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): November 3, 2022 (November 3, 2022)

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 November 3, 2022, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2022. 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 November 3, 2022, Reporting Third Quarter 2022 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: November 3, 2022 REGENERON PHARMACEUTICALS, INC.

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

REGENERON

Press Release

Regeneron Reports Third Quarter 2022 Financial and Operating Results

- *Third quarter 2022 revenues decreased 15% to $2.94 billion versus third quarter 2021; excluding REGEN-COV®[a][b], revenues increased 11%*
- *Third quarter 2022 EYLEA® U.S. net sales increased 11% versus third quarter 2021 to a record $1.63 billion*
- *Third quarter 2022 Dupixent® global net sales[c](recorded by Sanofi) increased 40% to $2.33 billion versus third quarter 2021*
- *Third quarter 2022 GAAP diluted EPS of $11.66; non-GAAP diluted EPS[a] of $11.14*
- *Positive results reported in aflibercept 8 mg pivotal trials for diabetic macular edema (DME) and neovascular age-related macular degeneration (wet AMD)*
- *EYLEA granted additional six months of pediatric exclusivity by the FDA*
- *FDA approved Dupixent for prurigo nodularis*
- *Inmazeb® won 2022 Prix Galien USA "Best Biotechnology Product" Award*

Tarrytown, New York (November 3, 2022) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2022 and provided a business update.

"We were thrilled to see positive results from the aflibercept 8 mg pivotal trials which demonstrated the potential to reduce the treatment burden for patients with diabetic macular edema (DME) and neovascular age-related macular degeneration (wet AMD)," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Global Dupixent sales and U.S. EYLEA sales once again achieved new quarterly records, with U.S. sales of EYLEA achieving double digit year-over-year percentage growth and Dupixent was bolstered by progress on launches in pediatric atopic dermatitis, eosinophilic esophagitis, and prurigo nodularis. Our oncology portfolio was furthered strengthened by positive data updates for our growing investigational oncology pipeline."

Financial Highlights

($ in millions, except per share data)	Q3 2022	Q3 2021	% Change
Total revenues	$ 2,936	$ 3,453	(15%)
Total revenues, excluding REGEN-COV[a][b]	$ 2,930	$ 2,649	11%
GAAP net income	$ 1,316	$ 1,632	(19%)
GAAP net income per share - diluted	$ 11.66	$ 14.33	(19%)
Non-GAAP net income[a]	$ 1,270	$ 1,773	(28%)
Non-GAAP net income per share - diluted[a]	$ 11.14	$ 15.37	(28%)

"Our third quarter 2022 financial performance reflects strong commercial momentum across our business, highlighted by 11% revenue growth when excluding contributions from REGEN-COV and Ronapreve," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We continued to drive shareholder value creation by realizing the benefits of our sustained investment in R&D, focusing on commercial execution, and allocating over $2.8 billion to share repurchases and business development initiatives in the first nine months of 2022."

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 Company announced that the primary endpoints were met in two pivotal trials investigating aflibercept 8 mg with 12- and 16-week dosing regimens in patients with diabetic macular edema (DME) and neovascular age-related macular degeneration (wet AMD). The PHOTON trial in DME and the PULSAR trial in wet AMD both demonstrated that aflibercept 8 mg 12- and 16-week dosing regimens achieved non-inferiority in vision gains compared to the EYLEA® 8-week dosing regimen. Furthermore, of the patients randomized to 12- and 16-week dosing intervals, 91% and 89% of DME patients, respectively, and 79% and 77% of wet AMD patients, respectively, maintained those intervals through 48 weeks. The safety of aflibercept 8 mg was similar to EYLEA in both trials, and consistent with the known safety profile of EYLEA from previous clinical trials. The Company intends to use a priority review voucher in connection with the submission of the aflibercept 8 mg Biologics License Application (BLA) for DME and wet AMD, which is currently planned for late 2022.

EYLEA (aflibercept) Injection

- The U.S. Food and Drug Administration (FDA) accepted for priority review the supplemental BLA (sBLA) for EYLEA to treat retinopathy of prematurity (ROP) in preterm infants, with a target action date of February 11, 2023.
- The FDA granted EYLEA pediatric exclusivity, extending the period of U.S. EYLEA market exclusivity by an additional six months through May 17, 2024.

Dupixent® (dupilumab)

- In September 2022, the FDA approved Dupixent for the treatment of adult patients with prurigo nodularis, making Dupixent the first and only medicine specifically indicated to treat prurigo nodularis in the United States.

