify any approvability issues with the clinical efficacy or safety, trial design, labeling, or manufacturing. A regulatory application for R/R DLBCL and R/R FL remains under review in the EU.
- In 2023, the Company initiated a Phase 2/3 study of the combination of fianlimab, an antibody to LAG-3, and Libtayo (cemiplimab) in first-line metastatic melanoma. This study is enrolling faster than expected and will be conducted solely as a Phase 3 study with the final analysis to be reported during 2025.

Other Programs

- The FDA has extended the approval of Praluent® (alirocumab) as an adjunct to diet and other low-density lipoprotein cholesterol (LDL-C) lowering therapies to include pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
- A Phase 2 study for itepekimab, an antibody to IL-33, for non-cystic fibrosis bronchiectasis (NCFB) was initiated.
- A Phase 2 study for ALN-APP, an investigational RNAi therapeutic targeting amyloid precursor protein (APP), was initiated by the Company's collaborator Alnylam Pharmaceuticals, Inc. in patients with cerebral amyloid angiopathy (CAA).

Corporate and Business Development Updates

- In April 2024, the Company acquired full development and commercialization rights to 2seventy bio, Inc.'s oncology and autoimmune preclinical and clinical stage cell therapy pipeline. Under the terms of the agreement, the Company made a \$5 million up-front payment, and has assumed ongoing program, infrastructure, and personnel costs related to the product candidates acquired. In addition, the Company is obligated to pay 2seventy bio a regulatory milestone upon the first major market approval of the first approved product; and, with respect to any approved product, a low single-digit percent royalty on sales.
- In April 2024, the Company and Mammoth Biosciences, Inc. entered into a collaboration agreement to research, develop, and commercialize *in vivo* CRISPR-based gene editing therapies for multiple tissues and cell types. Under the terms of the agreement, the Company purchased an aggregate of \$95 million of Mammoth preferred stock and is obligated to make a \$5 million up-front payment. The parties will jointly select and research collaboration targets, and then Regeneron will lead development and commercialization.
- 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. Repurchases may be made from time to time at management's discretion through a variety of methods. The program has no time limit and can be discontinued at any time.

First Quarter 2024 Financial Results

Revenues

<i>(\$ in millions)</i>	Q1 2024	Q1 2023	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 200	\$ —	*
EYLEA - U.S.	1,202	1,434	(16 %)
Total EYLEA HD and EYLEA - U.S.	1,402	1,434	(2 %)
Libtayo - Global	264	177	49 %
Praluent - U.S.	70	40	75 %
Evkeeza® - U.S.	24	15	60 %
Inmazoleb® - Global	1	2	*
Total net product sales	1,761	1,668	6 %
Collaboration revenue:			
Sanofi	910	798	14 %
Bayer	356	357	— %
Other	1	223	(100 %)
Other revenue	117	116	1 %
Total revenues	\$ 3,145	\$ 3,162	(1 %)

* Percentage not meaningful

Net product sales of EYLEA in the U.S. decreased in the first quarter of 2024, compared to the first quarter of 2023, primarily due to changing market dynamics, resulting in lower volumes and a lower net selling price. In addition, aggregate net product sales of EYLEA and EYLEA HD in the first quarter of 2024 were negatively impacted by approximately \$40 million due to a sequential net reduction in wholesaler inventory.

Sanofi collaboration revenue increased in the first quarter of 2024, compared to the first quarter of 2023, primarily due to the Company's share of profits from commercialization of antibodies, which were \$804 million in the first quarter of 2024, compared to \$637 million in the first 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.

