UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 3, 2023 (August 3, 2023)

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 August 3, 2023, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 30, 2023. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information included or incorporated in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release, dated August 3, 2023, Reporting Second Quarter 2023 Financial and Operating Results.

104 Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 3, 2023 REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa
Name: Joseph J. LaRosa
Title: Executive Vice President, General Counsel and Secretary

REGENERON

Press Release

Regeneron Reports Second Quarter 2023 Financial and Operating Results

- *Second quarter 2023 revenues increased 11% to $3.16 billion versus second quarter 2022*
- *Second quarter 2023 Dupixent® global net sales (recorded by Sanofi) increased 33% to $2.79 billion versus second quarter 2022*
- *Second quarter 2023 EYLEA® U.S. net sales were $1.50 billion*
- *Second quarter 2023 GAAP diluted EPS of $8.50 and non-GAAP diluted EPS[a] of $10.24*
- *Two-year results reported for aflibercept 8 mg from pivotal PHOTON trial demonstrated durable vision gains at extended dosing intervals in diabetic macular edema (DME)*
- *Aflibercept 8 mg BLA decision anticipated in third quarter 2023*

Tarrytown, New York (August 3, 2023) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2023 and provided a business update.

"Regeneron delivered strong financial results in the second quarter of 2023 through increasingly diversified revenue streams, and we remain well-positioned for long-term growth," said Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron. "In the past months, we have continued to advance our pipeline, in particular aflibercept 8 mg which we are progressing towards a potential FDA decision in the third quarter and for which we shared unprecedented two-year results in the pivotal PHOTON trial demonstrating durable vision gains at extended dosing intervals in patients with diabetic macular edema."

Financial Highlights

($ in millions, except per share data)	Q2 2023	Q2 2022	% Change
Total revenues	$ 3,158	$ 2,857	11 %
GAAP net income	$ 968	$ 852	14 %
GAAP net income per share - diluted	$ 8.50	$ 7.47	14 %
Non-GAAP net income[a]	$ 1,182	$ 1,127	5 %
Non-GAAP net income per share - diluted[a]	$ 10.24	$ 9.77	5 %

"I am pleased with the performance of our business in the second quarter of 2023, including incremental pipeline progress and exceptional commercial execution," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We continue to prioritize internal investments while allocating additional capital to opportunistic share repurchases and potential business development."

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

- In June 2023, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for aflibercept 8 mg for the treatment of patients with neovascular age-related macular degeneration (wet AMD), DME, and diabetic retinopathy (DR). The CRL was issued solely due to unresolved observations resulting from an FDA inspection at a third-party contract manufacturing organization, Catalent, that the Company engaged to complete vial-filling for aflibercept 8 mg. The CRL did not identify any issues with the aflibercept 8 mg clinical efficacy or safety profile, trial design, labeling, or drug substance manufacturing, and no additional clinical data or trials have been requested. The FDA has informed the Company and Catalent that certain manufacturing data and other information are required from Catalent to allow the FDA to approve aflibercept 8 mg; the Company expects that these data and information will be submitted to the FDA by mid-August 2023. The FDA has stated that it intends to prioritize the review of this submission, and therefore the Company anticipates the FDA will take action on the aflibercept 8 mg BLA during the third quarter of 2023.
- In June 2023, the Company announced top-line, two-year (96 weeks) data for aflibercept 8 mg from the pivotal PHOTON trial in patients with DME. The longer-term data among aflibercept 8 mg patients who completed the trial demonstrated that the vast majority of patients were able to maintain or further extend the dosing intervals through two years. In addition, visual gains for aflibercept 8 mg remained consistent with those observed in the first year of the trial. In PHOTON, the safety of aflibercept 8 mg continued to be similar to EYLEA through two years and remained consistent with the known safety profile of EYLEA from previous clinical trials for DME. Results from the PHOTON study were presented at the American Society of Retina Specialists annual meeting in July 2023.
- The two-year data from the pivotal PULSAR trial for aflibercept 8 mg in wet AMD continue to be expected in the third quarter of 2023.
- In May 2023, Bayer announced that it initiated a Phase 3 study to evaluate the efficacy and safety of aflibercept 8 mg at extended dosing intervals compared to the standard of care, EYLEA, in macular edema following retinal vein occlusion (RVO).