Oncology Programs

Libtayo® (cemiplimab)

- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Libtayo as a monotherapy for the treatment of adult patients with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy. The European Commission is expected to make a final decision on the application in the coming months.
- The Company presented positive data from the Phase 2 trial for Libtayo in neoadjuvant cutaneous squamous cell carcinoma (CSCC) at the European Society for Medical Oncology (ESMO) Congress 2022. The data were also published in the *New England Journal of Medicine*.

Fianlimab, an antibody to LAG-3

- Positive data were presented from a Phase 1 trial studying fianlimab in combination with Libtayo in advanced melanoma at the ESMO Congress 2022.

Bispecific Antibodies and Costimulatory Bispecifics

- The Company also presented at the ESMO Congress 2022 encouraging early data from the dose-escalation portions of two Phase 1/2 trials evaluating ubamatamab, a bispecific antibody targeting MUC16 and CD3, in platinum-resistant ovarian cancer; and REGN5093, a METxMET bispecific antibody, in MET-altered advanced non-small cell lung cancer (NSCLC).
- Enrollment was completed in the potentially pivotal Phase 2 study of linvoseltamab, a bispecific antibody targeting BCMA and CD3, in multiple myeloma.
- The Company continues to enroll patients in a Phase 1/2 study investigating REGN5678, a PSMAxCD28 costimulatory bispecific antibody, in combination with Libtayo in advanced metastatic castration-resistant prostate cancer. Preliminary clinical data from the study were disclosed in August 2022 and further detailed in Regeneron's ESMO 2022 Investor Event in September 2022.

Other Programs

- Inmazeb®, the first FDA-approved treatment for *Zaire ebolavirus*, has been recognized as the "Best Biotechnology Product" of 2022 by the Galien Foundation, which acknowledges extraordinary scientific innovations that improve the human condition.
- A Phase 3 study was initiated for garetosamab, an antibody to Activin A, in fibrodysplasia ossificans progressiva (FOP).
- The Company and Alnylam Pharmaceuticals, Inc. announced preliminary Phase 1 data of ALN-HSD, an RNAi therapeutic targeting *HSD17B13*, for the treatment of nonalcoholic steatohepatitis (NASH).
- Intellia Therapeutics, Inc. and the Company announced positive interim results from the cardiomyopathy arm of the ongoing Phase 1 trial of NTLA-2001, an *in vivo* CRISPR/Cas9 genome editing therapy, which is in development as a single-dose treatment for transthyretin (ATTR) amyloidosis.
- The Company has discontinued (i) further clinical development of fasinumab, an antibody to NGF, which was previously being studied in osteoarthritis pain of the knee or hip in collaboration with Teva and Mitsubishi Tanabe Pharma; and (ii) the Phase 3 study of REGN1908-1909, a multi-antibody therapy to Fel d 1, in cat allergy, due to futility.

Corporate and Business Development Updates

- Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi. Under the terms of the agreement, the Company made a $900 million up-front payment, and Sanofi is eligible to receive a $100 million regulatory milestone and up to an aggregate of $100 million in sales-based milestones upon achieving certain amounts of worldwide net product sales of Libtayo through 2023. The Company also pays Sanofi a royalty on net product sales of Libtayo.
- Pursuant to an amendment to the Antibody License and Collaboration Agreement, the percentage of the Company's share of profits used to reimburse Sanofi for its development balance reimbursement obligation increased from 10% to 20%.
- The Company announced that Craig B. Thompson, M.D., was elected to the Board of Directors. Dr. Thompson most recently served as the President and Chief Executive Officer of Memorial Sloan Kettering Cancer Center (MSK) and continues to oversee the Craig Thompson Lab at MSK studying cellular metabolism and its role in disease.

Third Quarter 2022 Financial Results

Revenues

($ in millions)	Q3 2022	Q3 2021	% Change
Net product sales:			
EYLEA - U.S.	$ 1,629	$ 1,473	11 %
Libtayo - U.S.	95	78	22 %
Libtayo - ROW**	31	—	*
Praluent® - U.S.	30	45	(33 %)
REGEN-COV® - U.S.	—	677	(100 %)
Evkeeza® - U.S.	14	7	100 %
Inmazeb® - U.S.	3	—	100 %
Collaboration revenue:			
Sanofi	711	582	22 %
Bayer	333	365	(9 %)
Roche	6	127	(95 %)
Other revenue	84	99	(15 %)
Total revenues	$ 2,936	$ 3,453	(15 %)

* 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 $17 million of net product sales recorded by Sanofi in the third quarter of 2022 in connection with sales in certain markets (Sanofi will record 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).

