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 6, 2021 (May 6, 2021)

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 6, 2021, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2021. 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 6, 2021, Reporting First Quarter 2021 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 6, 2021 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 2021 Financial and Operating Results

- *First quarter 2021 revenues increased 38% to $2.53 billion versus first quarter 2020; revenues excluding REGEN-COV™(1) increased 20%*
- *First quarter 2021 EYLEA® U.S. net sales increased 15% to $1.35 billion versus first quarter 2020*
- *First quarter 2021 Dupixent® global net sales(2), which are recorded by Sanofi, increased 48% to $1.26 billion versus first quarter 2020*
- *First quarter 2021 GAAP diluted EPS was $10.09 and non-GAAP diluted EPS(1) was $9.89*
- *Three FDA approvals received: Libtayo® for first-line advanced non-small cell lung cancer (NSCLC) and advanced basal cell carcinoma (BCC), and Evkeeza™ for homozygous familial hypercholesterolemia (HoFH)*
- *Positive data reported from Phase 3 trials with REGEN-COV used to treat and prevent COVID-19*

Tarrytown, New York (May 6, 2021) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2021 and provided a business update.

"Regeneron had a strong first quarter highlighting our continued evolution into a company with multiple durable product lines helping people with a range of serious diseases including COVID-19," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We recently reported positive Phase 3 results for REGEN-COV in both the COVID-19 outpatient treatment and prevention settings and are working with national and state authorities to improve access. We expect continued growth with EYLEA in retinal diseases, as well as with Dupixent through further penetration in existing indications and a broad Phase 3 development program. In oncology, we are in the early days of launching Libtayo for advanced basal cell carcinoma and non-small cell lung cancer and recently announced positive pivotal data in cervical cancer with regulatory submissions planned for later this year."

Financial Highlights

($ in millions, except per share data)	Q1 2021	Q1 2020	% Change
Total revenues	$ 2,529	$ 1,828	38%
GAAP net income	$ 1,115	$ 625	78%
GAAP net income per share - diluted	$ 10.09	$ 5.43	86%
Non-GAAP net income(1)	$ 1,109	$ 771	44%
Non-GAAP net income per share - diluted(1)	$ 9.89	$ 6.60	50%

"Our business is off to a strong start in 2021 with double-digit top- and bottom-line growth," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "Our financial strength and solid execution across the business continue to position the Company for sustainable long-term growth."

Business Highlights

Key Pipeline Progress

Regeneron has approximately 30 product candidates in clinical development, including six marketed products for which it is investigating additional indications. Updates from the clinical pipeline include:

EYLEA® (aflibercept) Injection

- In March 2021, *JAMA Ophthalmology* announced initial results from the National Institutes of Health-sponsored Protocol W trial evaluating EYLEA in patients with moderate to severe non-proliferative diabetic retinopathy (NPDR). The two-year data confirmed results from the Company-sponsored PANORAMA trial and demonstrated that EYLEA significantly reduced the risk of developing vision-threatening complications with an every-16-weeks dosing regimen. The Company plans to submit a supplemental Biologics License Application (sBLA) for an every-16-weeks dosing regimen in patients with NPDR later this year.

Dupixent® (dupilumab)

- The U.S. Food and Drug Administration (FDA) accepted for review, with a target action date of October 21, 2021, the sBLA for Dupixent for children aged 6 to 11 years with moderate-to-severe asthma. A regulatory application for Dupixent for children aged 6 to 11 years with severe asthma was also submitted in the European Union (EU).