Dupixent (dupilumab)

- The FDA granted Breakthrough Therapy designation for uncontrolled COPD with an eosiniphilic phenotype based on the positive results of the Phase 3 BOREAS study. Based on ongoing discussions with the FDA, the Company expects that in addition to the BOREAS study results, data from the replicate Phase 3 NOTUS study will be needed to support an sBLA, and such data requirements remain under discussion with the FDA. The Company expects final results for the NOTUS study in mid-2024.

- The Company and Sanofi presented positive Phase 3 results from the BOREAS trial in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled COPD and evidence of type 2 inflammation at the 2023 American Thoracic Society International Conference. The results were also published in the *New England Journal of Medicine*.
- In June 2023, the Ministry of Health, Labour and Welfare (MHLW) in Japan approved Dupixent for the treatment of adult patients with prurigo nodularis.

Oncology Programs

- The Company announced promising data from three independent expansion cohorts of a Phase 1 trial for fianlimab, an antibody to LAG-3, in combination with Libtayo® (cemiplimab) in adults with advanced melanoma, which were also presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. These results demonstrated that the combination led to clinically meaningful and durable results across multiple advanced melanoma patient populations. The safety profile of the combination was generally consistent with the safety profile of Libtayo monotherapy and other anti-PD-(L)1 agents, except for higher rates of adrenal insufficiency, which were successfully managed with steroid replacement.
- The Company also presented updated positive data from two expansion dose cohorts from a pivotal trial for linvoseltamab, a bispecific antibody targeting BCMA and CD3, in patients with heavily pre-treated, relapsed/refractory multiple myeloma at the ASCO Annual Meeting. No new safety signals were identified.
- The Company is investigating multiple CD28 costimulatory bispecific antibodies, including PSMAxCD28, EGFRxCD28, MUC16xCD28, and CD22xCD28, in ongoing Phase 1 trials in a variety of tumor settings in combination with Libtayo, or in combination with corresponding CD3 bispecifics. In the ongoing study of REGN5678, a costimulatory bispecific antibody targeting PSMA and CD28 in advanced prostate cancer, the Company has observed antitumor activity in combination with Libtayo as well as with REGN5678 monotherapy. In the Libtayo combination cohort, there have now been two immune-mediated Grade 5 adverse events (death), including one in July 2023. As a result, the Company has discontinued enrollment of patients receiving the combination of REGN5678 and full-dose Libtayo, and plans to explore REGN5678 combinations with lower doses of Libtayo. The Company also plans to enroll patients in a REGN5678 monotherapy cohort, as well as in combination with other immunotherapy modalities. Other costimulatory bispecific development programs continue their respective dose-escalation studies.

Itepekimab, an antibody to IL-33

- The Phase 3 program investigating itepekimab in patients with COPD who are former smokers passed a recent interim futility analysis. The analysis was conducted by an Independent Data Monitoring Committee, and the Company and Sanofi remain blinded to the data. Results from the AERIFY-1 and AERIFY-2 studies are expected to be reported in 2025.

Corporate Update

- The United States Supreme Court issued a unanimous opinion, ending a nearly decade-long patent dispute related to Praluent® (alirocumab). The decision affirms the United States Court of Appeals for the Federal Circuit's opinion, which held that Amgen's asserted U.S. PCSK9 patent claims were invalid.

Second Quarter 2023 Financial Results

Revenues

($ in millions)	Q2 2023	Q2 2022	% Change
Net product sales:			
EYLEA - U.S.	$ 1,500	$ 1,621	(7 %)
Libtayo - U.S.	130	91	43 %
Libtayo - ROW	80	—	*
Praluent - U.S.	41	31	32 %
Evkeeza® - U.S.	19	11	73 %
Inmazeb® - U.S.	2	—	*
Total net product sales	1,772	1,754	1 %
Collaboration revenue:			
Sanofi	944	678	39 %
Bayer	377	358	5 %
Other	(4)	8	*
Other revenue	69	59	17 %
Total revenues	$ 3,158	$ 2,857	11 %

* Percentage not meaningful.

Net product sales of EYLEA in the U.S. decreased in the second quarter of 2023, compared to the second quarter of 2022, primarily due to a lower net selling price driven by changing market dynamics, including increased competition.

