

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, 2022 (August 3, 2022)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York
(State or other jurisdiction of incorporation)

000-19034
(Commission File Number)

13-3444607
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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, 2022, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 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 August 3, 2022, Reporting Second 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: August 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 Second Quarter 2022 Financial and Operating Results

- Second quarter 2022 revenues decreased 44% to \$2.86 billion versus second quarter 2021; excluding REGEN-COV^{®(a)(b)}, revenues increased 20%
- Second quarter 2022 EYLEA[®] U.S. net sales increased 14% versus second quarter 2021 to a record \$1.62 billion
- Second quarter 2022 Dupixent[®] global net sales^(c) (recorded by Sanofi) increased 40% to \$2.09 billion versus second quarter 2021
- Second quarter 2022 GAAP diluted EPS of \$7.47; non-GAAP diluted EPS^(a) of \$9.77 including unfavorable \$1.71 impact from acquired IPR&D charges
- FDA approved Dupixent for atopic dermatitis in children aged 6 months to 5 years and eosinophilic esophagitis in adults and adolescents; FDA priority review granted for prurigo nodularis
- Encouraging preliminary anti-tumor activity observed for novel investigational PSMAxCD28 costimulatory bispecific antibody in combination with Libtayo[®] in advanced metastatic castration-resistant prostate cancer
- Strengthened commitment to oncology through purchase of Sanofi's stake in Libtayo and acquisition of Checkmate Pharmaceuticals

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

"The second quarter of 2022 was distinguished by record net product sales of EYLEA, Dupixent, and Libtayo, as well as multiple regulatory achievements for Dupixent, including U.S. approvals for atopic dermatitis among very young patients and for eosinophilic esophagitis in adults and adolescents, as well as European approval for pediatric asthma," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In addition, we have continued to strengthen our oncology franchise, including through the purchase of worldwide rights to Libtayo as well as encouraging but preliminary anti-tumor activity observed at higher doses of our novel PSMAxCD28 costimulatory bispecific in combination with Libtayo for advanced metastatic castration-resistant prostate cancer."

Financial Highlights

(\$ in millions, except per share data)

	Q2 2022	Q2 2021	% Change
Total revenues	\$ 2,857	\$ 5,139	(44%)
GAAP net income	\$ 852	\$ 3,099	(73%)
GAAP net income per share - diluted	\$ 7.47	\$ 27.97	(73%)
Non-GAAP net income ^(a)	\$ 1,127	\$ 2,895	(61%)
Non-GAAP net income per share - diluted ^(a)	\$ 9.77	\$ 25.80	(62%)

"We are pleased with our second quarter 2022 financial performance, including 20% revenue growth when excluding contributions from REGEN-COV. This demonstrates the continued strength of our core business," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "Additionally, we updated our full-year 2022 financial guidance primarily to reflect the recently completed acquisition of Libtayo global rights from Sanofi, a transaction that we believe will deliver significant shareholder value over time. In the second half of 2022, we look forward to advancing our pipeline with important clinical data readouts in oncology and ophthalmology as well as continued commercial execution and prudent capital allocation to drive value creation for 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:

Dupixent® (dupilumab)

- In June 2022, the U.S. Food and Drug Administration (FDA) approved Dupixent as the first biologic medicine for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis.
- In May 2022, the FDA approved Dupixent for adults and adolescents aged 12 years and older with eosinophilic esophagitis (EoE).
- In April 2022, the European Commission (EC) approved Dupixent for the treatment of severe asthma in children aged 6 to 11 years.
- The Company and Sanofi announced positive results from a Phase 3 trial in children aged 1 to 11 years with EoE. The trial met its primary endpoint of histological disease remission at 16 weeks with both higher and lower dose weight-tiered regimens.
- The FDA accepted for priority review the supplemental Biologics License Application (sBLA) for Dupixent for adults with prurigo nodularis, with a target action date of September 30, 2022. Regulatory applications have also been submitted in the European Union (EU) and Japan.

EYLEA® (afibercept) Injection

- The FDA accepted for review the sBLA for EYLEA for an every-16-weeks dosing regimen in patients with diabetic retinopathy (DR), with a target action date of February 28, 2023.

REGN5678, a PSMAxCD28 costimulatory bispecific antibody

- Reported preliminary, first-in-human data in combination with Libtayo® in patients with advanced metastatic castration-resistant prostate cancer.

Antibodies to SARS-CoV-2 virus

- The Company is continuing to progress investigational "next generation" antibodies that are active against multiple variants including those of Omicron-lineage.

