Regeneron Reports Third Quarter 2023 Financial and Operating Results

November 2, 2023 at 6:30 AM EDT

- *Third quarter 2023 revenues increased 15% to $3.36 billion versus third quarter 2022*
- *Third quarter 2023 Dupixent® global net sales (recorded by Sanofi) increased 33% to $3.10 billion versus third quarter 2022*
- *Third quarter 2023 U.S. net sales for EYLEA® and EYLEA HD were $1.49 billion, including $43 million from EYLEA HD*
- *Third quarter 2023 Libtayo® global net sales increased 62% to $232 million versus third quarter 2022*
- *Third quarter 2023 GAAP diluted EPS of $8.89 and non-GAAP diluted EPS[(a)] of $11.59; includes unfavorable $0.77 impact from acquired IPR&D charge*
- *FDA approved EYLEA HD for wet age-related macular degeneration (wAMD), diabetic macular edema (DME), and diabetic retinopathy (DR) and Veopoz ™ for CHAPLE disease*
- *Two-year results reported for EYLEA HD from pivotal PULSAR trial demonstrated durable vision gains at extended dosing intervals in wAMD*
- *FDA accepted for priority review BLA for odronextamab for follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) and sBLA for Dupixent in eosinophilic esophagitis (EoE) in children aged 1 to 11 years of age*
- *Acquisition of Decibel Therapeutics completed, strengthening genetic medicines portfolio*

TARRYTOWN, N.Y., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2023 and provided a business update.

"We have continued our momentum in the third quarter of 2023 with double-digit year-over-year revenue growth, driven by strong Dupixent and Libtayo performance, as well as strong initial uptake of EYLEA HD following its late August launch," said Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron. "We are also making significant progress across our diversified pipeline, with FDA priority review designations for odronextamab in relapsed/refractory (R/R) follicular lymphoma and R/R diffuse large B-cell lymphoma as well as for Dupixent in pediatric eosinophilic esophagitis, while also adding a promising gene therapy platform to our portfolio through the recent acquisition of Decibel Therapeutics."

Financial Highlights

($ in millions, except per share data)	Q3 2023	Q3 2022	% Change
Total revenues	$ 3,363	$ 2,936	15%
GAAP net income	$ 1,008	$ 1,316	(23%)
GAAP net income per share - diluted	$ 8.89	$ 11.66	(24%)
Non-GAAP net income[(a)]	$ 1,329	$ 1,270	5%
Non-GAAP net income per share - diluted[(a)]	$ 11.59	$ 11.14	4%

"Our third quarter financial results reflect robust execution across the enterprise, including notable pipeline advances and strong commercial performance," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We also continued to deliver on our capital allocation priorities, primarily investing in internal and external innovation coupled with opportunistic share repurchases."

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:

EYLEA HD (aflibercept) 8 mg

- In August 2023, the U.S. Food and Drug Administration (FDA) approved EYLEA HD for the treatment of patients with wAMD, DME, and DR.
- The Company announced top-line, two-year (96 weeks) data from the pivotal PULSAR trial in patients with wAMD. The longer-term data follow the positive two-year results from the PHOTON trial in DME, with PULSAR similarly demonstrating that the vast majority of patients with wAMD were able to maintain or further extend the dosing intervals. In addition, visual gains for EYLEA HD remained largely consistent with those observed in the first year of the trial. In PULSAR, the safety of EYLEA HD continued to be similar to EYLEA through two years and remained consistent with the known safety profile of EYLEA from previous clinical trials for wAMD. These results were also presented at the 23rd EURETINA Congress in

October 2023.

