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): May 4, 2022 (May 4, 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 May 4, 2022, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 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 May 4, 2022, Reporting First 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: May 4, 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 First Quarter 2022 Financial and Operating Results

- *First quarter 2022 revenues increased 17% to $2.97 billion versus first quarter 2021; excluding REGEN-COV®[a][b], revenues increased 25%*
- *First quarter 2022 EYLEA® U.S. net sales increased 13% to $1.52 billion versus first quarter 2021*
- *First quarter 2022 Dupixent® global net sales[c] (recorded by Sanofi) increased 43% to $1.81 billion versus first quarter 2021*
- *First quarter 2022 GAAP diluted EPS of $8.61; non-GAAP diluted EPS[a] of $11.49*
- *Dupixent approved in EU for children aged 6–11 years with severe asthma; FDA priority review granted for atopic dermatitis in children aged 6 months to 5 years and eosinophilic esophagitis*

Tarrytown, New York (May 4, 2022) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2022 and provided a business update.

"Our strong first quarter performance was marked by top- and bottom-line growth, accompanied by R&D progress and continued investment in our pipeline," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We continued to see substantial U.S. sales growth for EYLEA and Dupixent worldwide. We are well-positioned to reach even more patients with type 2 inflammatory disease through FDA priority review designations for Dupixent in children with atopic dermatitis and in adults and adolescents with eosinophilic esophagitis."

Financial Highlights

($ in millions, except per share data)	Q1 2022	Q1 2021	% Change
Total revenues	$ 2,965	$ 2,529	17%
GAAP net income	$ 974	$ 1,115	(13%)
GAAP net income per share - diluted	$ 8.61	$ 10.09	(15%)
Non-GAAP net income[a]	$ 1,318	$ 1,109	19%
Non-GAAP net income per share - diluted[a]	$ 11.49	$ 9.89	16%

"Our business achieved strong revenue growth in the first quarter of 2022 as we continue to realize the benefits of our sustained R&D investment and our focus on commercial execution," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We remain confident that our differentiated products and significant pipeline opportunities position us well to deliver strong results and provide sustainable value to patients and shareholders."

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® (aflibercept) Injection

- A supplemental Biologics License Application (sBLA) for EYLEA for an every-16-weeks dosing regimen in patients with non-proliferative diabetic retinopathy (NPDR) was submitted.

Aflibercept 8 mg

- In February 2022, the Company announced detailed results from its Phase 2 trial evaluating an investigational 8 mg high dose of aflibercept compared to the currently-approved 2 mg dose of EYLEA in patients with neovascular age-related macular degeneration (wet AMD). The trial met its primary endpoints for safety, and no new safety signals were observed through week 44. Consistent with initial data announced last year, aflibercept 8 mg continued to show numeric improvements in anatomical and vision outcomes compared to EYLEA through 44 weeks.

Dupixent® (dupilumab)

- In April 2022, the European Commission (EC) approved Dupixent for the treatment of severe asthma in children aged 6 to 11 years.
- The U.S. Food and Drug Administration (FDA) accepted for priority review the sBLA for Dupixent for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis, with a target action date of June 9, 2022. A regulatory application was also submitted in the European Union (EU).
- The FDA accepted for priority review the sBLA for Dupixent for adults and adolescents aged 12 years and older with eosinophilic esophagitis (EoE), with a target action date of August 3, 2022. A regulatory application was also submitted in the EU.
- In January 2022, the Company and Sanofi announced positive results from a second Phase 3 trial in adults with uncontrolled prurigo nodularis. An sBLA and a regulatory submission in the EU for Dupixent for adults with uncontrolled prurigo nodularis were subsequently submitted.
- In February 2022, the Company and Sanofi provided an update on Dupixent in patients with chronic spontaneous urticaria (CSU), in which they had previously reported positive results from the first trial in biologic-naïve patients (i.e., not previously treated with omalizumab) that showed Dupixent significantly reduced itch and hives compared to standard-of-care antihistamines alone. The Company and Sanofi announced that they stopped a second trial in patients refractory to omalizumab due to futility.