REGN5381, an agonist antibody to NPR1

- A Phase 2 study in heart failure was initiated.

Corporate and Business Development Updates

- In May 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. for a total equity value of approximately \$250 million. In connection with the acquisition, the

Company obtained the rights to vidutolimod (immune activator targeting TLR9), which is in clinical development for oncology.

- 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 will also pay Sanofi a royalty on net product sales of Libtayo.
- Also effective July 1, 2022, the Company will increase from 10% to 20% the share of its profits that are paid to Sanofi in connection with the development balance reimbursement under the antibody collaboration.

Second Quarter 2022 Financial Results

Revenues

<i>(\$ in millions)</i>	Q2 2022	Q2 2021	% Change
Net product sales in the United States:			
EYLEA	\$ 1,621	\$ 1,425	14 %
Libtayo**	91	78	17 %
Praluent®	31	42	(26 %)
REGEN-COV®	—	2,591	(100 %)
Evkeeza®	11	2	*
Collaboration revenue:			
Sanofi	678	438	55 %
Bayer	358	349	3 %
Roche	8	168	(95 %)
Other collaboration revenue	—	—	*
Other revenue	59	46	28 %
Total revenues	\$ 2,857	\$ 5,139	(44 %)

* Percentage not meaningful

** Effective July 1, 2022, the Company will record global net product sales of Libtayo.

Total revenues decreased by 44% to \$2.857 billion in the second quarter of 2022, compared to \$5.139 billion in the second quarter of 2021. Total revenues excluding REGEN-COV and Ronapreve^(b) revenues for both periods increased by 20% to \$2.849 billion in the second quarter of 2022, compared to the second 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 55% to \$678 million in the second quarter of 2022, compared to the second quarter of 2021. This increase was primarily due to the Company's share of profits from commercialization of antibodies, which were \$497 million in the second quarter of 2022, compared to \$328 million in the second quarter of 2021. The change in the Company's share of profits from commercialization of antibodies was driven by higher Dupixent profits. Roche collaboration revenue decreased in the second quarter of 2022, compared to the second quarter of 2021, due to lower sales of Ronapreve.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

(\$ in millions)	GAAP			Non-GAAP ^(a)		
	Q2 2022	Q2 2021	% Change	Q2 2022	Q2 2021	% Change
Research and development (R&D)	\$ 794	\$ 714	11%	\$ 690	\$ 643	7%
Acquired in-process research and development (IPR&D)**	\$ 197	\$ —	100%	*	*	n/a
Selling, general, and administrative (SG&A)	\$ 476	\$ 415	15%	\$ 418	\$ 365	15%
Cost of goods sold (COGS)	\$ 149	\$ 539	(72%)	\$ 137	\$ 514	(73%)
Cost of collaboration and contract manufacturing (COCM)	\$ 148	\$ 154	(4%)	*	*	n/a
Other operating (income) expense, net	\$ (17)	\$ (31)	(45%)	*	*	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 six months ended June 30, 2021 as the Company recorded no such charges during either of these periods.

- GAAP and non-GAAP R&D expenses increased in the second quarter of 2022, compared to the second quarter of 2021, primarily due to higher headcount and headcount-related costs and an increase in clinical manufacturing activities, partly offset by lower costs incurred in connection with REGEN-COV development activities.
- Acquired IPR&D in the second quarter of 2022 included a \$195 million charge related to the Company's acquisition of Checkmate Pharmaceuticals.
- The increase in GAAP and non-GAAP SG&A expenses in the second quarter of 2022, compared to the second quarter of 2021, was primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses for EYLEA, partly offset by costs in 2021 for educational campaigns related to COVID-19 that did not recur in 2022.
- GAAP and non-GAAP COGS decreased in the second quarter of 2022, compared to the second quarter of 2021, primarily due to the Company not recognizing any REGEN-COV net product sales in the United States during 2022.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of \$164 million in the second quarter of 2022, compared to \$409 million of net unrealized gains in the second quarter of 2021.

In the second quarter of 2022, the Company's GAAP effective tax rate (ETR) was 11.5%, compared to 17.4% in the second quarter of 2021. The decrease in the GAAP ETR was primarily driven by the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, the impact of income earned in the United States during 2021 related to REGEN-COV, and, to a lesser extent, stock-based compensation. In the second quarter of 2022, the non-GAAP ETR was 13.6%, compared to 17.0% in the second quarter of 2021.