The decrease in other collaboration revenue in the first quarter of 2024, compared to the first quarter of 2023, was due to lower sales of Ronapreve. Under the Company's Roche collaboration agreement, the Company records collaboration revenue in connection with payments from Roche attributable to gross profits from sales of Ronapreve; however, the Company does not expect any additional Roche collaboration revenue from Ronapreve in future periods.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

(\$ in millions)	GAAP			Non-GAAP ^(a)		
	Q1 2024	Q1 2023	% Change	Q1 2024	Q1 2023	% Change
Research and development (R&D)	\$ 1,248	\$ 1,101	13 %	\$ 1,122	\$ 960	17 %
Acquired in-process research and development (IPR&D)	\$ 7	\$ 56	(88 %)	*	*	n/a
Selling, general, and administrative (SG&A)	\$ 689	\$ 601	15 %	\$ 584	\$ 515	13 %
Cost of goods sold (COGS)	\$ 240	\$ 208	15 %	\$ 196	\$ 168	17 %
Cost of collaboration and contract manufacturing (COCM)	\$ 193	\$ 249	(22 %)	*	*	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 first quarter of 2024, compared to the first 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 first quarter of 2023 included a \$45 million up-front payment in connection with the Company's collaboration agreement with Sonoma Biotherapeutics, Inc.
- GAAP and non-GAAP SG&A expenses increased in the first quarter of 2024, compared to the first 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 primarily related to the international expansion in support of Libtayo and hematology product launch preparations.
- GAAP and non-GAAP COGS increased in the first quarter of 2024, compared to the first quarter of 2023, primarily due to higher start-up costs for the Company's Rensselaer, New York fill/finish facility.
- COCM decreased in the first quarter of 2024, compared to the first quarter of 2023, primarily due to lower Dupixent manufacturing costs as a result of the transition to a higher-yielding manufacturing process.
- GAAP other operating expense (income), net, for the first 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 losses on equity securities of \$196 million in the first quarter of 2024, compared to \$165 million of net unrealized losses in the first quarter of 2023. GAAP and Non-GAAP other income (expense) also included interest income of \$162 million in the first quarter of 2024, compared to \$95 million in the first quarter of 2023.

In the first quarter of 2024, the Company's GAAP effective tax rate (ETR) was (3.0%), compared to 4.7% in the first quarter of 2023. The GAAP ETR in the first quarter of 2024, compared to the first quarter of 2023, included a higher benefit from stock-based compensation. In the first quarter of 2024, the non-GAAP ETR was 6.1%, compared to 9.7% in the first quarter of 2023.

GAAP net income per diluted share was \$6.27 in the first quarter of 2024, compared to \$7.17 in the first quarter of 2023. Non-GAAP net income per diluted share was \$9.55 in the first quarter of 2024, compared to \$10.09 in the first quarter of 2023. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

During the first quarter of 2024, the Company repurchased shares of its common stock and recorded the cost of the shares, or \$298 million, as Treasury Stock. As of March 31, 2024, \$1.2 billion remained available for share repurchases under the Company's share repurchase program then in effect (excluding the additional \$3.0 billion share repurchase program authorized in April 2024).

2024 Financial Guidance^(c)

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

	2024 Guidance	
	Prior	Updated
GAAP R&D	\$4.820–\$5.070 billion	\$4.920–\$5.170 billion**
Non-GAAP R&D ^(a)	\$4.300–\$4.500 billion	\$4.400–\$4.600 billion**
GAAP SG&A	\$2.890–\$3.090 billion	\$2.940–\$3.090 billion
Non-GAAP SG&A ^(a)	\$2.500–\$2.650 billion	\$2.550–\$2.650 billion
GAAP gross margin on net product sales ^(d)	86%–88%	Unchanged
Non-GAAP gross margin on net product sales ^{(a)(d)}	89%–91%	Unchanged
COCM ^{(e)*}	\$850–\$910 million	Unchanged
Capital expenditures*	\$825–\$950 million	\$780–\$880 million
GAAP effective tax rate	8%–10%	7%–9%
Non-GAAP effective tax rate ^(a)	10%–12%	Unchanged

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

** Updates to GAAP and non-GAAP amounts reflect ongoing program, infrastructure, and personnel costs assumed in connection with the acquisition of 2seventy bio's preclinical and clinical pipeline as described above.