Antibodies to SARS-CoV-2 virus

- In April 2022, the Company announced that the FDA extended by three months its review of the BLA for REGEN-COV® (casirivimab and imdevimab) to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals. The extension is due to ongoing discussions with the FDA on pre-exposure prophylactic use, for which Regeneron has submitted additional data from its completed prophylaxis trial that the FDA has accepted for review. The FDA determined these additional data constitute a Major Amendment to the BLA and provided a new target action date of July 13, 2022.
- A regulatory application was submitted in the EU for Ronapreve™[(b)] for the treatment of COVID-19 in hospitalized patients.
- In January 2022, the FDA revised the Emergency Use Authorization (EUA) for REGEN-COV to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. If, in the future, patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to REGEN-COV, then the limitation on use may be revised.
- The Company is progressing investigational "next generation" antibodies that are active against multiple variants including those of Omicron-lineage, and has initiated a first-in-human clinical trial.

Fianlimab, an antibody to LAG-3

- A Phase 3 study in first-line metastatic melanoma was initiated.

Odronextamab, a CD20xCD3 bispecific antibody

- The FDA granted Fast Track designation for follicular lymphoma and diffuse large B-cell lymphoma.

NTLA-2001, a CRISPR/Cas9 therapeutic for TTR gene knockout

- In February 2022, Intellia Therapeutics, Inc. and the Company reported updated positive interim data from the Phase 1 trial in transthyretin (ATTR) amyloidosis.

Business Development Update

- In April 2022, the Company entered into a definitive merger agreement to acquire Checkmate Pharmaceuticals, Inc. at a total equity value of approximately $250 million. On May 2, 2022, the Company initiated a tender offer to acquire any and all outstanding shares of Checkmate common stock at a price of $10.50 per share, to be paid to each shareholder tendering Checkmate shares in cash, without interest, subject to reduction for any applicable withholding taxes. The transaction is expected to close, subject to the satisfaction of customary closing conditions including regulatory approvals, in mid-2022.

First Quarter 2022 Financial Results

Revenues

Total revenues increased by 17% to $2.965 billion in the first quarter of 2022, compared to $2.529 billion in the first quarter of 2021. Total revenues excluding REGEN-COV and Ronapreve[(b)] revenues for both periods increased by 25% to $2.749 billion in the first quarter of 2022, compared to the first quarter of 2021[(a)].

Net product sales recorded by the Company consist of the following:

($ in millions)	Q1 2022	Q1 2021	% Change
EYLEA	$ 1,518	$ 1,347	13 %
Libtayo	79	69	14 %
Praluent®	34	43	(21 %)
REGEN-COV	—	262	(100 %)
Evkeeza	8	1	**
ARCALYST®	— *	2	**
Total net product sales in the U.S.	$ 1,639	$ 1,724	(5 %)

* Effective April 1, 2021, Kiniksa records net product sales of ARCALYST in the United States. Previously, the Company recorded net product sales of ARCALYST in the United States.

** Percentage not meaningful

Total revenues also include collaboration revenues[(c)] of $1.233 billion in the first quarter of 2022, compared to $754 million in the first quarter of 2021. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which were $415 million in the first quarter of 2022, compared to $261 million in the first quarter of 2021. The change in the Company's share of profits from commercialization of antibodies was driven by higher Dupixent profits. In the first quarter of 2022, the Company earned a $50 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States exceeding $2.0 billion on a rolling twelve-month basis.

Bayer collaboration revenue increased to $385 million in the first quarter of 2022, compared to $323 million in the first quarter of 2021.

The Company also recorded Roche collaboration revenue of $216 million for the first quarter of 2022, compared to $67 million in the first quarter of 2021, in connection with payments from Roche attributable to global gross profits from sales of Ronapreve.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue in the first quarter of 2022 included a $30 million up-front payment received from Ultragenyx in connection with the Company's Evkeeza license and collaboration agreement.