GAAP net income per diluted share was \$7.47 in the second quarter of 2022, compared to \$27.97 in the second quarter of 2021. Non-GAAP net income per diluted share was \$9.77 in the

second quarter of 2022, compared to \$25.80 in the second 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 second quarter of 2022, the Company repurchased shares of common stock under its share repurchase program, and recorded the cost of the shares received, or \$394 million, as Treasury Stock. As of June 30, 2022, \$2.099 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 (inclusive of updates made in connection with the Company's purchase of Sanofi's stake in Libtayo and acquisition of Checkmate Pharmaceuticals):

	GAAP	Non-GAAP ^(a)
R&D	\$3.485 billion–\$3.655 billion <i>(previously \$3.270 billion–\$3.500 billion)</i>	\$3.100 billion–\$3.240 billion <i>(previously \$2.900 billion–\$3.100 billion)</i>
SG&A	\$1.990 billion–\$2.110 billion <i>(previously \$1.890 billion–\$2.030 billion)</i>	\$1.740 billion–\$1.840 billion <i>(previously \$1.650 billion–\$1.770 billion)</i>
Gross margin on net product sales ^(e)	90%–91% <i>(previously 89%–91%)</i>	92%–93% <i>(previously 90%–92%)</i>
COCM ^(f)	\$710 million–\$760 million <i>(previously \$750 million–\$830 million)</i>	*
Other operating (income) expense, net	(\$40) million–(\$60) million <i>(previously (\$60) million–(\$80) million)</i>	*
Capital expenditures	\$620 million–\$670 million <i>(previously \$630 million–\$700 million)</i>	*
Effective tax rate	12%–13%** <i>(previously 11%–13%)</i>	13%–14%** <i>(previously 12%–14%)</i>

* 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	\$ 3,485	\$ 3,655
Stock-based compensation expense	(370)	(400)
Acquisition-related integration costs	(15)	(15)
Non-GAAP R&D	\$ 3,100	\$ 3,240
GAAP SG&A	\$ 1,990	\$ 2,110
Stock-based compensation expense	(240)	(260)
Acquisition-related integration costs	(10)	(10)
Non-GAAP SG&A	\$ 1,740	\$ 1,840
GAAP gross margin on net product sales	90%	91%
Stock-based compensation expense	<1%	<1%
Charges related to REGEN-COV	<1%	<1%
Amortization of intangible assets	<1%	<1%
Non-GAAP gross margin on net product sales	92%	93%
GAAP ETR	12%	13%
Income tax effect of GAAP to non-GAAP reconciling items and other	1%	1%
Non-GAAP ETR	13%	14%

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- (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.
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Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its second quarter 2022 financial and operating results on Wednesday, August 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[®] (afibercept) Injection, Dupixent[®] (dupilumab), Libtayo[®] (cemiplimab), Praluent[®] (alirocumab), Kevzara[®] (sarilumab), Evkeeza[®] (evinacumab), fasinumab, REGEN-COV[®] (casirivimab and imdevimab), afibercept 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 ETR; 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), 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, 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 June 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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TABLE 1

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

	June 30, 2022	December 31, 2021
Assets:		
Cash and marketable securities	\$ 13,982.3	\$ 12,532.7
Accounts receivable, net	5,161.4	6,036.5
Inventories	2,218.5	1,951.3
Property, plant, and equipment, net	3,637.7	3,482.2
Deferred tax assets	1,352.4	876.9
Other assets	853.5	555.2
Total assets	\$ 27,205.8	\$ 25,434.8
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 3,192.3	\$ 3,451.0
Finance lease liabilities	720.0	719.7
Deferred revenue	625.0	515.3
Long-term debt	1,980.7	1,980.0
Stockholders' equity	20,687.8	18,768.8
Total liabilities and stockholders' equity	\$ 27,205.8	\$ 25,434.8

