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

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

**Date of Report (Date of earliest event reported): October 31, 2024 (October 31, 2024)**

# REGENERON PHARMACEUTICALS, INC.

**(Exact name of registrant as specified in its charter)**

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

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

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

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

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

On October 31, 2024, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 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 October 31, 2024, Reporting Third 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: October 31, 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 Third Quarter 2024 Financial and Operating Results

- *Third quarter 2024 revenues increased 11% to $3.72 billion versus third quarter 2023*
- *Third quarter 2024 Dupixent® global net sales (recorded by Sanofi) increased 23% to $3.82 billion versus third quarter 2023*
- *Third quarter 2024 U.S. net sales for EYLEA HD® and EYLEA® increased 3% versus third quarter 2023 to $1.54 billion, including $392 million from EYLEA HD*
- *Third quarter 2024 Libtayo® global net sales increased 24% to $289 million versus third quarter 2023*
- *Third quarter 2024 GAAP diluted EPS increased 30% to $11.54 and non-GAAP diluted EPS[(a)] increased 8% to $12.46 versus third quarter 2023; third quarter 2024 includes unfavorable $0.43 impact from acquired IPR&D charge*
- *FDA approved Dupixent as first-ever biologic therapy in U.S. for treatment of inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype*
- *Positive results reported for Dupixent pivotal trials in chronic spontaneous urticaria (CSU) and bullous pemphigoid (BP); CSU sBLA resubmitted and BP sBLA submission planned for fourth quarter 2024*

**Tarrytown, New York (October 31, 2024) --** Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2024 and provided a business update.

"Regeneron had a strong third quarter marked by 11% revenue growth. We continued to deepen the impact of our commercialized medicines this quarter, with ongoing leadership for our retinal franchise, expanded global reach of Libtayo, and notable growth from Dupixent," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "Over one million patients around the globe are currently being treated with Dupixent, with more to come following the approvals for COPD in the U.S., Europe and China. Our remarkably diverse clinical portfolio now includes approximately 40 product candidates and many pivotal studies underway. We continue to invest in the world-class research and development engine that drives our scientific and clinical productivity, with data expected over the next twelve months in diseases as varied as non-small cell lung cancer, thrombosis, retinal vein occlusion, severe allergy, COPD, melanoma, and obesity."

### *Financial Highlights*

| *($ in millions, except per share data)* | Q3 2024 | Q3 2023 | % Change |
|---|---|---|---|
| Total revenues | $ 3,721 | $ 3,363 | 11 % |
| GAAP net income | $ 1,341 | $ 1,008 | 33 % |
| GAAP net income per share - diluted | $ 11.54 | $ 8.89 | 30 % |
| Non-GAAP net income[(a)] | $ 1,462 | $ 1,329 | 10 % |
| Non-GAAP net income per share - diluted[(a)] | $ 12.46 | $ 11.59 | 8 % |

"Our strong third quarter financial performance was highlighted by double-digit revenue growth and continued investment in our growing pipeline," said Christopher Fenimore, Senior Vice President, Finance and Chief Financial Officer of Regeneron. "We remain focused on translating cutting-edge science into differentiated medicines that have the greatest potential to serve patients, while deploying capital with the goal of maximizing shareholder returns, primarily through investing in innovation coupled with opportunistic share repurchases."

***Business Highlights***

**Key Pipeline Progress**

Regeneron has approximately 40 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 (aflibercept) 8 mg

- The Company announced positive three-year (156-week) data from an extension study of the Phase 3 PHOTON trial in patients with diabetic macular edema (DME). At three years, the longer-term data showed the vast majority of EYLEA HD patients who entered the extension study sustained the visual gains and anatomic improvements achieved by the end of the second year. Of the EYLEA HD patients who completed the full 156 weeks of treatment, 48% were assigned a dosing interval of ≥20 weeks at the end of the third year. The results were presented at the American Academy of Ophthalmology (AAO) Annual Meeting.