Total revenues decreased 15% to $2.936 billion in the third quarter of 2022, compared to $3.453 billion in the third quarter of 2021. Total revenues excluding REGEN-COV and Ronapreve[(b)] revenues for both periods increased by 11% to $2.930 billion in the third quarter of 2022, compared to the third quarter of 2021[(a)]. There have been no sales of REGEN-COV in the United States during 2022 as the Company had completed its final deliveries of drug product under its agreements with the U.S. government as of December 31, 2021.

Sanofi collaboration revenue increased by 22% to $711 million in the third quarter of 2022, compared to the third quarter of 2021. This increase was primarily due to the Company's share of profits from commercialization of antibodies, which were $551 million in the third quarter of 2022, compared to $387 million in the third quarter of 2021. The change in the Company's share of profits from commercialization of antibodies was driven by higher Dupixent profits, partly offset by a one-time payment of $57 million, recorded during the third quarter of 2022, in connection with the amended Antibody License and Collaboration Agreement as described above. In addition, in the third quarter of 2021, the Company earned a $50 million sales-based milestone from Sanofi based upon sales of antibodies outside the United States on a rolling twelve-month basis.

Roche collaboration revenue decreased in the third quarter of 2022, compared to the third quarter of 2021, due to lower sales of Ronapreve.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

($ in millions)	GAAP Q3 2022	GAAP Q3 2021	GAAP % Change	Non-GAAP[(a)] Q3 2022	Non-GAAP[(a)] Q3 2021	Non-GAAP[(a)] % Change
Research and development (R&D)	$ 911	$ 665	37%	$ 817	$ 592	38%
Acquired in-process research and development (IPR&D)**	$ —	$ —	n/a	*	*	n/a
Selling, general, and administrative (SG&A)	$ 529	$ 445	19%	$ 467	$ 391	19%
Cost of goods sold (COGS)	$ 141	$ 239	(41%)	$ 109	$ 224	(51%)
Cost of collaboration and contract manufacturing (COCM)	$ 177	$ 214	(17%)	*	*	n/a
Other operating (income) expense, net	$ (46)	$ 42	(210%)	*	*	n/a

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

** Beginning with the first quarter of 2022, the Company added this new line item to its Statements of Operations, which includes IPR&D acquired in connection with asset acquisitions as well as up-front/opt-in payments related to license and collaboration agreements. Amounts recorded in this line would have historically been recorded to R&D. This change does not affect previously reported non-GAAP results for the three and nine months ended September 30, 2021 as the Company recorded no such charges during either of these periods.

- GAAP and non-GAAP R&D expenses increased in the third quarter of 2022, compared to the third quarter of 2021, partially driven by the impact of the amendments to the Sanofi collaboration agreements described above. The increase was also due to higher headcount and headcount-related costs, an increase in clinical manufacturing activities, and additional costs incurred in connection with the Company's oncology and earlier-stage pipeline.
- GAAP and non-GAAP SG&A expenses increased in the third quarter of 2022, compared to the third quarter of 2021, primarily due to an increase in commercialization-related expenses for Libtayo.
- GAAP and non-GAAP COGS decreased in the third quarter of 2022, compared to the third quarter of 2021, primarily due to the Company not recognizing any REGEN-COV net product sales in the United States during 2022 and the Company no longer being obligated to pay Sanofi for their share of U.S. Libtayo gross profits following the acquisition of Libtayo worldwide rights.
- Other operating (income) expense, net, in the third quarter of 2022 included the recognition of $44 million (an increase to other operating income) as a result of discontinuing further clinical development of fasinumab related to the Company's Teva and Mitsubishi Tanabe Pharma collaborative arrangements. During the third quarter of 2021, the Company recognized a cumulative catch-up adjustment of $67 million (a reduction to other operating income) arising from an update to the estimate of the total R&D costs expected to be incurred under the Sanofi Immuno-oncology collaboration agreement.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized gains on equity securities of $254 million in the third quarter of 2022, compared to $29 million of net unrealized losses in the third quarter of 2021.

In the third quarter of 2022, the Company's GAAP effective tax rate (ETR) was 12.9%, compared to 10.2% in the third quarter of 2021. The GAAP ETR in the third quarter of 2022, compared to the third quarter of 2021, included a lower benefit from stock-based compensation and a higher benefit from the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate (mainly due to no sales of REGEN-COV in the United States during 2022). In the third quarter of 2022, the non-GAAP ETR was 12.1%, compared to 10.8% in the third quarter of 2021.