Dupixent (dupilumab)

- In September 2023, the Ministry of Health, Labour and Welfare (MHLW) in Japan approved Dupixent for the treatment of pediatric and adolescent patients with atopic dermatitis.
- The FDA accepted for priority review the supplemental Biologics License Application (sBLA) for the treatment of children aged 1 to 11 years with EoE, with a target action date of January 31, 2024. The Company and Sanofi also presented, at the American College of Gastroenterology (ACG) 2023 Annual Scientific Meeting, positive results from a Phase 3 trial that showed consistent efficacy and safety for up to one year (52 weeks) in children aged 1 to 11 years with EoE.
- In October 2023, the FDA issued a Complete Response Letter (CRL) for the sBLA for Dupixent in chronic spontaneous urticaria (CSU). The CRL states that additional efficacy data are required to support an approval; it did not identify any issues with safety or manufacturing. An ongoing Phase 3 clinical trial (in biologic-naïve patients) continues to enroll patients, with results expected in late 2024.
- Based on recent feedback from the FDA, in addition to the positive results of the Phase 3 BOREAS study, a positive interim analysis of the replicate Phase 3 NOTUS study in chronic obstructive pulmonary disease (COPD) would enable an sBLA submission. The independent data monitoring committee will conduct an interim analysis of the NOTUS study later this year.

Oncology Programs

- In September 2023, the FDA accepted for priority review the BLA for odronextamab, a bispecific antibody targeting CD20 and CD3, to treat adult patients with relapsed/refractory FL and relapsed/refractory DLBCL who have progressed after at least two prior systemic therapies, with a target action date of March 31, 2024. A regulatory application for odronextamab has also been submitted in the European Union (EU).
- Phase 3 studies were initiated for odronextamab in earlier lines of FL and DLBCL.
- The FDA granted Fast Track designation to fianlimab, an antibody to LAG-3, in combination with Libtayo (cemiplimab) for the first-line treatment of patients with metastatic melanoma (for which a Phase 3 study is ongoing).
- A Phase 3 study was initiated for linvoseltamab, a bispecific antibody targeting BCMA and CD3, in multiple myeloma.
- The Company presented key secondary endpoints, demonstrating encouraging event-free survival, from a Phase 2 trial with Libtayo as a neoadjuvant monotherapy in cutaneous squamous cell carcinoma (CSCC) at the European Society for Medical Oncology (ESMO) Congress 2023. These results were also concurrently published in *The Lancet Oncology*.

Other Programs

- The FDA approved Veopoz (pozelimab-bbfg), an antibody to C5, for the treatment of adult and pediatric patients 1 year of age and older with CHAPLE disease, also known as CD55-deficient protein-losing enteropathy. CHAPLE is an ultra-rare hereditary disease that can cause potentially life-threatening gastrointestinal and cardiovascular symptoms.
- The Company announced preliminary, positive safety and efficacy results from the first patient (<2 years of age) dosed in the Phase 1/2 trial of DB-OTO, an AAV-based gene therapy, in children with profound genetic hearing loss due to mutations of the otoferlin gene.

Business Development Updates

- In September 2023, the Company completed its acquisition of Decibel Therapeutics, Inc. and paid $101 million in cash, and may also pay up to a maximum of approximately $97 million to Decibel shareholders upon achievement of certain clinical development and regulatory milestones for DB-OTO within specified time periods. The acquisition builds upon a prior collaboration between the companies and includes several ongoing gene therapy programs targeting different forms of congenital, monogenic hearing loss, including DB-OTO.
- In August 2023, the Company expanded its agreement with the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) to support clinical development, clinical manufacturing, and the regulatory licensure process of a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection. The new contract has an estimated value of up to approximately $326 million of government funding for certain development activities.
- In September 2023, the Company and Intellia Therapeutics, Inc. expanded their existing collaboration to develop additional *in vivo* CRISPR-based gene editing therapies focused on neurological and muscular diseases. The collaboration will leverage the Company's proprietary antibody-targeted adeno-associated virus (AAV) vectors and delivery systems and Intellia's proprietary Nme2 CRISPR/Cas9 (Nme2Cas9) systems adapted for viral vector delivery and designed to precisely modify a target gene.

Corporate Updates

- The Company is participating in Together for CHANGE™, a national health and education equity initiative established by

Nashville, Tennessee-based Meharry Medical College. The Together for CHANGE initiative seeks to address inequities in science, technology, engineering, and mathematics (STEM) careers and research. In addition, the Company announced a five-year, $5 million strategic investment to bolster Nashville's STEM ecosystem through high-quality, equitable engagement programs for students and science teachers.

