# Regeneron Reports First Quarter 2023 Financial and Operating Results

May 4, 2023

- *First quarter 2023 revenues increased 7% to $3.16 billion versus first quarter 2022*
- *First quarter 2023 Dupixent® global net sales (recorded by Sanofi) increased 37% to $2.49 billion versus first quarter 2022*
- *First quarter 2023 EYLEA® U.S. net sales were $1.43 billion*
- *First quarter 2023 GAAP diluted EPS of $7.17 and non-GAAP diluted EPS[(a)] of $10.09; includes unfavorable $0.42 impact from acquired IPR&D charge*
- *European Commission approved Dupixent for atopic dermatitis in children aged 6 months to 5 years and Libtayo® in combination with chemotherapy for advanced PD-L1 positive non-small cell lung cancer (NSCLC)*
- *Aflibercept 8 mg BLA for neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME) accepted for FDA priority review with a target action date of June 27, 2023*
- *Positive results reported in Dupixent pivotal trial for chronic obstructive pulmonary disease (COPD) with evidence of type 2 inflammation; potential to become first biologic to treat COPD by showing significant reduction in exacerbations*
- *Positive interim Phase 1 data reported for ALN-APP, an investigational RNAi therapeutic in development for Alzheimer's disease and cerebral amyloid angiopathy*

TARRYTOWN, N.Y., May 04, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2023 and provided a business update.

"In the first quarter of 2023, we achieved six FDA and EC approvals across five products, allowing our homegrown medicines to reach even more patients around the world, while we also continued to grow revenue," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We remain focused on advancing our robust pipeline at all stages, and we were pleased to announce positive data from a late-stage study of Dupixent in COPD and make continued progress with our costimulatory and bispecific antibody candidates in oncology."

***Financial Highlights***

| *($ in millions, except per share data)* | Q1 2023 | Q1 2022 | % Change |
|---|---|---|---|
| Total revenues | $ 3,162 | $ 2,965 | 7% |
| GAAP net income | $ 818 | $ 974 | (16%) |
| GAAP net income per share - diluted | $ 7.17 | $ 8.61 | (17%) |
| Non-GAAP net income[(a)] | $ 1,168 | $ 1,318 | (11%) |
| Non-GAAP net income per share - diluted[(a)] | $ 10.09 | $ 11.49 | (12%) |

"Our business is off to a strong start in 2023, marked by our solid first quarter financial results and the pipeline progress we have achieved," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We continue to make investing in innovation, both internal and external, our top priority for capital allocation."

***Business Highlights***

**Key Pipeline Progress**
Regeneron has approximately 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:

Aflibercept 8 mg

- The U.S. Food and Drug Administration (FDA) accepted for priority review the Biologics License Application (BLA) for the treatment of wet AMD, DME, and diabetic retinopathy, with a target action date of June 27, 2023. A regulatory application has also been submitted for the treatment of wet AMD and DME in the European Union (EU) and Japan.

EYLEA (aflibercept) Injection

- In February 2023, the FDA approved EYLEA for the treatment of retinopathy of prematurity (ROP) in preterm infants.

Dupixent (dupilumab)

- In January 2023, the European Commission (EC) approved Dupixent for the treatment of adults and adolescents with eosinophilic esophagitis (EoE).
- In March 2023, the EC also approved Dupixent as the first and only targeted medicine indicated to treat children aged 6 months to 5 years with severe atopic dermatitis in Europe.

- The Company and Sanofi announced the primary and all key secondary endpoints were met in a Phase 3 trial in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled COPD and evidence of type 2 inflammation. Dupixent is the first and only biologic to demonstrate a clinically meaningful and highly significant reduction (30%) in moderate or severe acute exacerbations of COPD (rapid and acute worsening of respiratory symptoms) over 52 weeks, while also demonstrating significant improvements in lung function, quality of life, and COPD respiratory symptoms. The safety results were generally consistent with the known safety profile of Dupixent in its approved indications.
- The FDA accepted for review the supplemental BLA (sBLA) for the treatment of adults and adolescents aged 12 years and older with chronic spontaneous urticaria (CSU), with a target action date of October 22, 2023. A regulatory application has also been submitted in Japan.
- The Phase 3 study in chronic cold induced urticaria did not meet its required efficacy endpoints and further development has been discontinued.
- A Phase 2/3 study in eosinophilic gastroenteritis and a Phase 2 study in ulcerative colitis were initiated.