REGEN-COV™ (casirivimab with imdevimab), a dual antibody cocktail to SARS-CoV-2 virus

- In March 2021, the Company announced positive top-line results from the Phase 3 treatment trial in high-risk COVID-19 outpatients. The trial met its primary endpoint, showing that REGEN-COV significantly reduced the risk of hospitalization or death by approximately 70% with both REGEN-COV doses (1,200 mg and 2,400 mg) compared to placebo. The trial also met key secondary endpoints, including the ability to reduce symptom duration. Based on these results, the Company submitted a request to the FDA to update the Emergency Use Authorization (EUA) to the lower 1,200 mg dose.
- In April 2021, the National Institutes of Health (NIH) COVID-19 Treatment Guidelines were updated to strongly recommended that REGEN-COV be used in non-hospitalized COVID-19 patients at high risk of clinical progression.
- In April 2021, the Company announced positive results from the Phase 3 COVID-19 prevention trial in uninfected household contacts of SARS-CoV-2 infected individuals. The trial met its primary and key secondary endpoints, showing that REGEN-COV 1,200 mg administered subcutaneously reduced the risk of symptomatic infections by 81%. The Company has shared this data with the FDA and requested that the EUA be expanded to include COVID-19 prevention for appropriate populations.

- In April 2021, the Company also announced positive data from a Phase 3 treatment trial in recently infected asymptomatic COVID-19 patients. The trial met all primary and key secondary endpoints, and demonstrated that the 1,200 mg subcutaneous injection of REGEN-COV reduced the risk of progressing to symptomatic COVID-19 by 31%, and by 76% after the third day.
- In January 2021, the Company announced a second agreement with the U.S. government to manufacture and deliver REGEN-COV. The U.S. government has agreed to acquire up to 1.25 million additional doses at the lowest treatment dose authorized or approved by the FDA for the indication authorized under the EUA, resulting in payments to the Company of up to $2.625 billion in the aggregate. The Company anticipates being able to provide at least 1 million doses by June 30, 2021 if the EUA is updated to the lower 1,200 mg dose. The U.S. government is obligated to purchase all filled and finished doses of drug product delivered by June 30, 2021, and may accept additional doses through September 30, 2021 at its discretion. A number of factors may impact the quantity of filled and finished product supplied by June 30, 2021, including manufacturing considerations and authorized dose levels.

Libtayo® (cemiplimab)
- In February 2021, the FDA approved Libtayo for the first-line treatment of patients with advanced NSCLC.
- In February 2021, the FDA also approved Libtayo for the treatment of metastatic or locally advanced BCC.
- In March 2021, the Company and Sanofi announced positive results from the Phase 3 trial in cervical cancer, which was stopped early based on a recommendation by the Independent Data Monitoring Committee (IDMC). The results demonstrated an overall survival benefit compared to chemotherapy. Regulatory submissions are planned for later this year.

Evkeeza™, an antibody to ANGPTL3
- In February 2021, the FDA approved Evkeeza for the treatment of adults and adolescents with HoFH.

Bispecific Antibodies
- The Company retained the exclusive rights to develop and commercialize two bispecific antibodies targeting BCMAxCD3 (REGN5458 and REGN5459) and a bispecific antibody targeting MUC16xCD3 (REGN4018) as Sanofi did not exercise its options to license rights to these product candidates under the companies' immuno-oncology collaboration. REGN5458 and REGN5459 are in clinical development for multiple myeloma, and REGN4018 is being studied in ovarian cancer.

REGN1908-1909, a multi-antibody therapy to Fel d 1
- In February 2021, the Company announced that the Phase 2 study in cat allergic patients with mild asthma met its primary and key secondary endpoints. The Company plans to initiate a Phase 3 study in cat allergic asthmatics later this year.

First Quarter 2021 Financial Results

Revenues

Total revenues increased by 38% to $2.529 billion in the first quarter of 2021, compared to $1.828 billion in the first quarter of 2020. Total revenues excluding REGEN-COV increased by 20% to $2.200 billion in the first quarter of 2021, compared to the first quarter of 2020.

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

($ in millions)	Q1 2021	Q1 2020
EYLEA	$ 1,347	$ 1,172
Libtayo	69	62
Praluent®	43	*
REGEN-COV	262	—
Evkeeza	1	—
ARCALYST®	2	3
Total net product sales in the U.S.	$ 1,724	$ 1,237

* Effective April 1, 2020, the Company became solely responsible for the development and commercialization of Praluent in the United States and records net product sales of Praluent in the United States.