Sanofi collaboration revenue increased in the second quarter of 2023, compared to the second quarter of 2022, primarily due to the Company's share of profits from commercialization of antibodies, which were $751 million in the second quarter of 2023, compared to $497 million in the second 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.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

	GAAP			Non-GAAP[(a)]		
($ in millions)	Q2 2023	Q2 2022	% Change	Q2 2023	Q2 2022	% Change
Research and development (R&D)	$ 1,085	$ 794	37 %	$ 974	$ 690	41 %
Acquired in-process research and development (IPR&D)	$ —	$ 197	(100 %)	*	*	n/a
Selling, general, and administrative (SG&A)	$ 652	$ 476	37 %	$ 562	$ 418	34 %
Cost of goods sold (COGS)	$ 192	$ 149	29 %	$ 163	$ 137	19 %
Cost of collaboration and contract manufacturing (COCM)	$ 213	$ 148	44 %	*	*	n/a
Other operating (income) expense, net	$ (1)	$ (17)	(94 %)	*	*	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 second quarter of 2023, compared to the second 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, the impact of the 2022 amendments to the Sanofi collaboration agreements, and increased manufacturing activity associated with the Company's earlier-stage product candidates.
- Acquired IPR&D in the second quarter of 2022 included a $195 million charge related to the Company's acquisition of Checkmate Pharmaceuticals, Inc.
- GAAP and non-GAAP SG&A expenses increased in the second quarter of 2023, compared to the second 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.
- COCM expenses increased in the second quarter of 2023, compared to the second quarter of 2022, primarily due to the recognition of costs in connection with manufacturing commercial supplies of Dupixent.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $31 million in the second quarter of 2023, compared to $164 million in the second quarter of 2022. GAAP and Non-GAAP other income (expense) also included interest income of $118 million in the second quarter of 2023, compared to $28 million in the second quarter of 2022.

In the second quarter of 2023, the Company's GAAP effective tax rate (ETR) was 10.6%, compared to 11.5% in the second quarter of 2022. In the second quarter of 2023, the non-GAAP ETR was 12.2%, compared to 13.6% in the second quarter of 2022.

GAAP net income per diluted share was $8.50 in the second quarter of 2023, compared to $7.47 in the second quarter of 2022. Non-GAAP net income per diluted share was $10.24 in the second quarter of 2023, compared to $9.77 in the second 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 second quarter of 2023, the Company repurchased shares of its common stock and recorded the cost of the shares, or $723 million, as Treasury Stock. As of June 30, 2023, an aggregate of $2.3 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	$4.225–$4.465 billion	$4.315–$4.455 billion
Non-GAAP R&D[(a)]	$3.725–$3.925 billion	$3.825–$3.925 billion
GAAP SG&A	$2.490–$2.680 billion	$2.540–$2.680 billion
Non-GAAP SG&A[(a)]	$2.130–$2.280 billion	$2.180–$2.280 billion
GAAP gross margin on net product sales[(d)]	87%–89%	Unchanged
Non-GAAP gross margin on net product sales[(a)(d)]	89%–91%	Unchanged
COCM[(e)*]	$820–$880 million	Unchanged
Capital expenditures[*]	$800–$900 million	$760–$830 million
GAAP effective tax rate	8%–10%	8%–9%
Non-GAAP effective tax rate[(a)]	10%–12%	10%–11%

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

A reconciliation of full year 2023 GAAP to non-GAAP financial guidance is included below:

($ in millions)	Projected Range	
	Low	**High**
GAAP R&D	$ 4,315	$ 4,455
Stock-based compensation expense	480	510
Acquisition-related integration costs	10	20
Non-GAAP R&D	$ 3,825	$ 3,925
GAAP SG&A	$ 2,540	$ 2,680
Stock-based compensation expense	300	320
Acquisition-related integration costs	60	80
Non-GAAP SG&A	$ 2,180	$ 2,280
GAAP gross margin on net product sales	87%	89%
Stock-based compensation expense	1%	1%
Intangible asset amortization expense	1%	1%
Acquisition-related integration costs	<1%	<1%
Charges related to REGEN-COV	<(1%)	<(1%)
Non-GAAP gross margin on net product sales	89%	91%
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-related 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 second quarter 2023 financial and operating results on Thursday, August 3, 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, 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 (such as aflibercept 8 mg, including the timing of any action by the U.S. Food and Drug Administration on the Biologics License Application resubmission for aflibercept 8 mg); 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 June 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.