Oncology Programs

- In March 2023, the EC approved Libtayo (cemiplimab) in combination with platinum-based chemotherapy for the first-line treatment of adult patients with advanced NSCLC with ≥1% PD-L1 expression.
- A Phase 2/3 pivotal study was initiated for fianlimab, an antibody to LAG-3, in combination with Libtayo for first-line advanced NSCLC.
- A Phase 1 study was initiated for Libtayo in combination with BioNTech's BNT116 in patients with first-line NSCLC.
- A Phase 1 study was initiated for REGN5837, a bispecific antibody targeting CD22 and CD28, in B-cell non-Hodgkin lymphoma (B-NHL).
- The FDA granted Fast Track designation to linvoseltamab, a bispecific antibody targeting BCMA and CD3, for multiple myeloma.

Other Programs

- The FDA approved Kevzara® (sarilumab) as the first and only biologic for the treatment of polymyalgia rheumatica (PMR).
- The FDA approved Evkeeza® (evinacumab) as an adjunct to other lipid-lowering therapies to treat children with homozygous familial hypercholesterolemia (HoFH), which extended the approved indication to children as young as 5 years of age.
- The FDA accepted for priority review the BLA for pozelimab, an antibody to C5, for the treatment of ultra-rare CD55-deficient protein-losing enteropathy (CHAPLE) in adults and children as young as 1 year of age, with a target action date of August 20, 2023.
- The Company and Alnylam Pharmaceuticals, Inc. reported positive interim results from the ongoing single dose part of the Phase 1 study of ALN-APP, an investigational RNAi therapeutic targeting amyloid precursor protein (APP), in patients with early-onset Alzheimer's disease. Patients treated with ALN-APP experienced dose-dependent, rapid, and sustained reduction in cerebrospinal fluid of both soluble APPα (sAPPα) and APPβ (sAPPβ), biomarkers of target engagement, with maximum reduction of 84% and 90%, respectively. These interim results demonstrated encouraging safety and tolerability to date.
- A Phase 2 study was initiated for ALN-HSD, an RNAi therapeutic targeting HSD17B13, in nonalcoholic steatohepatitis (NASH).

**Corporate and Business Development Updates**

- The Company announced that P. Roy Vagelos, M.D., will retire from his role as Chair of the Company's Board of Directors and will not stand for reelection at the Company's 2023 Annual Meeting of Shareholders on June 9, 2023. Dr. Vagelos will complete his current term through the conclusion of the Annual Meeting, at which time the Board plans to appoint Leonard S. Schleifer, M.D., Ph.D., and George D. Yancopoulos, M.D., Ph.D., as Co-Chairs of the Board, in addition to their roles as President and Chief Executive Officer and President and Chief Scientific Officer, respectively. The Board also plans to appoint current director Christine A. Poon as the Lead Independent Director of the Board.
- In March 2023, the Company and Sonoma Biotherapeutics, Inc. entered into a license and collaboration agreement to bring together the Company's *VelociSuite*® technologies with Sonoma's technology platform for the discovery, development, and commercialization of novel regulatory T cell ($T_{reg}$) therapies for autoimmune diseases. In connection with the agreement, the Company made a $45 million up-front payment and, in April 2023, the Company purchased an aggregate of $30 million of Sonoma preferred stock. Sonoma is also eligible to receive a $45 million development milestone payment. The Company and Sonoma will co-fund research and development activities and share equally any future commercial expenses and profits. The Company will have the option to lead late-stage development and commercialization on all products globally, with Sonoma retaining rights to co-promote all such products in the United States.