Operating Expenses

($ in millions)	GAAP			Non-GAAP[a]		
	Q1 2022	Q1 2021	% Change	Q1 2022	Q1 2021	% Change
Research and development (R&D)	$ 844	$ 743	14%	$ 751	$ 673	12%
Acquired in-process research and development (IPR&D)**	$ 28	$ —	100%	*	*	n/a
Selling, general, and administrative (SG&A)	$ 450	$ 406	11%	$ 389	$ 355	10%
Cost of goods sold (COGS)	$ 207	$ 183	13%	$ 136	$ 173	(21%)
Cost of collaboration and contract manufacturing (COCM)	$ 198	$ 125	58%	*	*	n/a
Other operating (income) expense, net	$ (20)	$ (41)	(51%)	*	*	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 in-process R&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. In addition, the Company has modified its presentation of non-GAAP reporting and will no longer exclude such expenses from its non-GAAP results. This change does not affect previously reported first quarter 2021 non-GAAP results as the Company recorded no significant charges related to such transactions during that period.

- GAAP and non-GAAP R&D expenses increased in the first quarter of 2022, compared to the first quarter of 2021, primarily due to higher headcount and headcount-related costs, an increase in clinical manufacturing activities, and lower reimbursements from Roche related to REGEN-COV. The increase was partly offset by lower costs incurred in connection with REGEN-COV development activities.
- Acquired IPR&D in the first quarter of 2022 included a $20 million opt-in payment in connection with a product candidate under the Company's collaboration agreement with Adicet Bio, Inc.
- The increase in GAAP and non-GAAP SG&A expenses in the first quarter of 2022, compared to the first quarter of 2021, was primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses for EYLEA.
- GAAP COGS in the first quarter of 2022 included $58 million of costs related to REGEN-COV, including inventory write-offs and reserves, as a result of the FDA revision of the EUA for REGEN-COV (as described above). GAAP and non-GAAP COGS in the first quarter of 2022 included lower REGEN-COV manufacturing costs since there were no net product sales in the United States.
- COCM increased in the first quarter of 2022, compared to the first quarter of 2021, primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent and an increase in shipments of commercial supplies of Praluent for Sanofi outside the United States.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $211 million in the first quarter of 2022, compared to $144 million of net unrealized gains in the first quarter of 2021.

In the first quarter of 2022, the Company's GAAP effective tax rate was 8.3%, compared to 11.0% in the first quarter of 2021. The decrease in the GAAP effective tax rate was due in part to the impact of stock-based compensation. In the first quarter of 2022, the non-GAAP effective tax rate was 11.6%, compared to 10.5% in the first quarter of 2021.

GAAP net income per diluted share was $8.61 in the first quarter of 2022, compared to $10.09 in the first quarter of 2021. Non-GAAP net income per diluted share was $11.49 in the first quarter of 2022, compared to $9.89 in the first 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 first quarter of 2022, the Company repurchased shares of common stock under its share repurchase program, and recorded the cost of the shares received, or $352 million, as Treasury Stock. As of March 31, 2022, $2.493 billion remained available for share repurchases under the program.

Net cash provided by operating activities in the first quarter of 2022 was $2.102 billion, compared to $669 million in the first quarter of 2021, resulting in $1.960 billion in free cash flow for the first quarter of 2022, compared to $553 million for the first quarter of 2021. The increase in free cash flow in the first quarter of 2022 was primarily due to the Company's collection of amounts due from the U.S. government in connection with REGEN-COV sales in the fourth quarter of 2021.

2022 Financial Guidance[(d)]

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

	GAAP	**Non-GAAP[(a)]**
R&D	$3.270 billion–$3.500 billion *(previously $3.170 billion–$3.400 billion)*	$2.900 billion–$3.100 billion *(previously $2.800 billion–$3.000 billion)*
SG&A	$1.890 billion–$2.030 billion	$1.650 billion–$1.770 billion
Gross margin on net product sales[(e)]	89%–91%	90%–92%
COCM[(f)]	$750 million–$830 million	*
Other operating (income) expense, net	($60) million–($80) million	*
Capital expenditures	$630 million–$700 million *(previously $650 million–$730 million)*	*
Effective tax rate (ETR)	11%–13%** *(previously 12%–14%)*	12%–14%** *(previously 13%–15%)*