Total revenues also include collaboration revenues[(2)] of $754 million in the first quarter of 2021, compared to $528 million in the first quarter of 2020. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which were $261 million in the first quarter of 2021, compared to $171 million in the first quarter of 2020. The change in the Company's share of profits from commercialization of antibodies was primarily driven by higher Dupixent profits. In the first quarter of 2021, the Company also recorded Roche collaboration revenue of $67 million in connection with the Company's share of gross profits from sales of the casirivimab with imdevimab antibody cocktail (known as REGEN-COV in the United States).

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

	GAAP			Non-GAAP[(1)]		
($ in millions)	Q1 2021	Q1 2020	% Change	Q1 2021	Q1 2020	% Change
Research and development (R&D)	$ 743	$ 584	27%	$ 673	$ 527	28%
Selling, general, and administrative (SG&A)	$ 406	$ 367	11%	$ 355	$ 307	16%
Cost of goods sold (COGS)	$ 183	$ 79	132%	$ 173	$ 70	147%
Cost of collaboration and contract manufacturing (COCM)	$ 125	$ 139	(10%)	*	*	n/a
Other operating (income) expense, net	$ (41)	$ (40)	3%	*	*	n/a

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

- The higher GAAP and non-GAAP R&D expenses in the first quarter of 2021 were primarily due to costs incurred in connection with development activities related to REGEN-COV.
- The increase in GAAP and non-GAAP SG&A expenses in the first quarter of 2021 was primarily due to an increase in product launch-related costs and higher headcount-related costs.
- The increase in COGS in the first quarter of 2021 was primarily due to the recognition of manufacturing costs in connection with product sales of REGEN-COV in the United States, as well as Praluent in the United States (which were recorded by Sanofi prior to April 1, 2020).

- Other operating (income) expense, net, includes recognition of a portion of amounts previously deferred in connection with up-front and development milestone payments, as applicable, received in connection with the Company's collaborative arrangements.

Other Financial Information

GAAP other income (expense), net, includes the recognition of net gains on equity securities of $144 million in the first quarter of 2021, compared to net losses of $57 million in the first quarter of 2020.

In the first quarter of 2021, the Company's GAAP effective tax rate was 11.0%, compared to 6.6% in the first quarter of 2020. The GAAP effective tax rate for the first quarter 2021 was positively impacted, compared to the U.S. federal statutory rate, primarily by the reversal of liabilities related to uncertain tax positions, stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and federal tax credits for research activities. In the first quarter of 2021, the non-GAAP effective tax rate was 10.5%, compared to 9.5% in the first quarter of 2020.

GAAP net income per diluted share was $10.09 in the first quarter of 2021, compared to GAAP net income per diluted share of $5.43 in the first quarter of 2020. Non-GAAP net income per diluted share was $9.89 in the first quarter of 2021, compared to non-GAAP net income per diluted share of $6.60 in the first quarter of 2020. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

In January 2021, the Company's board of directors authorized a new share repurchase program to repurchase up to $1.5 billion of the Company's common stock. Repurchases may be made from time to time at management's discretion through a variety of methods. The program has no time limit and can be discontinued at any time. During the first quarter of 2021, the Company repurchased shares of common stock under the program, and recorded the cost of the shares received, or $323 million, as Treasury Stock. As of March 31, 2021, $1.177 billion remained available for share repurchases under the program.

Net cash provided by operating activities in the first quarter of 2021 was $669 million, compared to $698 million in the first quarter of 2020, resulting in $553 million in free cash flow for the first quarter of 2021, compared to $528 million for the first quarter of 2020.

2021 Financial Guidance[3]

The Company's full year 2021 financial guidance consists of the following components:

	GAAP	Non-GAAP[1]
R&D	$3.000 billion–$3.175 billion	$2.700 billion–$2.850 billion
SG&A	$1.690 billion–$1.840 billion *(previously $1.700 billion–$1.850 billion)*	$1.500 billion–$1.630 billion
Gross margin on net product sales[4]	86%–88%	87%–89%
COCM[5]	$660 million–$730 million *(previously $670 million–$750 million)*	*
Other operating (income) expense, net	($150) million–($175) million	*
Capital expenditures	$585 million–$650 million *(previously $600 million–$680 million)*	*
Effective tax rate (ETR)	12–14% *(previously 11–13%)*	13–15% *(previously 12–14%)*