- The Company announced that Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron, will retire in February 2024. Christopher Fenimore, current Senior Vice President, Head of Accounting and Controller at Regeneron, will succeed Mr. Landry as Chief Financial Officer upon his retirement.
- The Company announced that Kathryn Guarini, Ph.D., and David P. Schenkein, M.D., joined the Company's Board of Directors effective September 8, 2023. Dr. Guarini recently retired as Chief Information Officer of IBM. Dr. Schenkein is a General Partner and Co-lead of the Life Sciences team at GV (Google Ventures).

Third Quarter 2023 Financial Results

Revenues

($ in millions)	Q3 2023	Q3 2022	% Change
Net product sales:			
EYLEA - U.S.	$ 1,448	$ 1,629	(11%)
EYLEA HD - U.S.	43	—	*
Libtayo - Global**	232	126	84%
Praluent® - U.S.	40	30	33%
Evkeeza® - U.S.	19	13	46%
Inmazeb® - U.S.	4	3	33%
Total net product sales	1,786	1,801	(1%)
Collaboration revenue:			
Sanofi	1,065	711	50%
Bayer	377	333	13%
Other	(3)	6	*
Other revenue	138	85	62%
Total revenues	$ 3,363	$ 2,936	15%

* Percentage not meaningful

** Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States. Excluded from the third quarter of 2022 is approximately $17 million of net product sales recorded by Sanofi in connection with sales in certain markets (Sanofi recorded net product sales in such markets during a transition period). The percentage change shown would be 62% if such sales were included (see Table 5).

Net product sales of EYLEA in the U.S. decreased in the third quarter of 2023, compared to the third quarter of 2022, primarily due to a lower net selling price driven by changing market dynamics, including increased competition. In August 2023, the FDA approved EYLEA HD and the Company commenced recording sales in the United States in the third quarter of 2023.

Sanofi collaboration revenue increased in the third quarter of 2023, compared to the third quarter of 2022, primarily due to the Company's share of profits from commercialization of antibodies, which were $863 million in the third quarter of 2023, compared to $551 million in the third quarter of 2022. 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. In addition, during the third quarter of 2023, the Company earned the final $50 million sales-based milestone from Sanofi upon aggregate annual sales of antibodies outside the U.S. exceeding $3.0 billion on a rolling twelve-month basis.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue during the third quarter of 2023 included the recognition of $34 million of revenue in connection with the Company's agreement with BARDA to fund certain costs for a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection.

Operating Expenses

($ in millions)	GAAP		%	Non-GAAP[(a)]		%
	Q3 2023	Q3 2022	Change	Q3 2023	Q3 2022	Change
Research and development (R&D)	$ 1,075	$ 911	18%	$ 954	$ 817	17%
Acquired in-process research and development (IPR&D)	$ 100	$ —	**	*	*	n/a
Selling, general, and administrative (SG&A)	$ 641	$ 529	21%	$ 534	$ 467	14%
Cost of goods sold (COGS)	$ 225	$ 141	60%	$ 181	$ 109	66%
Cost of collaboration and contract manufacturing (COCM)	$ 212	$ 177	20%	*	*	n/a
Other operating (income) expense, net	$ (1)	$ (46)	(98%)	*	*	n/a

* 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 2023, compared to the third 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 increased manufacturing activity associated with the Company's product candidates.
- Acquired IPR&D expense in the third quarter of 2023 related to a $100 million development milestone in connection with the Phase 1 ALN-APP program, which is in collaboration with Alnylam Pharmaceuticals, Inc.
- GAAP and non-GAAP SG&A expenses increased in the third quarter of 2023, compared to the third quarter of 2022, primarily due to higher headcount and headcount-related costs and higher contributions to an independent not-for-profit patient assistance organization.
- Other operating (income) expense, net, decreased in the third quarter of 2023, compared to the third quarter of 2022, due to the recognition of $44 million of income in 2022 that did not recur during 2023 as a result of discontinuing further clinical development of fasinumab related to the Company's Teva and Mitsubishi Tanabe Pharma collaborative arrangements.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $100 million in the third quarter of 2023, compared to $254 million of net unrealized gains in the third quarter of 2022. GAAP and Non-GAAP other income (expense) also included interest income of $134 million in the third quarter of 2023, compared to $43 million in the third quarter of 2022.