A reconciliation of full year 2024 GAAP to non-GAAP financial guidance is included below:

(\$ in millions)	Projected Range	
	Low	High
GAAP R&D	\$ 4,920	\$ 5,170
Stock-based compensation expense	510	540
Acquisition and integration costs	10	30
Non-GAAP R&D	\$ 4,400	\$ 4,600
GAAP SG&A	\$ 2,940	\$ 3,090
Stock-based compensation expense	350	380
Acquisition and integration costs	40	60
Non-GAAP SG&A	\$ 2,550	\$ 2,650
GAAP gross margin on net product sales	86%	88%
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	89%	91%
GAAP ETR	7%	9%
Income tax effect of GAAP to non-GAAP reconciling items	3%	3%
Non-GAAP ETR	10%	12%

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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, 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 first quarter 2024 financial and operating results on Thursday, May 2, 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 March 31, 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)

	March 31, 2024	December 31, 2023
Assets:		
Cash and marketable securities	\$ 17,498.3	\$ 16,241.3
Accounts receivable, net	5,222.2	5,667.3
Inventories	2,714.9	2,580.5
Property, plant, and equipment, net	4,225.5	4,146.4
Intangible assets, net	1,058.7	1,038.6
Deferred tax assets	2,764.9	2,575.4
Other assets	885.1	830.7
Total assets	\$ 34,369.6	\$ 33,080.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 3,972.7	\$ 3,818.6
Finance lease liabilities	720.0	720.0
Deferred revenue	702.5	585.6
Long-term debt	1,983.3	1,982.9
Stockholders' equity	26,991.1	25,973.1
Total liabilities and stockholders' equity	\$ 34,369.6	\$ 33,080.2

TABLE 2

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

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Net product sales	\$ 1,761.3	\$ 1,668.0
Collaboration revenue	1,266.8	1,378.1
Other revenue	116.9	116.0
	<u>3,145.0</u>	<u>3,162.1</u>
Expenses:		
Research and development	1,248.4	1,101.2
Acquired in-process research and development	7.1	56.1
Selling, general, and administrative	689.0	601.1
Cost of goods sold	240.4	208.4
Cost of collaboration and contract manufacturing	193.4	249.1
Other operating expense (income), net	15.3	(0.5)
	<u>2,393.6</u>	<u>2,215.4</u>
Income from operations	751.4	946.7
Other income (expense):		
Other (expense) income, net	(34.6)	(70.7)
Interest expense	(16.1)	(18.0)
	<u>(50.7)</u>	<u>(88.7)</u>
Income before income taxes	700.7	858.0
Income tax (benefit) expense	(21.3)	40.2
Net income	<u>\$ 722.0</u>	<u>\$ 817.8</u>
Net income per share - basic	\$ 6.70	\$ 7.64
Net income per share - diluted	\$ 6.27	\$ 7.17
Weighted average shares outstanding - basic	107.8	107.1
Weighted average shares outstanding - diluted	115.1	114.0

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,	
	2024	2023
GAAP R&D	\$ 1,248.4	\$ 1,101.2
Stock-based compensation expense	123.0	139.5
Acquisition and integration costs	3.8	1.6
Non-GAAP R&D	<u>\$ 1,121.6</u>	<u>\$ 960.1</u>
GAAP SG&A	\$ 689.0	\$ 601.1
Stock-based compensation expense	86.2	76.8
Acquisition and integration costs	18.8	9.6
Non-GAAP SG&A	<u>\$ 584.0</u>	<u>\$ 514.7</u>
GAAP COGS	\$ 240.4	\$ 208.4
Stock-based compensation expense	20.9	22.4
Acquisition and integration costs	0.4	—
Intangible asset amortization expense	23.2	18.5
Non-GAAP COGS	<u>\$ 195.9</u>	<u>\$ 167.5</u>
GAAP other operating expense (income), net	\$ 15.3	\$ (0.5)
Change in fair value of contingent consideration	15.3	—
Non-GAAP other operating expense (income), net	<u>\$ —</u>	<u>\$ (0.5)</u>
GAAP other income (expense), net	\$ (50.7)	\$ (88.7)
Losses on investments, net	196.1	166.6
Non-GAAP other income (expense), net	<u>\$ 145.4</u>	<u>\$ 77.9</u>
GAAP net income	\$ 722.0	\$ 817.8
Total of GAAP to non-GAAP reconciling items above	487.7	435.0
Income tax effect of GAAP to non-GAAP reconciling items	(93.8)	(85.3)
Non-GAAP net income	<u>\$ 1,115.9</u>	<u>\$ 1,167.5</u>
Non-GAAP net income per share - basic	\$ 10.35	\$ 10.90
Non-GAAP net income per share - diluted	\$ 9.55	\$ 10.09
<i>Shares used in calculating:</i>		
Non-GAAP net income per share - basic	107.8	107.1
Non-GAAP net income per share - diluted	116.8	115.7