###

Contact Information:

Ryan Crowe
Investor Relations
914-847-8790
ryan.crowe@regeneron.com

Christina Chan
Corporate Affairs
914-847-8827
christina.chan@regeneron.com

TABLE 1

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In millions)

	June 30, 2023	December 31, 2022
Assets:		
Cash and marketable securities	$ 15,254.9	$ 14,334.1
Accounts receivable, net	5,121.3	5,328.7
Inventories	2,507.7	2,401.9
Property, plant, and equipment, net	3,922.6	3,763.0
Intangible assets, net	953.0	915.5
Deferred tax assets	2,138.5	1,723.7
Other assets	759.5	747.6
Total assets	$ 30,657.5	$ 29,214.5
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,440.1	$ 3,301.4
Finance lease liabilities	720.0	720.0
Deferred revenue	497.3	547.7
Long-term debt	1,982.2	1,981.4
Stockholders' equity	24,017.9	22,664.0
Total liabilities and stockholders' equity	$ 30,657.5	$ 29,214.5

TABLE 2

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Net product sales	$ 1,772.1	$ 1,754.4	$ 3,440.1	$ 3,393.0
Collaboration revenue	1,316.7	1,043.6	2,694.8	2,276.1
Other revenue	69.3	59.2	185.3	153.2
	3,158.1	2,857.2	6,320.2	5,822.3
Expenses:				
Research and development	1,085.3	794.3	2,186.5	1,638.1
Acquired in-process research and development	—	197.0	56.1	225.1
Selling, general, and administrative	652.0	476.3	1,253.1	926.3
Cost of goods sold	192.4	149.2	400.8	356.5
Cost of collaboration and contract manufacturing	212.5	147.9	461.6	345.5
Other operating (income) expense, net	(0.6)	(17.4)	(1.1)	(37.6)
	2,141.6	1,747.3	4,357.0	3,453.9
Income from operations	1,016.5	1,109.9	1,963.2	2,368.4
Other income (expense):				
Other income (expense), net	85.3	(133.6)	14.6	(317.4)
Interest expense	(18.9)	(13.1)	(36.9)	(26.7)
	66.4	(146.7)	(22.3)	(344.1)
Income before income taxes	1,082.9	963.2	1,940.9	2,024.3
Income tax expense	114.5	111.1	154.7	198.7
Net income	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Net income per share - basic	$ 9.05	$ 7.90	$ 16.69	$ 17.01
Net income per share - diluted	$ 8.50	$ 7.47	$ 15.68	$ 16.07
Weighted average shares outstanding - basic	107.0	107.9	107.0	107.3
Weighted average shares outstanding - diluted	113.9	114.0	113.9	113.6

TABLE 3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
GAAP R&D	$ 1,085.3	$ 794.3	$ 2,186.5	$ 1,638.1
Stock-based compensation expense	109.1	89.7	248.6	182.1
Acquisition-related integration costs	2.6	14.6	4.2	14.6
Non-GAAP R&D	$ 973.6	$ 690.0	$ 1,933.7	$ 1,441.4
GAAP SG&A	$ 652.0	$ 476.3	$ 1,253.1	$ 926.3
Stock-based compensation expense	73.3	57.5	150.1	118.2
Acquisition-related integration costs	16.5	1.1	26.1	1.1
Non-GAAP SG&A	$ 562.2	$ 417.7	$ 1,076.9	$ 807.0
GAAP COGS	$ 192.4	$ 149.2	$ 400.8	$ 356.5
Stock-based compensation expense	19.6	12.6	42.0	26.4
Acquisition-related integration costs	0.5	—	0.5	—
Intangible asset amortization expense	19.8	—	38.3	—
Charges related to REGEN-COV	(10.0)	—	(10.0)	58.0
Non-GAAP COGS	$ 162.5	$ 136.6	$ 330.0	$ 272.1
GAAP other income (expense), net	$ 66.4	$ (146.7)	$ (22.3)	$ (344.1)
Other income/expense: Losses (gains) on investments, net	30.9	166.3	197.5	370.8
Non-GAAP other income (expense), net	$ 97.3	$ 19.6	$ 175.2	$ 26.7
GAAP net income	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Total of GAAP to non-GAAP reconciling items above	262.3	341.8	697.3	771.2
Income tax effect of GAAP to non-GAAP reconciling items	(49.1)	(67.0)	(134.4)	(152.3)
Non-GAAP net income	$ 1,181.6	$ 1,126.9	$ 2,349.1	$ 2,444.5
Non-GAAP net income per share - basic	$ 11.04	$ 10.44	$ 21.95	$ 22.78
Non-GAAP net income per share - diluted	$ 10.24	$ 9.77	$ 20.32	$ 21.26
Shares used in calculating:				
Non-GAAP net income per share - basic	107.0	107.9	107.0	107.3
Non-GAAP net income per share - diluted	115.4	115.4	115.6	115.0