Dupixent (dupilumab)

- In September 2024, the U.S. Food and Drug Administration (FDA) approved Dupixent as an add-on maintenance treatment for adults with inadequately controlled COPD and an eosinophilic phenotype. With this approval, Dupixent is the first biologic medicine approved in the United States, European Union (EU), and China to treat these patients.
- In September 2024, the FDA approved Dupixent as an add-on maintenance treatment for adolescents aged 12 to 17 years with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending expanded approval of Dupixent in the EU to treat children aged 1 to 11 years with eosinophilic esophagitis (EoE). The European Commission (EC) is expected to announce a final decision in the coming months.
- The Company and Sanofi announced that a confirmatory Phase 3 trial met the primary and key secondary endpoints for the investigational treatment of patients with uncontrolled, biologic-naïve CSU receiving background therapy with antihistamines, showing treatment with Dupixent resulted in a nearly 50% reduction in itch and urticaria activity scores from baseline. This positive trial confirms results from the first Phase 3 trial of Dupixent in this setting and these data supported the recent resubmission of a supplemental Biologics License Application (sBLA) to the FDA.
- The Company and Sanofi announced that a Phase 3 trial in bullous pemphigoid met the primary and all key secondary endpoints evaluating the investigational use in adults with moderate-to-severe disease. In the trial, five times more Dupixent patients achieved sustained disease remission compared to those on placebo. This trial will support global regulatory submissions, including the anticipated fourth quarter 2024 submission in the United States.

Oncology Programs

- In August 2024, the EC approved Ordspono™ (odronextamab) to treat adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) or R/R diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy.
- The Company announced five-year results from the final pre-specified overall survival (OS) analysis of a Phase 3 trial, which evaluated Libtayo (cemiplimab) monotherapy versus chemotherapy as a first-line treatment for certain adults with advanced non-small cell lung cancer (NSCLC) with ≥50% PD-L1 expression. The results were presented at the IASLC 2024 World Conference on Lung Cancer.
- The Company submitted a regulatory application in Japan for Libtayo for first-line advanced NSCLC (monotherapy and chemotherapy combination).
- A Phase 2 study for Libtayo in neoadjuvant NSCLC was initiated.
- The Company presented new, two-year results at the European Society for Medical Oncology (ESMO) Annual Meeting, evaluating the investigational combination of fianlimab, an antibody to LAG-3, and Libtayo in adults with advanced melanoma across three independent expansion cohorts of a first-in-human, multi-cohort trial. These longer-term results show high clinical activity, including deepening responses, per a blinded independent central review.
- In August 2024, the FDA issued a Complete Response Letter (CRL) for the BLA for linvoseltamab, a bispecific antibody targeting BCMA and CD3, in R/R multiple myeloma that has progressed after at least three prior therapies. The sole approvability issue identified is related to findings from a pre-approval inspection at a third-party fill/finish manufacturer. Resolution of this issue will be required for both FDA and EC regulatory approvals.

Other Programs

- A Phase 3 study was initiated for pozelimab, an antibody to C5, in combination with cemdisiran, an siRNA therapy, in geographic atrophy.
- A Phase 2 study for REGN7999, an antibody to TMPRSS6, for the treatment of iron overload in patients with beta-thalassemia was initiated.

## Third Quarter 2024 Financial Results

### *Revenues*

| *($ in millions)* | Q3 2024 | Q3 2023 | % Change |
|---|---|---|---|
| Net product sales: | | | |
| EYLEA HD - U.S. | $ 392 | $ 43 | * |
| EYLEA - U.S. | 1,145 | 1,448 | (21 %) |
| Total EYLEA HD and EYLEA - U.S. | 1,537 | 1,491 | 3 % |
| Libtayo - Global | 289 | 232 | 25 % |
| Praluent® - U.S. | 53 | 40 | 33 % |
| Evkeeza® - U.S. | 32 | 19 | 68 % |
| Inmazeb® - Global | 35 | 4 | * |
| Total net product sales | 1,946 | 1,786 | 9 % |
| Collaboration revenue: | | | |
| Sanofi | 1,263 | 1,065 | 19 % |
| Bayer | 391 | 377 | 4 % |
| Other | 6 | (3) | * |
| Other revenue | 114 | 138 | (17 %) |
| Total revenues | $ 3,720 | $ 3,363 | 11 % |

* Percentage not meaningful

Total EYLEA HD and EYLEA net product sales in the U.S. increased 3% in the third quarter of 2024 compared to the third quarter of 2023. EYLEA HD was approved by the FDA in August 2023 and net product sales in the third quarter of 2024 were driven by the transition of patients from other anti-VEGF products, including EYLEA, as well as new patients naïve to anti-VEGF therapy. Net product sales of EYLEA in the third quarter of 2024 were adversely impacted by a lower net selling price compared to the third quarter of 2023. In addition, third quarter 2024 total EYLEA HD and EYLEA net product sales were favorably impacted by approximately $40 million as a result of higher wholesaler inventory levels for EYLEA HD at the end of the third quarter of 2024 compared to the end of the second quarter of 2024, partially offset by lower wholesaler inventory levels for EYLEA.