In the third quarter of 2023, the Company's GAAP effective tax rate (ETR) was 9.3%, compared to 12.9% in the third quarter of 2022. In the third quarter of 2023, the non-GAAP ETR was 11.9%, compared to 12.1% in the third quarter of 2022.

GAAP net income per diluted share was $8.89 in the third quarter of 2023, compared to $11.66 in the third quarter of 2022. Non-GAAP net income per diluted share was $11.59 in the third quarter of 2023, compared to $11.14 in the third quarter of 2022. 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 2023, the Company repurchased shares of its common stock and recorded the cost of the shares, or $507 million, as Treasury Stock. As of September 30, 2023, $1.8 billion remained available for share repurchases under the Company's share repurchase program.

2023 Financial Guidance[(c)]

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

	2023 Guidance	
	Prior	**Updated**
GAAP R&D	$4.315–$4.455 billion	$4.370–$4.455 billion
Non-GAAP R&D[(a)]	$3.825–$3.925 billion	$3.875–$3.925 billion
GAAP SG&A	$2.540–$2.680 billion	$2.585–$2.685 billion
Non-GAAP SG&A[(a)]	$2.180–$2.280 billion	$2.210–$2.270 billion
GAAP gross margin on net product sales[(d)]	87%–89%	87%–88%
Non-GAAP gross margin on net product sales[(a)(d)]	89%–91%	89%–90%
COCM[(e)*]	$820–$880 million	$840–$880 million
Capital expenditures[*]	$760–$830 million	$660–$700 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 2023 GAAP to non-GAAP financial guidance is included below:

($ in millions)	Projected Range	
	Low	**High**
GAAP R&D	$ 4,370	$ 4,455
Stock-based compensation expense	475	500
Acquisition and integration costs	20	30
Non-GAAP R&D	$ 3,875	$ 3,925

GAAP SG&A	$ 2,585	$ 2,685
Stock-based compensation expense	300	320
Acquisition and integration costs	75	95
Non-GAAP SG&A	$ 2,210	$ 2,270
GAAP gross margin on net product sales	87%	88%
Stock-based compensation expense	1%	1%
Intangible asset amortization expense	1%	1%
Acquisition and integration costs	<1 %	<1 %
Charges related to REGEN-COV	<(1 %)	<(1 %)
Non-GAAP gross margin on net product sales	89%	90%
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 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 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 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. 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 third quarter 2023 financial and operating results on Thursday, November 2, 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, 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 LinkedIn.

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, EYLEA® HD (aflibercept) Injection 8 mg, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab), Veopoz ™ (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 (such as any potential regulatory approval of Dupixent in chronic obstructive pulmonary disease); 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 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 September 30, 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 (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, 2023	December 31, 2022
Assets:		
Cash and marketable securities	$ 15,692.1	$ 14,334.1
Accounts receivable, net	5,584.5	5,328.7
Inventories	2,562.0	2,401.9
Property, plant, and equipment, net	4,006.1	3,763.0
Intangible assets, net	1,017.2	915.5
Deferred tax assets	2,316.8	1,723.7
Other assets	984.6	747.6
Total assets	$ 32,163.3	$ 29,214.5
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 4,013.7	$ 3,301.4
Finance lease liabilities	720.0	720.0
Deferred revenue	542.6	547.7
Long-term debt	1,982.6	1,981.4
Stockholders' equity	24,904.4	22,664.0
Total liabilities and stockholders' equity	$ 32,163.3	$ 29,214.5