* 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 by Congress 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	$ 3,270	$ 3,500
R&D: Stock-based compensation expense	(370)	(400)
Non-GAAP R&D	$ 2,900	$ 3,100
GAAP SG&A	$ 1,890	$ 2,030
SG&A: Stock-based compensation expense	(240)	(260)
Non-GAAP SG&A	$ 1,650	$ 1,770
GAAP gross margin on net product sales	89%	91%
Stock-based compensation expense	<1%	<1%
Charges related to REGEN-COV	<1%	<1%
Non-GAAP gross margin on net product sales	90%	92%
GAAP ETR	11%	13%
Income tax effect of GAAP to non-GAAP reconciling items and other	1%	1%
Non-GAAP ETR	12%	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 effective tax rate, 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-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 first quarter 2022 financial and operating results on Wednesday, May 4, 2022, at 8:30 AM Eastern Time. Participants may access the conference call live via webcast on the "Investors and Media" page of Regeneron's website at www.regeneron.com. To participate via telephone, please register in advance at http://www.directeventreg.com/registration/event/7327199. 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), Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn), fasinumab, REGEN-COV®

(casirivimab and imdevimab), aflibercept 8 mg, pozelimab, odronextamab, itepekimab, fianlimab, REGN5458, REGN5713-5714-5715, REGN1908-1909, 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 effective tax rate; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's agreement with Roche relating to the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve™ in other countries), to be cancelled or terminated; the likelihood that any planned or future acquisitions, business combinations, or other related transactions, such as Regeneron's planned acquisition of Checkmate Pharmaceuticals, Inc. discussed in this press release, will close within the expected time period or at all and whether and to what extent Regeneron will realize any anticipated benefits of any such transaction; 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, Dupixent, Praluent, and REGEN-COV), 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 March 31, 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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TABLE 1

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

	March 31, 2022	December 31, 2021
Assets:		
Cash and marketable securities	$ 14,134.6	$ 12,532.7
Accounts receivable, net	4,839.0	6,036.5
Inventories	1,991.5	1,951.3
Property, plant, and equipment, net	3,556.4	3,482.2
Deferred tax assets	1,140.3	876.9
Other assets	686.9	555.2
Total assets	$ 26,348.7	$ 25,434.8
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,208.8	$ 3,451.0
Finance lease liabilities	720.0	719.7
Deferred revenue	524.8	515.3
Long-term debt	1,980.4	1,980.0
Stockholders' equity	19,914.7	18,768.8
Total liabilities and stockholders' equity	$ 26,348.7	$ 25,434.8

TABLE 2

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

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Net product sales	$ 1,638.6	$ 1,724.3
Collaboration revenue	1,232.5	754.4
Other revenue	94.0	50.0
	2,965.1	2,528.7
Expenses:		
Research and development	843.8	742.9
Acquired in-process research and development	28.1	—
Selling, general, and administrative	450.0	405.6
Cost of goods sold	207.3	183.2
Cost of collaboration and contract manufacturing	197.6	124.8
Other operating (income) expense, net	(20.2)	(40.5)
	1,706.6	1,416.0
Income from operations	1,258.5	1,112.7
Other income (expense):		
Other (expense) income, net	(183.8)	154.9
Interest expense	(13.6)	(14.6)
	(197.4)	140.3
Income before income taxes	1,061.1	1,253.0
Income tax expense	87.6	137.8
Net income	$ 973.5	$ 1,115.2
Net income per share - basic	$ 9.12	$ 10.58
Net income per share - diluted	$ 8.61	$ 10.09
Weighted average shares outstanding - basic	106.8	105.4
Weighted average shares outstanding - diluted	113.1	110.5