Sanofi collaboration revenue increased in the third quarter of 2024, compared to the third quarter of 2023, due to an increase in the Company's share of profits from commercialization of antibodies, which were $1.09 billion in the third quarter of 2024, compared to $863 million in the third 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. Sanofi collaboration revenue in the third quarter of 2023 was positively impacted by the recognition of the final $50 million sales-based milestone.

Refer to Table 4 for a summary of collaboration revenue.

***Operating Expenses***

| *($ in millions)* | GAAP Q3 2024 | GAAP Q3 2023 | GAAP % Change | Non-GAAP[(a)] Q3 2024 | Non-GAAP[(a)] Q3 2023 | Non-GAAP[(a)] % Change |
|---|---|---|---|---|---|---|
| Research and development (R&D) | $ 1,272 | $ 1,075 | 18 % | $ 1,146 | $ 954 | 20 % |
| Acquired in-process research and development (IPR&D) | $ 56 | $ 100 | (44 %) | * | * | n/a |
| Selling, general, and administrative (SG&A) | $ 714 | $ 641 | 11 % | $ 613 | $ 534 | 15 % |
| Cost of goods sold (COGS) | $ 262 | $ 225 | 16 % | $ 217 | $ 181 | 20 % |
| Cost of collaboration and contract manufacturing (COCM) | $ 229 | $ 212 | 8 % | * | * | n/a |
| Other operating expense (income), net | $ 8 | $ (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 third quarter of 2024, compared to the third quarter of 2023, driven by the advancement of the Company's clinical pipeline, including late-stage oncology programs, and higher headcount and headcount-related costs.
- Acquired IPR&D for the third quarter of 2024 included a $45 million development milestone in connection with the Company's collaboration agreement with Sonoma Biotherapeutics, Inc. Acquired IPR&D expense in the third quarter of 2023 related to a $100 million development milestone in connection with the Company's collaboration with Alnylam Pharmaceuticals, Inc.
- GAAP and non-GAAP SG&A expenses increased in the third quarter of 2024, compared to the third 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 third quarter of 2024, compared to the third quarter of 2023, primarily due to higher start-up costs for the Company's Rensselaer, New York fill/finish facility.

***Other Financial Information***

GAAP other income (expense) included the recognition of net unrealized gains on equity securities of $135 million in the third quarter of 2024, compared to $100 million of net unrealized losses in the third quarter of 2023. GAAP and Non-GAAP other income (expense) also included interest income of $187 million in the third quarter of 2024, compared to $134 million in the third quarter of 2023.

In the third quarter of 2024, the Company's GAAP effective tax rate (ETR) was 10.2%, compared to 9.3% in the third quarter of 2023. The GAAP ETR increased in the third quarter of 2024, compared to the third quarter of 2023, due to a lower benefit from income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate. In the third quarter of 2024, the non-GAAP ETR was 10.7%, compared to 11.9% in the third quarter of 2023.

GAAP net income per diluted share was $11.54 in the third quarter of 2024, compared to $8.89 in the third quarter of 2023. Non-GAAP net income per diluted share was $12.46 in the third quarter of 2024, compared to $11.59 in the third 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 third quarter of 2024, the Company repurchased shares of its common stock and recorded the cost of the shares, or $738 million, as Treasury Stock. As of September 30, 2024, $2.9 billion remained available for share repurchases under the Company's share repurchase program.

***2024 Financial Guidance*** [(c)]

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

| | 2024 Guidance | |
|---|---|---|
| | **Prior** | **Updated** |
| GAAP R&D | $5.020–$5.170 billion | $5.055–$5.145 billion |
| Non-GAAP R&D[(a)] | $4.500–$4.600 billion | $4.525–$4.575 billion |
| GAAP SG&A | $2.920–$3.060 billion | $2.930–$3.020 billion |
| Non-GAAP SG&A[(a)] | $2.550–$2.650 billion | $2.550–$2.600 billion |
| GAAP gross margin on net product sales[(d)] | Approximately 86% | Unchanged |
| Non-GAAP gross margin on net product sales[(a)(d)] | Approximately 89% | Unchanged |
| COCM[(e)*] | $850–$910 million | $860–$900 million |
| Capital expenditures[*] | $750–$820 million | $700–$740 million |
| GAAP effective tax rate | 8%–9% | Unchanged |
| Non-GAAP effective tax rate[(a)] | 10%–11% | 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 2024 GAAP to non-GAAP financial guidance is included below:

| *($ in millions)* | Projected Range | |
|---|---|---|
| | **Low** | **High** |
| GAAP R&D | $ 5,055 | $ 5,145 |
| Stock-based compensation expense | 520 | 540 |
| Acquisition and integration costs | 10 | 30 |
| Non-GAAP R&D | $ 4,525 | $ 4,575 |
| | | |
| GAAP SG&A | $ 2,930 | $ 3,020 |
| Stock-based compensation expense | 340 | 360 |
| Acquisition, integration, and other costs | 40 | 60 |
| Non-GAAP SG&A | $ 2,550 | $ 2,600 |
| | | |
| 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% |

(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.

**Conference Call Information**

Regeneron will host a conference call and simultaneous webcast to discuss its third quarter 2024 financial and operating results on Thursday, October 31, 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), Ordspono™ (odronextamab), itepekimab, fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, nexiguran ziclumeran (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 (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 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 September 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)***

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Assets: | | |
| Cash and marketable securities | $ 18,287.4 | $ 16,241.3 |
| Accounts receivable, net | 6,107.1 | 5,667.3 |
| Inventories | 3,018.0 | 2,580.5 |
| Property, plant, and equipment, net | 4,439.2 | 4,146.4 |
| Intangible assets, net | 1,120.1 | 1,038.6 |
| Deferred tax assets | 3,015.1 | 2,575.4 |
| Other assets | 1,455.0 | 830.7 |
| Total assets | $ 37,441.9 | $ 33,080.2 |
| | | |
| Liabilities and stockholders' equity: | | |
| Accounts payable, accrued expenses, and other liabilities | $ 4,577.4 | $ 3,818.6 |
| Finance lease liabilities | 720.0 | 720.0 |
| Deferred revenue | 834.6 | 585.6 |
| Long-term debt | 1,984.0 | 1,982.9 |
| Stockholders' equity | 29,325.9 | 25,973.1 |
| Total liabilities and stockholders' equity | $ 37,441.9 | $ 33,080.2 |

TABLE 2

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| Revenues: | | | | |
| Net product sales | $ 1,946.4 | $ 1,786.1 | $ 5,626.3 | $ 5,226.2 |
| Collaboration revenue | 1,660.1 | 1,438.3 | 4,450.9 | 4,133.1 |
| Other revenue | 114.2 | 138.3 | 335.6 | 323.6 |
| | 3,720.7 | 3,362.7 | 10,412.8 | 9,682.9 |
| Expenses: | | | | |
| Research and development | 1,271.5 | 1,075.3 | 3,719.9 | 3,261.8 |
| Acquired in-process research and development | 56.2 | 100.0 | 87.2 | 156.1 |
| Selling, general, and administrative | 714.4 | 640.5 | 2,162.2 | 1,893.6 |
| Cost of goods sold | 262.3 | 224.5 | 760.5 | 625.3 |
| Cost of collaboration and contract manufacturing | 228.8 | 211.9 | 644.6 | 673.5 |
| Other operating expense (income), net | 8.0 | (0.5) | 37.9 | (1.6) |
| | 2,541.2 | 2,251.7 | 7,412.3 | 6,608.7 |
| Income from operations | 1,179.5 | 1,111.0 | 3,000.5 | 3,074.2 |
| Other income (expense): | | | | |
| Other income (expense), net | 327.3 | 17.6 | 866.0 | 32.2 |
| Interest expense | (13.8) | (17.8) | (44.7) | (54.7) |
| | 313.5 | (0.2) | 821.3 | (22.5) |
| Income before income taxes | 1,493.0 | 1,110.8 | 3,821.8 | 3,051.7 |
| Income tax expense | 152.4 | 103.0 | 326.9 | 257.7 |
| Net income | $ 1,340.6 | $ 1,007.8 | $ 3,494.9 | $ 2,794.0 |
| Net income per share - basic | $ 12.40 | $ 9.48 | $ 32.36 | $ 26.16 |
| Net income per share - diluted | $ 11.54 | $ 8.89 | $ 30.23 | $ 24.57 |
| Weighted average shares outstanding - basic | 108.1 | 106.3 | 108.0 | 106.8 |
| Weighted average shares outstanding - diluted | 116.2 | 113.4 | 115.6 | 113.7 |