GAAP net income per diluted share was $11.66 in the third quarter of 2022, compared to $14.33 in the third quarter of 2021. Non-GAAP net income per diluted share was $11.14 in the third quarter of 2022, compared to $15.37 in the third quarter of 2021. 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 2022, the Company repurchased shares of common stock under its share repurchase program, and recorded the cost of the shares, or $913 million, as Treasury Stock. As of September 30, 2022, $1.186 billion remained available for share repurchases under the program.

2022 Financial Guidance[(d)]

The Company's full year 2022 financial guidance consists of the following components:

	GAAP	**Non-GAAP[(a)]**
R&D	$3.515–$3.600 billion *(previously $3.485–$3.655 billion)*	$3.110–$3.170 billion *(previously $3.100–$3.240 billion)*
SG&A	$2.010–$2.090 billion *(previously $1.990–$2.110 billion)*	$1.760–$1.820 billion *(previously $1.740–$1.840 billion)*
Gross margin on net product sales[(e)]	90.5%–91% *(previously 90%–91%)*	92.5%–93% *(previously 92%–93%)*
COCM[(f)]	$710–$740 million *(previously $710–$760 million)*	*
Other operating (income) expense, net	Approximately ($85) million *(previously ($40)–($60) million)*	*
Capital expenditures	$580–$615 million *(previously $620–$670 million)*	*
Effective tax rate	12%–13%** *(unchanged)*	13%–14%** *(unchanged)*

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

** ETR guidance excludes the impact of the provision requiring capitalization and amortization of R&D expenses enacted as part of the Tax Cuts and Job Act (TCJA), as management's current expectation is it will be deferred or repealed in 2022. If this provision of the TCJA is not deferred or repealed, the Company would expect its ETR to be lower than the guidance disclosed herein.

A reconciliation of full year 2022 GAAP to non-GAAP financial guidance is included below:

($ in millions)	Projected Range	
	Low	**High**
GAAP R&D	$ 3,515	$ 3,600
Stock-based compensation expense	(390)	(415)
Acquisition-related integration costs	(15)	(15)
Non-GAAP R&D	$ 3,110	$ 3,170
GAAP SG&A	$ 2,010	$ 2,090
Stock-based compensation expense	(240)	(260)
Acquisition-related integration costs	(10)	(10)
Non-GAAP SG&A	$ 1,760	$ 1,820
GAAP gross margin on net product sales	90.5%	91%
Stock-based compensation expense	<1%	<1%
Charges related to REGEN-COV	<1%	<1%
Intangible asset amortization expense	<1%	<1%
Non-GAAP gross margin on net product sales	92.5%	93%
GAAP ETR	12%	13%
Income tax effect of GAAP to non-GAAP reconciling items and other	1%	1%
Non-GAAP ETR	13%	14%

(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 REGEN-COV and 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 restructuring- or 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 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 collaborators provide it with estimates of the collaborators' respective sales and the Company's share of the profits or losses (if applicable) from commercialization of products for the most recent fiscal quarter. These estimates are revised, if necessary, in subsequent periods if the Company's actual share of the profits or losses differ from those estimates.

(d) The Company's 2022 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(e) 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.

(f) 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 2022 financial and operating results on Thursday, November 3, 2022, 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 nearly 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron’s business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron’s and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of 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, other operating (income) expense, net, 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; 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, 2021 and its Form 10-Q for the quarterly period ended September 30, 2022. 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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Contact Information:

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

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

TABLE 1

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

	September 30, 2022	December 31, 2021
Assets:		
Cash and marketable securities	$ 12,990.3	$ 12,532.7
Accounts receivable, net	5,548.3	6,036.5
Inventories	2,412.2	1,951.3
Property, plant, and equipment, net	3,704.2	3,482.2
Intangible assets, net	804.1	6.7
Deferred tax assets	1,452.1	876.9
Other assets	766.6	548.5
Total assets	$ 27,677.8	$ 25,434.8
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 2,930.6	$ 3,451.0
Finance lease liabilities	720.0	719.7
Deferred revenue	607.3	515.3
Long-term debt	1,981.1	1,980.0
Stockholders' equity	21,438.8	18,768.8
Total liabilities and stockholders' equity	$ 27,677.8	$ 25,434.8