**First Quarter 2023 Financial Results**

***Revenues***

| *($ in millions)* | Q1 2023 | Q1 2022 | % Change |
|---|---|---|---|
| Net product sales: | | | |
| EYLEA - U.S. | $ 1,434 | $ 1,518 | (6%) |
| Libtayo - U.S. | 110 | 79 | 39% |
| Libtayo - ROW** | 67 | — | * |
| Praluent® - U.S. | 40 | 34 | 18% |
| Evkeeza - U.S. | 15 | 8 | 88% |
| Inmazeb® - U.S. | 2 | — | * |
| Total net product sales | 1,668 | 1,639 | 2% |
| Collaboration revenue: | | | |
| Sanofi | 798 | 631 | 26% |
| Bayer | 357 | 385 | (7%) |
| Roche | 222 | 216 | 3% |
| Other | 1 | — | * |
| Other revenue | 116 | 94 | 23% |
| Total revenues | $ 3,162 | $ 2,965 | 7% |
| Total revenues excluding Ronapreve[a][b] | $ 2,940 | $ 2,749 | 7% |

* Percentage not meaningful.

** Rest of world (ROW). Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States. Excluded from this line item is approximately $6 million of net product sales recorded by Sanofi in the first quarter of 2023 in connection with sales in certain markets (Sanofi records net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 is sold through to the end customers).

Net product sales of EYLEA in the U.S. decreased in the first quarter of 2023, compared to the first quarter in 2022, primarily due to an increase in sales-related deductions, partly offset by higher sales volume.

Sanofi collaboration revenue increased in the first quarter of 2023, compared to the first quarter of 2022, primarily due to the Company's share of profits from commercialization of antibodies, which were $637 million in the first quarter of 2023, compared to $415 million in the first quarter of 2022. The change in the Company's share of profits from commercialization of antibodies was driven by profits associated with higher Dupixent sales. Additionally, in the first quarter of 2022, the Company earned a $50 million sales-based milestone from Sanofi, which did not recur in the first quarter of 2023.

The Company recorded Roche collaboration revenue during the first quarter of 2023 and 2022 in connection with payments from Roche attributable to global gross profits from sales of Ronapreve ™.

Refer to Table 4 for a summary of collaboration revenue.

***Operating Expenses***

| | GAAP | | % Change | Non-GAAP[a] | | % Change |
|---|---|---|---|---|---|---|
| *($ in millions)* | Q1 2023 | Q1 2022 | | Q1 2023 | Q1 2022 | |
| Research and development (R&D) | $ 1,101 | $ 844 | 30% | $ 960 | $ 751 | 28% |
| Acquired in-process research and development (IPR&D) | $ 56 | $ 28 | 100% | * | * | n/a |
| Selling, general, and administrative (SG&A) | $ 601 | $ 450 | 34% | $ 515 | $ 389 | 32% |
| Cost of goods sold (COGS) | $ 208 | $ 207 | —% | $ 168 | $ 136 | 24% |
| Cost of collaboration and contract manufacturing (COCM) | $ 249 | $ 198 | 26% | * | * | n/a |
| Other operating (income) expense, net | $ (1) | $ (20) | (95%) | * | * | n/a |

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

- GAAP and non-GAAP R&D expenses increased in the first quarter of 2023, compared to the first quarter of 2022, driven by additional costs incurred in connection with higher headcount and headcount-related costs, the advancement of the Company's late-stage pipeline, and the impact of the 2022 amendments to the Sanofi collaboration agreements.
- 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. Acquired IPR&D for the first quarter of 2022 included a $20 million opt-in payment in connection with a product candidate under the Company's collaboration agreement with Adicet Bio, Inc.
- GAAP and non-GAAP SG&A expenses increased in the first quarter of 2023, compared to the first quarter of 2022, primarily due to an increase in commercialization-related expenses for Libtayo outside the U.S. (as effective July 1, 2022,

the Company became solely responsible for the commercialization of Libtayo worldwide), higher headcount and headcount-related costs, and higher contributions to an independent not-for-profit patient assistance organization. These increases were partly offset by a decrease in commercialization-related expenses for EYLEA.

- COCM expenses increased in the first quarter of 2023, compared to the first quarter of 2022, primarily due to the recognition of costs in connection with manufacturing commercial supplies for Sanofi related to Praluent outside the U.S. and Dupixent globally.

***Other Financial Information***

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $165 million in the first quarter of 2023, compared to $211 million of net unrealized losses in the first quarter of 2022. GAAP and Non-GAAP other income (expense) also included interest income of $95 million in the first quarter of 2023, compared to $19 million in the first quarter of 2022.