TABLE 3

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| GAAP R&D | $ 1,271.5 | $ 1,075.3 | $ 3,719.9 | $ 3,261.8 |
| Stock-based compensation expense | 123.7 | 107.4 | 369.1 | 356.0 |
| Acquisition and integration costs | 2.0 | 13.5 | 11.1 | 17.7 |
| Non-GAAP R&D | $ 1,145.8 | $ 954.4 | $ 3,339.7 | $ 2,888.1 |
| | | | | |
| GAAP SG&A | $ 714.4 | $ 640.5 | $ 2,162.2 | $ 1,893.6 |
| Stock-based compensation expense | 83.1 | 74.4 | 251.9 | 224.5 |
| Acquisition, integration, and other costs | 18.2 | 32.4 | 46.7 | 58.5 |
| Non-GAAP SG&A | $ 613.1 | $ 533.7 | $ 1,863.6 | $ 1,610.6 |
| | | | | |
| GAAP COGS | $ 262.3 | $ 224.5 | $ 760.5 | $ 625.3 |
| Stock-based compensation expense | 18.3 | 22.1 | 57.4 | 64.1 |
| Acquisition and integration costs | 0.5 | 0.9 | 1.7 | 1.4 |
| Intangible asset amortization expense | 26.1 | 20.7 | 74.4 | 59.0 |
| Charges related to REGEN-COV | — | — | — | (10.0) |
| Non-GAAP COGS | $ 217.4 | $ 180.8 | $ 627.0 | $ 510.8 |
| | | | | |
| GAAP other operating expense (income), net | $ 8.0 | $ (0.5) | $ 37.9 | $ (1.6) |
| Change in fair value of contingent consideration | 8.0 | — | 37.9 | — |
| Non-GAAP other operating expense (income), net | $ — | $ (0.5) | $ — | $ (1.6) |
| | | | | |
| GAAP other income (expense), net | $ 313.5 | $ (0.2) | $ 821.3 | $ (22.5) |
| (Gains) losses on investments, net | (134.7) | 127.0 | (331.2) | 324.5 |
| Non-GAAP other income (expense), net | $ 178.8 | $ 126.8 | $ 490.1 | $ 302.0 |
| | | | | |
| GAAP net income | $ 1,340.6 | $ 1,007.8 | $ 3,494.9 | $ 2,794.0 |
| Total of GAAP to non-GAAP reconciling items above | 145.2 | 398.4 | 519.0 | 1,095.7 |
| Income tax effect of GAAP to non-GAAP reconciling items | (23.4) | (77.1) | (84.4) | (211.5) |
| Non-GAAP net income | $ 1,462.4 | $ 1,329.1 | $ 3,929.5 | $ 3,678.2 |
| | | | | |
| Non-GAAP net income per share - basic | $ 13.53 | $ 12.50 | $ 36.38 | $ 34.44 |
| Non-GAAP net income per share - diluted | $ 12.46 | $ 11.59 | $ 33.53 | $ 31.90 |
| | | | | |
| *Shares used in calculating:* | | | | |
| Non-GAAP net income per share - basic | 108.1 | 106.3 | 108.0 | 106.8 |
| Non-GAAP net income per share - diluted | 117.4 | 114.7 | 117.2 | 115.3 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| *Revenue reconciliation:* | | | | |
| Total revenues | $ 3,720.7 | $ 3,362.7 | $ 10,412.8 | $ 9,682.9 |
| Global gross profits earned in connection with sales of Ronapreve | 0.5 | — | 1.4 | 222.2 |
| Other | — | (5.7) | — | (9.5) |
| Total revenues excluding Ronapreve | $ 3,720.2 | $ 3,368.4 | $ 10,411.4 | $ 9,470.2 |
| *Effective tax rate reconciliation:* | | | | |
| GAAP ETR | 10.2% | 9.3% | 8.6% | 8.4% |
| Income tax effect of GAAP to non-GAAP reconciling items | 0.5% | 2.6% | 0.9% | 2.9% |
| Non-GAAP ETR | 10.7% | 11.9% | 9.5% | 11.3% |

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| *Free cash flow reconciliation:* | | |
| Net cash provided by operating activities | $ 3,157.7 | $ 3,504.3 |
| Capital expenditures | (556.3) | (467.2) |
| Free cash flow | $ 2,601.4 | $ 3,037.1 |