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

A reconciliation of full year 2021 GAAP to Non-GAAP financial guidance is included below:

($ in millions)	Projected Range	
	Low	High
GAAP R&D	$ 3,000	$ 3,175
R&D: Non-cash share-based compensation expense	(300)	(325)
Non-GAAP R&D	$ 2,700	$ 2,850
GAAP SG&A	$ 1,690	$ 1,840
SG&A: Non-cash share-based compensation expense	(190)	(210)
Non-GAAP SG&A	$ 1,500	$ 1,630
GAAP gross margin on net product sales	86%	88%
Non-cash share-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	87%	89%
GAAP ETR	12%	14%
Income tax effect of GAAP to non-GAAP reconciling items and other	1%	1%
Non-GAAP ETR	13%	15%

(1) This press release uses non-GAAP R&D, non-GAAP SG&A, 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 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.

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, including employee separation costs). Management uses these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. With respect to free cash flows, the Company believes that this non-GAAP measure provides a further measure of the Company’s operations' ability to generate cash flows. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the Company's historical GAAP to non-GAAP results is included in Table 3 of this press release.

(2) The Company's collaborators provide it with estimates of the collaborators' respective sales and the Company's share of the profits or losses from commercialization of products for the most recent fiscal quarter. The Company's estimates for such quarter are reconciled to actual results in the subsequent fiscal quarter, and the Company's share of the profit or loss is adjusted on a prospective basis accordingly, if necessary.

(3) The Company's 2021 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(4) 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.

(5) 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 2021 financial and operating results on Thursday, May 6, 2021, at 8:30 AM Eastern Time. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International), conference ID 7794757. A link to the webcast may be accessed from the "Investors and Media" page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for at least 30 days.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous 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 the Company, 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 (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 (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 with imdevimab), garetosmab, pozelimab, odronextamab, itepekimab, REGN5458, 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 (such as EYLEA, Dupixent, Libtayo, Praluent, Kevzara, Evkeeza, and Inmazeb), 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 with imdevimab antibody cocktail (known as REGEN-COV in the United States), 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, 2020 and its Form 10-Q for the quarterly period ended March 31, 2021. 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, 2021	December 31, 2020
Assets:		
Cash and marketable securities	$ 7,047.5	$ 6,722.6
Accounts receivable, net	4,173.0	4,114.7
Inventories	2,164.7	1,916.6
Property, plant, and equipment, net	3,262.6	3,221.6
Deferred tax assets	765.1	858.9
Other assets	359.3	328.9
Total assets	$ 17,772.2	$ 17,163.3
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 2,606.6	$ 2,806.8
Finance lease liabilities	717.8	717.2
Deferred revenue	491.9	635.5
Long-term debt	1,978.9	1,978.5
Stockholders' equity	11,977.0	11,025.3
Total liabilities and stockholders' equity	$ 17,772.2	$ 17,163.3

TABLE 2

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

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Net product sales	$ 1,724.3	$ 1,236.7
Collaboration revenue	754.4	528.3
Other revenue	50.0	63.2
	2,528.7	1,828.2
Expenses:		
Research and development	742.9	583.9
Selling, general, and administrative	405.6	367.3
Cost of goods sold	183.2	78.8
Cost of collaboration and contract manufacturing	124.8	138.5
Other operating (income) expense, net	(40.5)	(40.4)
	1,416.0	1,128.1
Income from operations	1,112.7	700.1
Other income (expense):		
Other income (expense), net	154.9	(25.4)
Interest expense	(14.6)	(6.1)
	140.3	(31.5)
Income before income taxes	1,253.0	668.6
Income tax expense	137.8	44.0
Net income	$ 1,115.2	$ 624.6
Net income per share - basic	$ 10.58	$ 5.69
Net income per share - diluted	$ 10.09	$ 5.43
Weighted average shares outstanding - basic	105.4	109.8
Weighted average shares outstanding - diluted	110.5	115.1