In the first quarter of 2023, the Company's GAAP effective tax rate (ETR) was 4.7%, compared to 8.3% in the first quarter of 2022. The decrease in the GAAP ETR was primarily due to a higher benefit of stock-based compensation. In the first quarter 2023, the non-GAAP ETR was 9.7%, compared to 11.6% in the first quarter of 2022.

GAAP net income per diluted share was $7.17 in the first quarter of 2023, compared to $8.61 in the first quarter of 2022. Non-GAAP net income per diluted share was $10.09 in the first quarter of 2023, compared to $11.49 in the first quarter of 2022. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

In January 2023, the Company's Board of Directors authorized a new share repurchase program to repurchase up to an additional $3.0 billion of the Company's common stock. During the first quarter of 2023, the Company repurchased shares of its common stock and recorded the cost of the shares, or $694 million, as Treasury Stock. As of March 31, 2023, an aggregate of $3.051 billion remained available for share repurchases under the Company's share repurchase programs.

***2023 Financial Guidance[(c)]***

The Company's full year 2023 financial guidance consists of the following components:

| | 2023 Guidance | |
|---|---|---|
| | **Prior** | **Updated** |
| GAAP R&D | $4.200–$4.435 billion | $4.225–$4.465 billion |
| Non-GAAP R&D[(a)] | $3.725–$3.925 billion | Unchanged |
| GAAP SG&A | $2.460–$2.650 billion | $2.490–$2.680 billion |
| Non-GAAP SG&A[(a)] | $2.130–$2.280 billion | Unchanged |
| GAAP gross margin on net product sales[(d)] | 88%–90% | 87%–89% |
| Non-GAAP gross margin on net product sales[(a)(d)] | 90%–92% | 89%–91% |
| COCM[(e)]* | $720–$800 million | $820–$880 million |
| Capital expenditures* | $825–$950 million | $800–$900 million |
| GAAP effective tax rate | 10%–12% | 8%–10% |
| Non-GAAP effective tax rate[(a)] | 11%–13% | 10%–12% |

* 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 2023 GAAP to non-GAAP financial guidance is included below:

| | Projected Range | |
|---|---|---|
| *($ in millions)* | **Low** | **High** |
| GAAP R&D | $ 4,225 | $ 4,465 |
| Stock-based compensation expense | 490 | 520 |
| Acquisition-related integration costs | 10 | 20 |
| Non-GAAP R&D | $ 3,725 | $ 3,925 |
| | | |
| GAAP SG&A | $ 2,490 | $ 2,680 |
| Stock-based compensation expense | 310 | 330 |
| Acquisition-related integration costs | 50 | 70 |
| Non-GAAP SG&A | $ 2,130 | $ 2,280 |
| | | |
| GAAP gross margin on net product sales | 87% | 89% |
| Stock-based compensation expense | 1% | 1% |
| Intangible asset amortization expense | 1% | 1% |
| Non-GAAP gross margin on net product sales | 89% | 91% |
| | | |
| GAAP ETR | 8% | 10% |

| | | |
|---|---|---|
| Income tax effect of GAAP to non-GAAP reconciling items | 2% | 2% |
| Non-GAAP ETR | 10% | 12% |

(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 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 integration-related expenses). 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 operations' ability to generate cash flows. 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 Regeneron 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. The Company records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States.

(c) The Company's 2023 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 first quarter 2023 financial and operating results on Thursday, May 4, 2023, 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 for 35 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all 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, pain, hematologic conditions, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center®, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about Regeneron, please visit www.regeneron.com or follow @Regeneron on Twitter.

**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® (aflibercept) Injection, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab), aflibercept 8 mg, pozelimab, odronextamab, itepekimab,

fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, 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, Praluent, and REGEN-COV® (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil litigation initiated by 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, 2022 and its Form 10-Q for the quarterly period ended March 31, 2023. 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 (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