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,	
	2022	2021	2022	2021
Revenues:				
Net product sales	\$ 1,754.4	\$ 4,137.8	\$ 3,393.0	\$ 5,862.1
Collaboration revenue	1,043.6	954.7	2,276.1	1,709.1
Other revenue	59.2	46.0	153.2	96.0
	<u>2,857.2</u>	<u>5,138.5</u>	<u>5,822.3</u>	<u>7,667.2</u>
Expenses:				
Research and development	794.3	714.2	1,638.1	1,457.1
Acquired in-process research and development	197.0	—	225.1	—
Selling, general, and administrative	476.3	414.7	926.3	820.3
Cost of goods sold	149.2	539.4	356.5	722.6
Cost of collaboration and contract manufacturing	147.9	154.3	345.5	279.1
Other operating (income) expense, net	(17.4)	(31.3)	(37.6)	(71.8)
	<u>1,747.3</u>	<u>1,791.3</u>	<u>3,453.9</u>	<u>3,207.3</u>
Income from operations	1,109.9	3,347.2	2,368.4	4,459.9
Other income (expense):				
Other (expense) income, net	(133.6)	420.0	(317.4)	574.9
Interest expense	(13.1)	(14.4)	(26.7)	(29.0)
	<u>(146.7)</u>	<u>405.6</u>	<u>(344.1)</u>	<u>545.9</u>
Income before income taxes	963.2	3,752.8	2,024.3	5,005.8
Income tax expense	111.1	653.9	198.7	791.7
Net income	<u>\$ 852.1</u>	<u>\$ 3,098.9</u>	<u>\$ 1,825.6</u>	<u>\$ 4,214.1</u>
Net income per share - basic	\$ 7.90	\$ 29.51	\$ 17.01	\$ 40.06
Net income per share - diluted	\$ 7.47	\$ 27.97	\$ 16.07	\$ 38.07
Weighted average shares outstanding - basic	107.9	105.0	107.3	105.2
Weighted average shares outstanding - diluted	114.0	110.8	113.6	110.7

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,	
	2022	2021	2022	2021
GAAP R&D	\$ 794.3	\$ 714.2	\$ 1,638.1	\$ 1,457.1
R&D: Stock-based compensation expense	89.7	70.9	182.1	140.6
R&D: Acquisition-related integration costs	14.6	—	14.6	—
Non-GAAP R&D	<u>\$ 690.0</u>	<u>\$ 643.3</u>	<u>\$ 1,441.4</u>	<u>\$ 1,316.5</u>
GAAP SG&A	\$ 476.3	\$ 414.7	\$ 926.3	\$ 820.3
SG&A: Stock-based compensation expense	57.5	49.6	118.2	100.4
SG&A: Acquisition-related integration costs	1.1	—	1.1	—
Non-GAAP SG&A	<u>\$ 417.7</u>	<u>\$ 365.1</u>	<u>\$ 807.0</u>	<u>\$ 719.9</u>
GAAP COGS	\$ 149.2	\$ 539.4	\$ 356.5	\$ 722.6
COGS: Stock-based compensation expense	12.6	25.0	26.4	35.4
COGS: Charges related to REGEN-COV	—	—	58.0	—
Non-GAAP COGS	<u>\$ 136.6</u>	<u>\$ 514.4</u>	<u>\$ 272.1</u>	<u>\$ 687.2</u>
GAAP other income (expense), net	\$ (146.7)	\$ 405.6	\$ (344.1)	\$ 545.9
Other income/expense: Losses (gains) on investments	166.3	(409.6)	370.8	(553.9)
Non-GAAP other income (expense), net	<u>\$ 19.6</u>	<u>\$ (4.0)</u>	<u>\$ 26.7</u>	<u>\$ (8.0)</u>
GAAP net income	\$ 852.1	\$ 3,098.9	\$ 1,825.6	\$ 4,214.1
Total of GAAP to non-GAAP reconciling items above	341.8	(264.1)	771.2	(277.5)
Income tax effect of GAAP to non-GAAP reconciling items	(67.0)	60.2	(152.3)	67.6
Non-GAAP net income	<u>\$ 1,126.9</u>	<u>\$ 2,895.0</u>	<u>\$ 2,444.5</u>	<u>\$ 4,004.2</u>
Non-GAAP net income per share - basic	\$ 10.44	\$ 27.57	\$ 22.78	\$ 38.06
Non-GAAP net income per share - diluted	\$ 9.77	\$ 25.80	\$ 21.26	\$ 35.72
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	107.9	105.0	107.3	105.2
Non-GAAP net income per share - diluted	115.4	112.2	115.0	112.1

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<i>Revenue reconciliation:</i>				
Total revenues	\$ 2,857.2	\$ 5,138.5	\$ 5,822.3	\$ 7,667.2
REGEN-COV net product sales in the United States	—	2,591.2	—	2,853.4
Global gross profit payment from Roche in connection with sales of Ronapreve	8.2	167.9	224.5	234.7
Total revenues excluding REGEN-COV and Ronapreve	\$ 2,849.0	\$ 2,379.4	\$ 5,597.8	\$ 4,579.1
<i>Effective tax rate reconciliation:</i>				
GAAP ETR	11.5%	17.4%	9.8%	15.8%
Income tax effect of GAAP to non-GAAP reconciling items	2.1%	(0.4%)	2.8%	(0.5%)
Non-GAAP ETR	align="right">13.6%	align="right">17.0%	align="right">12.6%	align="right">15.3%