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,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Net product sales	$ 1,801.4	$ 2,279.9	$ 5,194.4	$ 8,142.0
Collaboration revenue	1,050.6	1,073.9	3,326.7	2,783.0
Other revenue	84.2	99.0	237.4	195.0
	2,936.2	3,452.8	8,758.5	11,120.0
Expenses:				
Research and development	911.3	665.4	2,549.4	2,122.5
Acquired in-process research and development	—	—	225.1	—
Selling, general, and administrative	529.1	445.0	1,455.4	1,265.3
Cost of goods sold	141.3	238.8	497.8	961.4
Cost of collaboration and contract manufacturing	176.5	214.4	522.0	493.5
Other operating (income) expense, net	(45.7)	42.0	(83.3)	(29.8)
	1,712.5	1,605.6	5,166.4	4,812.9
Income from operations	1,223.7	1,847.2	3,592.1	6,307.1
Other income (expense):				
Other income (expense), net	301.4	(16.4)	(16.0)	558.5
Interest expense	(15.3)	(14.2)	(42.0)	(43.2)
	286.1	(30.6)	(58.0)	515.3
Income before income taxes	1,509.8	1,816.6	3,534.1	6,822.4
Income tax expense	194.1	184.4	392.8	976.1
Net income	$ 1,315.7	$ 1,632.2	$ 3,141.3	$ 5,846.3
Net income per share - basic	$ 12.31	$ 15.37	$ 29.30	$ 55.42
Net income per share - diluted	$ 11.66	$ 14.33	$ 27.73	$ 52.29
Weighted average shares outstanding - basic	106.9	106.2	107.2	105.5
Weighted average shares outstanding - diluted	112.8	113.9	113.3	111.8

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,	
	2022	**2021**	**2022**	**2021**
GAAP R&D	$ 911.3	$ 665.4	$ 2,549.4	$ 2,122.5
R&D: Stock-based compensation expense	93.7	73.1	275.8	213.7
R&D: Acquisition-related integration costs	1.0	—	15.6	—
Non-GAAP R&D	$ 816.6	$ 592.3	$ 2,258.0	$ 1,908.8
GAAP SG&A	$ 529.1	$ 445.0	$ 1,455.4	$ 1,265.3
SG&A: Stock-based compensation expense	59.8	48.7	178.0	149.1
SG&A: Acquisition-related integration costs and other	2.0	5.6	3.1	5.6
Non-GAAP SG&A	$ 467.3	$ 390.7	$ 1,274.3	$ 1,110.6
GAAP COGS	$ 141.3	$ 238.8	$ 497.8	$ 961.4
COGS: Stock-based compensation expense	12.8	15.1	39.2	50.5
COGS: Intangible asset amortization expense	15.1	—	15.1	—
COGS: Charges related to REGEN-COV	4.9	—	62.9	—
Non-GAAP COGS	$ 108.5	$ 223.7	$ 380.6	$ 910.9
GAAP other income (expense), net	$ 286.1	$ (30.6)	$ (58.0)	$ 515.3
Other income/expense: (Gains) losses on investments	(253.5)	29.3	117.3	(524.6)
Non-GAAP other income (expense), net	$ 32.6	$ (1.3)	$ 59.3	$ (9.3)
GAAP net income	$ 1,315.7	$ 1,632.2	$ 3,141.3	$ 5,846.3
Total of GAAP to non-GAAP reconciling items above	(64.2)	171.8	707.0	(105.7)
Income tax effect of GAAP to non-GAAP reconciling items	18.9	(31.3)	(133.4)	36.3
Non-GAAP net income	$ 1,270.4	$ 1,772.7	$ 3,714.9	$ 5,776.9
Non-GAAP net income per share - basic	$ 11.88	$ 16.69	$ 34.65	$ 54.76
Non-GAAP net income per share - diluted	$ 11.14	$ 15.37	$ 32.39	$ 50.99
Shares used in calculating:				
Non-GAAP net income per share - basic	106.9	106.2	107.2	105.5
Non-GAAP net income per share - diluted	114.0	115.3	114.7	113.3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue reconciliation:				
Total revenues	$ 2,936.2	$ 3,452.8	$ 8,758.5	$ 11,120.0
REGEN-COV net product sales in the United States	—	676.7	—	3,530.1
Global gross profit payment from Roche in connection with sales of Ronapreve	6.4	127.1	230.9	361.8
Total revenues excluding REGEN-COV and Ronapreve	$ 2,929.8	$ 2,649.0	$ 8,527.6	$ 7,228.1
Effective tax rate reconciliation:				
GAAP ETR	12.9%	10.2%	11.1%	14.3%
Income tax effect of GAAP to non-GAAP reconciling items	(0.8%)	0.6%	1.3%	(0.3%)
Non-GAAP ETR	12.1%	10.8%	12.4%	14.0%