TABLE 3

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

	Three Months Ended March 31,	
	2022	**2021**
GAAP R&D	$ 843.8	$ 742.9
R&D: Stock-based compensation expense	92.4	69.7
Non-GAAP R&D	$ 751.4	$ 673.2
GAAP SG&A	$ 450.0	$ 405.6
SG&A: Stock-based compensation expense	60.7	50.8
Non-GAAP SG&A	$ 389.3	$ 354.8
GAAP COGS	$ 207.3	$ 183.2
COGS: Stock-based compensation expense	13.8	10.4
COGS: Charges related to REGEN-COV	58.0	—
Non-GAAP COGS	$ 135.5	$ 172.8
GAAP other income (expense), net	$ (197.4)	$ 140.3
Other income/expense: Losses (gains) on investments	204.5	(144.3)
Non-GAAP other income (expense), net	$ 7.1	$ (4.0)
GAAP net income	$ 973.5	$ 1,115.2
Total of GAAP to non-GAAP reconciling items above	429.4	(13.4)
Income tax effect of GAAP to non-GAAP reconciling items	(85.3)	7.4
Non-GAAP net income	$ 1,317.6	$ 1,109.2
Non-GAAP net income per share - basic	$ 12.34	$ 10.52
Non-GAAP net income per share - diluted	$ 11.49	$ 9.89
Shares used in calculating:		
Non-GAAP net income per share - basic	106.8	105.4
Non-GAAP net income per share - diluted	114.7	112.1

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue reconciliation:		
Total revenues	$ 2,965.1	$ 2,528.7
REGEN-COV net product sales in the United States	—	262.2
Global gross profit payment from Roche in connection with sales of Ronapreve	216.3	66.8
Total revenues excluding REGEN-COV and Ronapreve	$ 2,748.8	$ 2,199.7
Effective tax rate reconciliation:		
GAAP effective tax rate	8.3%	11.0%
Income tax effect of GAAP to non-GAAP reconciling items	3.3%	(0.5%)
Non-GAAP effective tax rate	11.6%	10.5%
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 2,101.7	$ 668.5
Capital expenditures	(141.8)	(115.3)
Free cash flow	$ 1,959.9	$ 553.2

TABLE 4

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

	Three Months Ended March 31,	
	2022	**2021**
Sanofi collaboration revenue:		
Antibody:		
Regeneron's share of profits in connection with commercialization of antibodies	$ 415.3	$ 260.6
Sales-based milestone earned	50.0	—
Reimbursement for manufacturing of commercial supplies	160.8	105.6
Immuno-oncology:		
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	2.8	(6.1)
Reimbursement for manufacturing of ex-U.S. commercial supplies	2.0	4.7
Total Sanofi collaboration revenue	630.9	364.8
Bayer collaboration revenue:		
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	338.4	308.9
Reimbursement for manufacturing of ex-U.S. commercial supplies	25.0	13.9
One-time payment in connection with change in Japan arrangement	21.9	—
Total Bayer collaboration revenue	385.3	322.8
Roche collaboration revenue:		
Global gross profit payment from Roche in connection with sales of Ronapreve	216.3	66.8
Total collaboration revenue	$ 1,232.5	$ 754.4

TABLE 5

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

	Three Months Ended March 31,						
	2022			2021			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,517.6	$ 868.5	$ 2,386.1	$ 1,347.0	$ 811.2 *	$ 2,158.2	11 %
Dupixent[b]	$ 1,325.6	$ 484.8	$ 1,810.4	$ 961.5	$ 301.4	$ 1,262.9	43 %
Libtayo[c]	$ 78.9	$ 45.8	$ 124.7	$ 69.1	$ 31.7	$ 100.8	24 %
Praluent[d]	$ 33.6	$ 77.8	$ 111.4	$ 43.3	$ 61.3	$ 104.6	7 %
REGEN-COV[e]	$ —	$ 635.6	$ 635.6	$ 262.2	$ 176.6	$ 438.8	45 %
Kevzara[b]	$ 57.0	$ 49.4	$ 106.4	$ 30.7	$ 38.4	$ 69.1	54 %
Other products[f]	$ 9.9	$ 20.4	$ 30.3	$ 4.1	$ 23.0	$ 27.1	12 %

* 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] Regeneron records net product sales of Libtayo in the United States and Sanofi records net product sales of Libtayo outside the United States. The parties equally share profits/losses in connection with global sales of Libtayo.

[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 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 $18.7 million for the fourth quarter of 2021.