**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, 2023 | December 31, 2022 |
|---|---|---|
| Assets: | | |
| Cash and marketable securities | $ 15,026.3 | $ 14,334.1 |
| Accounts receivable, net | 5,118.6 | 5,328.7 |
| Inventories | 2,424.7 | 2,401.9 |
| Property, plant, and equipment, net | 3,880.9 | 3,763.0 |
| Intangible assets, net | 928.7 | 915.5 |
| Deferred tax assets | 1,924.9 | 1,723.7 |
| Other assets | 755.8 | 747.6 |
| Total assets | $ 30,059.9 | $ 29,214.5 |

| | | |
|---|---|---|
| Liabilities and stockholders' equity: | | |
| Accounts payable, accrued expenses, and other liabilities | $ 3,351.1 | $ 3,301.4 |
| Finance lease liabilities | 720.0 | 720.0 |
| Deferred revenue | 511.8 | 547.7 |
| Long-term debt | 1,981.8 | 1,981.4 |
| Stockholders' equity | 23,495.2 | 22,664.0 |
| Total liabilities and stockholders' equity | $ 30,059.9 | $ 29,214.5 |

TABLE 2

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Revenues: | | |
| Net product sales | $ 1,668.0 | $ 1,638.6 |
| Collaboration revenue | 1,378.1 | 1,232.5 |
| Other revenue | 116.0 | 94.0 |
| | 3,162.1 | 2,965.1 |
| Expenses: | | |
| Research and development | 1,101.2 | 843.8 |
| Acquired in-process research and development | 56.1 | 28.1 |
| Selling, general, and administrative | 601.1 | 450.0 |
| Cost of goods sold | 208.4 | 207.3 |
| Cost of collaboration and contract manufacturing | 249.1 | 197.6 |
| Other operating (income) expense, net | (0.5) | (20.2) |
| | 2,215.4 | 1,706.6 |
| Income from operations | 946.7 | 1,258.5 |
| Other income (expense): | | |
| Other (expense) income, net | (70.7) | (183.8) |
| Interest expense | (18.0) | (13.6) |
| | (88.7) | (197.4) |
| Income before income taxes | 858.0 | 1,061.1 |
| Income tax expense | 40.2 | 87.6 |
| Net income | $ 817.8 | $ 973.5 |
| Net income per share - basic | $ 7.64 | $ 9.12 |
| Net income per share - diluted | $ 7.17 | $ 8.61 |
| Weighted average shares outstanding - basic | 107.1 | 106.8 |
| Weighted average shares outstanding - diluted | 114.0 | 113.1 |

TABLE 3

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| GAAP R&D | $ 1,101.2 | $ 843.8 |
| R&D: Stock-based compensation expense | 139.5 | 92.4 |
| R&D: Acquisition-related integration costs | 1.6 | — |

| | | |
|---|---|---|
| Non-GAAP R&D | $ 960.1 | $ 751.4 |
| | | |
| GAAP SG&A | $ 601.1 | $ 450.0 |
| SG&A: Stock-based compensation expense | 76.8 | 60.7 |
| SG&A: Acquisition-related integration costs | 9.6 | — |
| Non-GAAP SG&A | $ 514.7 | $ 389.3 |
| | | |
| GAAP COGS | $ 208.4 | $ 207.3 |
| COGS: Stock-based compensation expense | 22.4 | 13.8 |
| COGS: Intangible asset amortization expense | 18.5 | — |
| COGS: Charges related to REGEN-COV | — | 58.0 |
| Non-GAAP COGS | $ 167.5 | $ 135.5 |
| | | |
| GAAP other income (expense), net | $ (88.7) | $ (197.4) |
| Other income/expense: Losses (gains) on investments, net | 166.6 | 204.5 |
| Non-GAAP other income (expense), net | $ 77.9 | $ 7.1 |
| | | |
| GAAP net income | $ 817.8 | $ 973.5 |
| Total of GAAP to non-GAAP reconciling items above | 435.0 | 429.4 |
| Income tax effect of GAAP to non-GAAP reconciling items | (85.3) | (85.3) |
| Non-GAAP net income | $ 1,167.5 | $ 1,317.6 |
| | | |
| Non-GAAP net income per share - basic | $ 10.90 | $ 12.34 |
| Non-GAAP net income per share - diluted | $ 10.09 | $ 11.49 |
| | | |
| *Shares used in calculating:* | | |
| Non-GAAP net income per share - basic | 107.1 | 106.8 |
| Non-GAAP net income per share - diluted | 115.7 | 114.7 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| *Revenue reconciliation:* | | |
| Total revenues | $ 3,162.1 | $ 2,965.1 |
| Global gross profit payment from Roche in connection with sales of Ronapreve | 222.2 | 216.3 |
| Total revenues excluding Ronapreve | $ 2,939.9 | $ 2,748.8 |
| | | |
| *Effective tax rate reconciliation:* | | |
| GAAP ETR | 4.7% | 8.3% |
| Income tax effect of GAAP to non-GAAP reconciling items | 5.0% | 3.3% |
| Non-GAAP ETR | 9.7% | 11.6% |
| | | |
| *Free cash flow reconciliation:* | | |
| Net cash provided by operating activities | $ 1,367.6 | $ 2,101.7 |
| Capital expenditures | (178.2) | (141.8) |
| Free cash flow | $ 1,189.4 | $ 1,959.9 |