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue reconciliation:				
Total revenues	$ 3,158.1	$ 2,857.2	$ 6,320.2	$ 5,822.3
Global gross profit payment from Roche in connection with sales of Ronapreve	—	8.2	222.2	224.5
Other	(3.8)	—	(3.8)	—
Total revenues excluding Ronapreve	$ 3,161.9	$ 2,849.0	$ 6,101.8	$ 5,597.8
Effective tax rate reconciliation:				
GAAP ETR	10.6%	11.5%	8.0%	9.8%
Income tax effect of GAAP to non-GAAP reconciling items	1.6%	2.1%	3.0%	2.8%
Non-GAAP ETR	12.2%	13.6%	11.0%	12.6%

	Six Months Ended June 30,	
	2023	**2022**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 2,390.0	$ 2,666.1
Capital expenditures	(291.2)	(295.4)
Free cash flow	$ 2,098.8	$ 2,370.7

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 751.1	$ 496.6	$ 1,387.6	$ 911.9
Sales-based milestones earned	—	—	—	50.0
Reimbursement for manufacturing of commercial supplies	192.6	145.5	354.5	306.3
Other	—	28.9	—	28.9
Immuno-oncology:				
Regeneron's share of profits in connection with commercialization of Libtayo outside the United States	—	3.9	—	6.7
Reimbursement for manufacturing of ex-U.S. commercial supplies	—	2.6	—	4.6
Total Sanofi collaboration revenue	943.7	677.5	1,742.1	1,308.4
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	349.5	339.7	681.1	678.1
Reimbursement for manufacturing of ex-U.S. commercial supplies	27.2	17.8	52.5	42.8
One-time payment in connection with change in Japan arrangement	—	—	—	21.9
Total Bayer collaboration revenue	376.7	357.5	733.6	742.8
Other collaboration revenue:				
Global gross profit payment from Roche in connection with sales of Ronapreve	—	8.2	222.2	224.5
Other	(3.7)	0.4	(3.1)	0.4
Total collaboration revenue	$ 1,316.7	$ 1,043.6	$ 2,694.8	$ 2,276.1

TABLE 5

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

	Three Months Ended June 30,						
	2023			2022			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,500.1	$ 886.3	$ 2,386.4	$ 1,621.2	$ 869.8	$ 2,491.0	(4 %)
Dupixent[b]	$ 2,105.2	$ 684.2	$ 2,789.4	$ 1,582.1	$ 509.7	$ 2,091.8	33 %
Libtayo[c]	$ 130.2	$ 79.8	$ 210.0	$ 90.9	$ 50.4	$ 141.3	49 %
Praluent[d]	$ 40.5	$ 99.8	$ 140.3	$ 31.2	$ 77.7	$ 108.9	29 %
REGEN-COV[e]	$ —	$ —	$ —	$ —	$ 22.8	$ 22.8	(100 %)
Kevzara[b]	$ 56.9	$ 42.6	$ 99.5	$ 43.0	$ 39.3	$ 82.3	21 %
Other products[f]	$ 22.5	$ 16.9	$ 39.4	$ 12.1	$ 19.0	$ 31.1	27 %

	Six Months Ended June 30,						
	2023			2022			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 2,933.9	$ 1,733.4	$ 4,667.3	$ 3,138.8	$ 1,738.3	$ 4,877.1	(4 %)
Dupixent[b]	$ 4,003.3	$ 1,271.1	$ 5,274.4	$ 2,907.7	$ 994.5	$ 3,902.2	35 %
Libtayo[c]	$ 239.9	$ 152.7	$ 392.6	$ 169.8	$ 96.2	$ 266.0	48 %
Praluent[d]	$ 80.7	$ 205.5	$ 286.2	$ 64.8	$ 155.5	$ 220.3	30 %
REGEN-COV[e]	$ —	$ 613.2	$ 613.2	$ —	$ 658.4	$ 658.4	(7 %)
Kevzara[b]	$ 96.1	$ 81.9	$ 178.0	$ 100.0	$ 88.7	$ 188.7	(6 %)
Other products[f]	$ 40.6	$ 33.4	$ 74.0	$ 22.0	$ 39.4	$ 61.4	21 %

[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 for the six months ended June 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 "Second 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 $43 million for the first quarter of 2023.