TABLE 4

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| *Sanofi collaboration revenue:* | | | | |
| Regeneron's share of profits in connection with commercialization of antibodies | $ 1,088.3 | $ 863.0 | $ 2,880.6 | $ 2,250.6 |
| Sales-based milestones earned | — | 50.0 | — | 50.0 |
| Reimbursement for manufacturing of commercial supplies | 175.1 | 151.5 | 438.2 | 506.0 |
| Total Sanofi collaboration revenue | 1,263.4 | 1,064.5 | 3,318.8 | 2,806.6 |
| | | | | |
| *Bayer collaboration revenue:* | | | | |
| Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States | 367.6 | 349.9 | 1,054.5 | 1,031.0 |
| Reimbursement for manufacturing of ex-U.S. commercial supplies | 23.2 | 27.2 | 67.4 | 79.7 |
| Total Bayer collaboration revenue | 390.8 | 377.1 | 1,121.9 | 1,110.7 |
| | | | | |
| *Other collaboration revenue:* | | | | |
| Global gross profits earned from Roche in connection with sales of Ronapreve | 0.5 | — | 1.4 | 222.2 |
| Other | 5.4 | (3.3) | 8.8 | (6.4) |
| | | | | |
| Total collaboration revenue | $ 1,660.1 | $ 1,438.3 | $ 4,450.9 | $ 4,133.1 |

TABLE 5

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

| | Three Months Ended September 30, | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2024 | | | 2023 | | | % Change |
| | U.S. | ROW[g] | Total | U.S. | ROW | Total | (Total Sales) |
| EYLEA HD and EYLEA[a] | $ 1,536.9 | $ 931.7 | $ 2,468.6 | $ 1,490.9 | $ 872.2 | $ 2,363.1 | 4 % |
| Dupixent[b] | $ 2,824.7 | $ 992.5 | $ 3,817.2 | $ 2,366.3 | $ 731.3 | $ 3,097.6 | 23 % |
| Libtayo[c] | $ 194.5 | $ 94.1 | $ 288.6 | $ 144.1 | $ 88.3 | $ 232.4 | 24 % |
| Praluent[d] | $ 52.9 | $ 138.5 | $ 191.4 | $ 40.4 | $ 125.1 | $ 165.5 | 16 % |
| Kevzara[b] | $ 72.7 | $ 47.4 | $ 120.1 | $ 52.4 | $ 43.3 | $ 95.7 | 25 % |
| REGEN-COV[e] | $ — | $ 1.2 | $ 1.2 | $ — | $ — | $ — | * |
| Other products[f] | $ 68.2 | $ 23.2 | $ 91.4 | $ 23.4 | $ 15.5 | $ 38.9 | 135 % |

| | Nine Months Ended September 30, | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2024 | | | 2023 | | | % Change |
| | U.S. | ROW | Total | U.S. | ROW | Total | (Total Sales) |
| EYLEA HD and EYLEA[a] | $ 4,473.2 | $ 2,688.9 | $ 7,162.1 | $ 4,424.8 | $ 2,605.6 | $ 7,030.4 | 2 % |
| Dupixent[b] | $ 7,652.9 | $ 2,797.5 | $ 10,450.4 | $ 6,369.6 | $ 2,002.4 | $ 8,372.0 | 25 % |
| Libtayo[c] | $ 536.1 | $ 313.8 | $ 849.9 | $ 384.0 | $ 241.0 | $ 625.0 | 36 % |
| Praluent[d] | $ 179.0 | $ 405.6 | $ 584.6 | $ 121.1 | $ 330.6 | $ 451.7 | 29 % |
| Kevzara[b] | $ 187.8 | $ 136.1 | $ 323.9 | $ 148.5 | $ 125.2 | $ 273.7 | 18 % |
| REGEN-COV[e] | $ — | $ 3.5 | $ 3.5 | $ — | $ 613.2 | $ 613.2 | (99 %) |
| Other products[f] | $ 124.4 | $ 61.7 | $ 186.1 | $ 64.0 | $ 48.9 | $ 112.9 | 65 % |

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 nine months ended September 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, which is recorded within Collaboration revenue.

[f] Included in this line item are products which are sold by the Company and others. Refer to "Third 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 $103 million for the second quarter of 2024.

[g] Rest of world (ROW)