TABLE 4

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| *Sanofi collaboration revenue:* | | |
| Antibody: | | |

| | | |
|---|---|---|
| Regeneron's share of profits in connection with commercialization of antibodies | $ 636.5 | $ 415.3 |
| Sales-based milestones earned | — | 50.0 |
| Reimbursement for manufacturing of commercial supplies | 161.9 | 160.8 |
| Immuno-oncology: | | |
| Regeneron's share of profits in connection with commercialization of Libtayo outside the United States | — | 2.8 |
| Reimbursement for manufacturing of ex-U.S. commercial supplies | — | 2.0 |
| Total Sanofi collaboration revenue | 798.4 | 630.9 |
| *Bayer collaboration revenue:* | | |
| Regeneron's share of profits in connection with commercialization of EYLEA outside the United States | 331.6 | 338.4 |
| Reimbursement for manufacturing of ex-U.S. commercial supplies | 25.3 | 25.0 |
| One-time payment in connection with change in Japan arrangement | — | 21.9 |
| Total Bayer collaboration revenue | 356.9 | 385.3 |
| *Other collaboration revenue:* | | |
| Global gross profit payment from Roche in connection with sales of Ronapreve | 222.2 | 216.3 |
| Other | 0.6 | — |
| Total collaboration revenue | $ 1,378.1 | $ 1,232.5 |

TABLE 5

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

| | Three Months Ended March 31, | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2023 | | | 2022 | | | % Change |
| | U.S. | ROW | Total | U.S. | ROW | Total | (Total Sales) |
| EYLEA[a] | $ 1,433.8 | $ 847.1 | $ 2,280.9 | $ 1,517.6 | $ 868.5 | $ 2,386.1 | (4%) |
| Dupixent[b] | $ 1,898.1 | $ 586.9 | $ 2,485.0 | $ 1,325.6 | $ 484.8 | $ 1,810.4 | 37% |
| Libtayo[c] | $ 109.7 | $ 72.9 | $ 182.6 | $ 78.9 | $ 45.8 | $ 124.7 | 46% |
| Praluent[d] | $ 40.2 | $ 105.7 | $ 145.9 | $ 33.6 | $ 77.8 | $ 111.4 | 31% |
| REGEN-COV[e] | $ — | $ 613.2 | $ 613.2 | $ — | $ 635.6 | $ 635.6 | (4%) |
| Kevzara[b] | $ 39.2 | $ 39.3 | $ 78.5 | $ 57.0 | $ 49.4 | $ 106.4 | (26%) |
| Other products[f] | $ 18.1 | $ 16.5 | $ 34.6 | $ 9.9 | $ 20.4 | $ 30.3 | 14% |

[a] Regeneron records net product sales of EYLEA in the United States. Bayer records net product sales of EYLEA outside the United States. The Company records its share of profits/losses in connection with sales of EYLEA outside the United States.

[b] Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits/losses in connection with global sales of Dupixent and Kevzara.

[c] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. 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 is approximately $6 million of net product sales recorded by Sanofi in the first quarter of 2023 in connection with sales in certain markets outside the United States (Sanofi records net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 is sold through to the end customers).

[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] Regeneron records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States. The parties share gross profits from global sales of REGEN-COV and Ronapreve 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 2023 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 $40 million for the fourth quarter of 2022.

REGENERON

Source: Regeneron Pharmaceuticals, Inc.