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,	
	2023	2022	2023	2022
Revenues:				
Net product sales	$ 1,786.1	$ 1,801.4	$ 5,226.2	$ 5,194.4
Collaboration revenue	1,438.3	1,050.6	4,133.1	3,326.7
Other revenue	138.3	84.2	323.6	237.4
	3,362.7	2,936.2	9,682.9	8,758.5
Expenses:				
Research and development	1,075.3	911.3	3,261.8	2,549.4
Acquired in-process research and development	100.0	—	156.1	225.1
Selling, general, and administrative	640.5	529.1	1,893.6	1,455.4
Cost of goods sold	224.5	141.3	625.3	497.8
Cost of collaboration and contract manufacturing	211.9	176.5	673.5	522.0
Other operating (income) expense, net	(0.5)	(45.7)	(1.6)	(83.3)
	2,251.7	1,712.5	6,608.7	5,166.4
Income from operations	1,111.0	1,223.7	3,074.2	3,592.1
Other income (expense):				
Other income (expense), net	17.6	301.4	32.2	(16.0)
Interest expense	(17.8)	(15.3)	(54.7)	(42.0)
	(0.2)	286.1	(22.5)	(58.0)

Income before income taxes	1,110.8	1,509.8	3,051.7	3,534.1
Income tax expense	103.0	194.1	257.7	392.8
Net income	$ 1,007.8	$ 1,315.7	$ 2,794.0	$ 3,141.3
Net income per share - basic	$ 9.48	$ 12.31	$ 26.16	$ 29.30
Net income per share - diluted	$ 8.89	$ 11.66	$ 24.57	$ 27.73
Weighted average shares outstanding - basic	106.3	106.9	106.8	107.2
Weighted average shares outstanding - diluted	113.4	112.8	113.7	113.3

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,	
	2023	**2022**	**2023**	**2022**
GAAP R&D	$ 1,075.3	$ 911.3	$ 3,261.8	$ 2,549.4
Stock-based compensation expense	107.4	93.7	356.0	275.8
Acquisition and integration costs	13.5	1.0	17.7	15.6
Non-GAAP R&D	$ 954.4	$ 816.6	$ 2,888.1	$ 2,258.0
GAAP SG&A	$ 640.5	$ 529.1	$ 1,893.6	$ 1,455.4
Stock-based compensation expense	74.4	59.8	224.5	178.0
Acquisition and integration costs	32.4	2.0	58.5	3.1
Non-GAAP SG&A	$ 533.7	$ 467.3	$ 1,610.6	$ 1,274.3
GAAP COGS	$ 224.5	$ 141.3	$ 625.3	$ 497.8
Stock-based compensation expense	22.1	12.8	64.1	39.2
Acquisition and integration costs	0.9	—	1.4	—
Intangible asset amortization expense	20.7	15.1	59.0	15.1
Charges related to REGEN-COV	—	4.9	(10.0)	62.9
Non-GAAP COGS	$ 180.8	$ 108.5	$ 510.8	$ 380.6
GAAP other income (expense), net	$ (0.2)	$ 286.1	$ (22.5)	$ (58.0)
Losses (gains) on investments, net	127.0	(253.5)	324.5	117.3
Non-GAAP other income (expense), net	$ 126.8	$ 32.6	$ 302.0	$ 59.3
GAAP net income	$ 1,007.8	$ 1,315.7	$ 2,794.0	$ 3,141.3
Total of GAAP to non-GAAP reconciling items above	398.4	(64.2)	1,095.7	707.0
Income tax effect of GAAP to non-GAAP reconciling items	(77.1)	18.9	(211.5)	(133.4)
Non-GAAP net income	$ 1,329.1	$ 1,270.4	$ 3,678.2	$ 3,714.9
Non-GAAP net income per share - basic	$ 12.50	$ 11.88	$ 34.44	$ 34.65
Non-GAAP net income per share - diluted	$ 11.59	$ 11.14	$ 31.90	$ 32.39
Shares used in calculating:				
Non-GAAP net income per share - basic	106.3	106.9	106.8	107.2
Non-GAAP net income per share - diluted	114.7	114.0	115.3	114.7

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue reconciliation:				
Total revenues	$ 3,362.7	$ 2,936.2	$ 9,682.9	$ 8,758.5
Global gross profit payment from Roche in connection with sales of Ronapreve	—	6.4	222.2	230.9
Other	(5.7)	—	(9.5)	—
Total revenues excluding Ronapreve	$ 3,368.4	$ 2,929.8	$ 9,470.2	$ 8,527.6
Effective tax rate reconciliation:				
GAAP ETR	9.3%	12.9%	8.4%	11.1%
Income tax effect of GAAP to non-GAAP reconciling items	2.6%	(0.8%)	2.9%	1.3%
Non-GAAP ETR	11.9%	12.1%	11.3%	12.4%