	Nine Months Ended September 30,	
	2022	**2021**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 3,295.0	$ 4,708.8
Capital expenditures	(437.9)	(397.0)
Free cash flow	$ 2,857.1	$ 4,311.8

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 551.1	$ 387.0	$ 1,463.0	$ 975.2
Sales-based milestone earned	—	50.0	50.0	50.0
Reimbursement for manufacturing of commercial supplies	160.5	144.7	466.8	361.2
Other	(0.2)	—	28.7	—
Immuno-oncology:				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	—	(3.0)	6.7	(12.6)
Reimbursement for manufacturing of ex-U.S. commercial supplies	—	3.1	4.6	10.5
Total Sanofi collaboration revenue	711.4	581.8	2,019.8	1,384.3
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	315.3	351.0	993.4	995.3
Reimbursement for manufacturing of ex-U.S. commercial supplies	17.5	14.0	60.3	41.6
One-time payment in connection with change in Japan arrangement	—	—	21.9	—
Total Bayer collaboration revenue	332.8	365.0	1,075.6	1,036.9
Other collaboration revenue:				
Global gross profit payment from Roche in connection with sales of Ronapreve	6.4	127.1	230.9	361.8
Other	—	—	0.4	—
Total collaboration revenue	$ 1,050.6	$ 1,073.9	$ 3,326.7	$ 2,783.0

TABLE 5

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

	Three Months Ended September 30,						
	2022			2021			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,629.4	$ 816.9	$ 2,446.3	$ 1,473.4	$ 898.9 *	$ 2,372.3	3 %
Dupixent[b]	$ 1,824.0	$ 506.1	$ 2,330.1	$ 1,256.7	$ 406.2	$ 1,662.9	40 %
Libtayo[c]	$ 94.7	$ 48.5	$ 143.2	$ 78.4	$ 41.1	$ 119.5	20 %
Praluent[d]	$ 29.7	$ 84.0	$ 113.7	$ 44.8	$ 69.7	$ 114.5	(1 %)
REGEN-COV[e]	$ —	$ 22.8	$ 22.8	$ 676.7	$ 518.8	$ 1,195.5	(98 %)
Kevzara[b]	$ 53.1	$ 35.0	$ 88.1	$ 58.5	$ 39.3	$ 97.8	(10 %)
Other products[f]	$ 17.5	$ 14.7	$ 32.2	$ 7.8	$ 20.9	$ 28.7	12 %

	Nine Months Ended September 30,						
	2022			2021			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 4,768.2	$ 2,544.2	$ 7,312.4	$ 4,245.1	$ 2,567.7 *	$ 6,812.8	7 %
Dupixent[b]	$ 4,731.7	$ 1,500.6	$ 6,232.3	$ 3,364.8	$ 1,060.0	$ 4,424.8	41 %
Libtayo[c]	$ 264.5	$ 144.7	$ 409.2	$ 225.5	$ 111.7	$ 337.2	21 %
Praluent[d]	$ 94.5	$ 239.5	$ 334.0	$ 130.0	$ 188.5	$ 318.5	5 %
REGEN-COV[e]	$ —	$ 681.2	$ 681.2	$ 3,530.1	$ 1,173.2	$ 4,703.3	(86 %)
Kevzara[b]	$ 153.1	$ 123.7	$ 276.8	$ 119.9	$ 113.7	$ 233.6	18 %
Other products[f]	$ 39.5	$ 54.1	$ 93.6	$ 15.2	$ 66.1	$ 81.3	15 %

***** Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits and losses based on sales from Bayer to its distributor in Japan. Previously, the Company received from Bayer a tiered percentage of sales based on sales by Bayer's distributor in Japan. Consequently, the prior year net product sales amount has been revised for comparability purposes.

[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 $17 million of net product sales recorded by Sanofi in the third quarter of 2022 in connection with sales in certain markets (Sanofi will record 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 connection with its agreements with the U.S. government. Roche records net product sales of the antibody cocktail outside the United States and the parties share gross profits from global sales based on a pre-specified formula.

[f] Included in this line item are products which are sold by the Company and others. Refer to "Third Quarter 2022 Financial Results" section above for a complete listing of net product sales recorded by the Company. In addition, not included in this line item are net product sales of ARCALYST subsequent to the first quarter of 2021, which are recorded by Kiniksa; net product sales of ARCALYST were $27 million for the second quarter of 2022.