	Six Months Ended June 30,	
	2022	2021
<i>Free cash flow reconciliation:</i>		
Net cash provided by operating activities	\$ 2,666.1	\$ 1,295.2
Capital expenditures	(295.4)	(263.8)
Free cash flow	\$ 2,370.7	\$ 1,031.4

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<i>Sanofi collaboration revenue:</i>				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	\$ 496.6	\$ 327.6	\$ 911.9	\$ 588.2
Sales-based milestone earned	—	—	50.0	—
Reimbursement for manufacturing of commercial supplies	145.5	110.9	306.3	216.5
Other	28.9	—	28.9	—
Immuno-oncology:				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	3.9	(3.5)	6.7	(9.6)
Reimbursement for manufacturing of ex-U.S. commercial supplies	2.6	2.7	4.6	7.4
Total Sanofi collaboration revenue	<u>677.5</u>	<u>437.7</u>	<u>1,308.4</u>	<u>802.5</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	339.7	335.4	678.1	644.3
Reimbursement for manufacturing of ex-U.S. commercial supplies	17.8	13.7	42.8	27.6
One-time payment in connection with change in Japan arrangement	—	—	21.9	—
Total Bayer collaboration revenue	<u>357.5</u>	<u>349.1</u>	<u>742.8</u>	<u>671.9</u>
<i>Other collaboration revenue:</i>				
Global gross profit payment from Roche in connection with sales of Ronapreve	8.2	167.9	224.5	234.7
Other	0.4	—	0.4	—
Total collaboration revenue	<u>\$ 1,043.6</u>	<u>\$ 954.7</u>	<u>\$ 2,276.1</u>	<u>\$ 1,709.1</u>

TABLE 5

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

	Three Months Ended June 30,						% Change (Total Sales)
	2022			2021			
	U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA ^(a)	\$ 1,621.2	\$ 869.8	\$ 2,491.0	\$ 1,424.7	\$ 857.6 *	\$ 2,282.3	9 %
Dupixent ^(b)	\$ 1,582.1	\$ 509.7	\$ 2,091.8	\$ 1,146.6	\$ 352.4	\$ 1,499.0	40 %
Libtayo ^(c)	\$ 90.9	\$ 50.4	\$ 141.3	\$ 78.0	\$ 38.9	\$ 116.9	21 %
Praluent ^(d)	\$ 31.2	\$ 77.7	\$ 108.9	\$ 41.9	\$ 57.5	\$ 99.4	10 %
REGEN-COV ^(e)	\$ —	\$ 22.8	\$ 22.8	\$ 2,591.2	\$ 470.2	\$ 3,061.4	(99 %)
Kevzara ^(b)	\$ 43.0	\$ 39.3	\$ 82.3	\$ 30.7	\$ 36.0	\$ 66.7	23 %
Other products ^(f)	\$ 12.1	\$ 19.0	\$ 31.1	\$ 3.3	\$ 22.2	\$ 25.5	22 %

	Six Months Ended June 30,						% Change (Total Sales)
	2022			2021			
	U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA ^(a)	\$ 3,138.8	\$ 1,738.3	\$ 4,877.1	\$ 2,771.7	\$ 1,668.8 *	\$ 4,440.5	10 %
Dupixent ^(b)	\$ 2,907.7	\$ 994.5	\$ 3,902.2	\$ 2,108.1	\$ 653.8	\$ 2,761.9	41 %
Libtayo ^(c)	\$ 169.8	\$ 96.2	\$ 266.0	\$ 147.1	\$ 70.6	\$ 217.7	22 %
Praluent ^(d)	\$ 64.8	\$ 155.5	\$ 220.3	\$ 85.2	\$ 118.8	\$ 204.0	8 %
REGEN-COV ^(e)	\$ —	\$ 658.4	\$ 658.4	\$ 2,853.4	\$ 654.4	\$ 3,507.8	(81 %)
Kevzara ^(b)	\$ 100.0	\$ 88.7	\$ 188.7	\$ 61.4	\$ 74.4	\$ 135.8	39 %
Other products ^(f)	\$ 22.0	\$ 39.4	\$ 61.4	\$ 7.4	\$ 45.2	\$ 52.6	17 %

* 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 will record global net product sales of Libtayo and pay Sanofi a royalty on such sales.

^(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 \$22.2 million for the first quarter of 2022.