	Nine Months Ended September 30,	
	2023	**2022**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 3,504.3	$ 3,295.0
Capital expenditures	(467.2)	(437.9)
Free cash flow	$ 3,037.1	$ 2,857.1

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 863.0	$ 551.1	$ 2,250.6	$ 1,463.0
Sales-based milestones earned	50.0	—	50.0	50.0
Reimbursement for manufacturing of commercial supplies	151.5	160.5	506.0	466.8
Other	—	(0.2)	—	28.7
Immuno-oncology	—	—	—	11.3
Total Sanofi collaboration revenue	1,064.5	711.4	2,806.6	2,019.8
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	349.9	315.3	1,031.0	993.4
Reimbursement for manufacturing of ex-U.S. commercial supplies	27.2	17.5	79.7	60.3
One-time payment in connection with change in Japan arrangement	—	—	—	21.9
Total Bayer collaboration revenue	377.1	332.8	1,110.7	1,075.6
Other collaboration revenue:				
Global gross profit payment from Roche in connection with sales of Ronapreve	—	6.4	222.2	230.9
Other	(3.3)	—	(6.4)	0.4
Total collaboration revenue	$ 1,438.3	$ 1,050.6	$ 4,133.1	$ 3,326.7

TABLE 5

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

	Three Months Ended September 30,						
	2023			2022			% Change
	U.S.	ROW[g]	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,448.2	$ 872.2	$ 2,320.4	$ 1,629.4	$ 816.9	$ 2,446.3	(5%)
EYLEA HD[a]	$ 42.7	$ —	$ 42.7	$ —	$ —	$ —	(h)
Dupixent[b]	$ 2,366.3	$ 731.3	$ 3,097.6	$ 1,824.0	$ 506.1	$ 2,330.1	33%
Libtayo[c]	$ 144.1	$ 88.3	$ 232.4	$ 94.7	$ 48.5	$ 143.2	62%
Praluent[d]	$ 40.4	$ 125.1	$ 165.5	$ 29.7	$ 84.0	$ 113.7	46%
REGEN-COV[e]	$ —	$ —	$ —	$ —	$ 22.8	$ 22.8	(100%)
Kevzara[b]	$ 52.4	$ 43.3	$ 95.7	$ 53.1	$ 35.0	$ 88.1	9%
Other products[f]	$ 23.4	$ 15.5	$ 38.9	$ 17.5	$ 14.7	$ 32.2	21%

	Nine Months Ended September 30,						
	2023			2022			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 4,382.1	$ 2,605.6	$ 6,987.7	$ 4,768.2	$ 2,544.2	$ 7,312.4	(4%)
EYLEA HD[a]	$ 42.7	$ —	$ 42.7	$ —	$ —	$ —	(h)
Dupixent[b]	$ 6,369.6	$ 2,002.4	$ 8,372.0	$ 4,731.7	$ 1,500.6	$ 6,232.3	34%
Libtayo[c]	$ 384.0	$ 241.0	$ 625.0	$ 264.5	$ 144.7	$ 409.2	53%
Praluent[d]	$ 121.1	$ 330.6	$ 451.7	$ 94.5	$ 239.5	$ 334.0	35%
REGEN-COV[e]	$ —	$ 613.2	$ 613.2	$ —	$ 681.2	$ 681.2	(10%)
Kevzara[b]	$ 148.5	$ 125.2	$ 273.7	$ 153.1	$ 123.7	$ 276.8	(1%)
Other products[f]	$ 64.0	$ 48.9	$ 112.9	$ 39.5	$ 54.1	$ 93.6	21%

[a] Regeneron records net product sales of EYLEA and EYLEA HD 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 for the nine months ended September 30, 2023 is $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 until inventory on hand as of July 1, 2022 had been 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 "Third 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 $54 million for the second quarter of 2023.

[g] Rest of world (ROW)

[h] Percentage not meaningful

Source: Regeneron Pharmaceuticals, Inc.