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

	Three Months Ended March 31,	
	2024	2023
<i>Revenue reconciliation:</i>		
Total revenues	\$ 3,145.0	\$ 3,162.1
Global gross profit payment from Roche in connection with sales of Ronapreve	0.5	222.2
Total revenues excluding Ronapreve	<u>\$ 3,144.5</u>	<u>\$ 2,939.9</u>
<i>Effective tax rate reconciliation:</i>		
GAAP ETR	(3.0%)	4.7%
Income tax effect of GAAP to non-GAAP reconciling items	9.1%	5.0%
Non-GAAP ETR	<u>6.1%</u>	<u>9.7%</u>
<i>Free cash flow reconciliation:</i>		
Net cash provided by operating activities	\$ 1,512.5	\$ 1,367.6
Capital expenditures	(133.9)	(178.2)
Free cash flow	<u>\$ 1,378.6</u>	<u>\$ 1,189.4</u>

TABLE 4

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

	Three Months Ended March 31,	
	2024	2023
<i>Sanofi collaboration revenue:</i>		
Regeneron's share of profits in connection with commercialization of antibodies	\$ 804.0	\$ 636.5
Reimbursement for manufacturing of commercial supplies	105.8	161.9
Total Sanofi collaboration revenue	909.8	798.4
<i>Bayer collaboration revenue:</i>		
Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States	333.9	331.6
Reimbursement for manufacturing of ex-U.S. commercial supplies	22.1	25.3
Total Bayer collaboration revenue	356.0	356.9
<i>Other collaboration revenue:</i>		
Global gross profit payment from Roche in connection with sales of Ronapreve	0.5	222.2
Other	0.5	0.6
Total collaboration revenue	<u>\$ 1,266.8</u>	<u>\$ 1,378.1</u>

TABLE 5

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

	Three Months Ended March 31,						% Change (Total Sales)
	2024			2023			
	U.S.	ROW ^(g)	Total	U.S.	ROW	Total	
EYLEA HD and EYLEA ^(a)	\$ 1,401.6	\$ 849.4	\$ 2,251.0	\$ 1,433.8	\$ 847.1	\$ 2,280.9	(1 %)
Dupixent ^(b)	\$ 2,218.0	\$ 858.8	\$ 3,076.8	\$ 1,898.1	\$ 586.9	\$ 2,485.0	24 %
Libtayo ^(c)	\$ 159.2	\$ 104.7	\$ 263.9	\$ 109.7	\$ 72.9	\$ 182.6	45 %
Praluent ^(d)	\$ 70.0	\$ 131.3	\$ 201.3	\$ 40.2	\$ 105.7	\$ 145.9	38 %
Kevzara ^(b)	\$ 50.0	\$ 44.1	\$ 94.1	\$ 39.2	\$ 39.3	\$ 78.5	20 %
REGEN-COV ^(e)	\$ —	\$ 1.2	\$ 1.2	\$ —	\$ 613.2	\$ 613.2	(100 %)
Other products ^(f)	\$ 25.3	\$ 17.7	\$ 43.0	\$ 18.1	\$ 16.5	\$ 34.6	24 %

^(a) Regeneron 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.

^(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.

^(c) Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Included in this line item for the first quarter of 2023 is approximately \$6 million of 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) Regeneron 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.

^(e) Roche records net product sales outside the United States and the parties share gross profits from sales based on a pre-specified formula.

^(f) Included in this line item are products which are sold by the Company and others. Refer to "First 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 \$71 million for the fourth quarter of 2023.

^(g) Rest of world (ROW)