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,	
	2021	**2020**
GAAP R&D	$ 742.9	$ 583.9
R&D: Non-cash share-based compensation expense	69.7	56.7
Non-GAAP R&D	$ 673.2	$ 527.2
GAAP SG&A	$ 405.6	$ 367.3
SG&A: Non-cash share-based compensation expense	50.8	40.3
SG&A: Litigation contingencies and other	—	20.2
Non-GAAP SG&A	$ 354.8	$ 306.8
GAAP COGS	$ 183.2	$ 78.8
COGS: Non-cash share-based compensation expense	10.4	8.8
Non-GAAP COGS	$ 172.8	$ 70.0
GAAP other income (expense), net	$ 140.3	$ (31.5)
Other income/expense: (Gains) losses on investments	(144.3)	56.8
Non-GAAP other income (expense), net	$ (4.0)	$ 25.3
GAAP net income	$ 1,115.2	$ 624.6
Total of GAAP to non-GAAP reconciling items above	(13.4)	182.8
Income tax effect of GAAP to non-GAAP reconciling items	7.4	(36.8)
Non-GAAP net income	$ 1,109.2	$ 770.6
Non-GAAP net income per share - basic	$ 10.52	$ 7.02
Non-GAAP net income per share - diluted	$ 9.89	$ 6.60
Shares used in calculating:		
Non-GAAP net income per share - basic	105.4	109.8
Non-GAAP net income per share - diluted	112.1	116.7
Effective tax rate reconciliation:		
GAAP effective tax rate	11.0%	6.6%
Income tax effect of GAAP to non-GAAP reconciling items	(0.5%)	2.9%
Non-GAAP effective tax rate	10.5%	9.5%
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 668.5	$ 698.0
Capital expenditures	(115.3)	(170.1)
Free cash flow	$ 553.2	$ 527.9

TABLE 4

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

	Three Months Ended March 31,	
	2021	**2020**
Sanofi collaboration revenue:		
Antibody:		
Regeneron's share of profits in connection with commercialization of antibodies	$ 260.6	$ 170.9
Reimbursement for manufacturing of commercial supplies	105.6	80.1
Immuno-oncology:		
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(6.1)	(6.2)
Reimbursement for manufacturing of commercial supplies	4.7	2.1
Total Sanofi collaboration revenue	364.8	246.9
Bayer collaboration revenue:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	308.9	253.8
Reimbursement for manufacturing of commercial supplies	13.9	27.6
Total Bayer collaboration revenue	322.8	281.4
Roche collaboration revenue:		
Regeneron's share of gross profits in connection with sales of casirivimab with imdevimab	66.8	—
Total collaboration revenue	$ 754.4	$ 528.3

TABLE 5

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

	Three Months Ended March 31,						
	2021			2020			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,347.0	$ 824.3	$ 2,171.3	$ 1,172.0	$ 681.7	$ 1,853.7	17 %
Dupixent[b]	$ 961.5	$ 301.4	$ 1,262.9	$ 679.0	$ 176.2	$ 855.2	48 %
Libtayo[c]	$ 69.1	$ 31.7	$ 100.8	$ 61.7	$ 13.1	$ 74.8	35 %
Praluent[d]	$ 43.3	$ 61.3	$ 104.6	$ 35.1	$ 44.7	$ 79.8	31 %
Kevzara[b]	$ 30.7	$ 38.4	$ 69.1	$ 35.3	$ 24.8	$ 60.1	15 %
REGEN-COV[e]	$ 262.2	$ 176.6	$ 438.8	—	—	—	(h)
Evkeeza[f]	$ 0.5	—	$ 0.5	—	—	—	(h)
ZALTRAP[b]	$ 1.4	$ 23.0	$ 24.4	$ 1.5	$ 26.5	$ 28.0	(13 %)
ARCALYST[g]	$ 2.2	—	$ 2.2	$ 3.0	—	$ 3.0	(27 %)

[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, Kevzara, and ZALTRAP. The Company records its share of profits/losses in connection with global sales of Dupixent and Kevzara, and Sanofi pays the Company a percentage of net sales of ZALTRAP.

[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] Effective April 1, 2020, Regeneron records net product sales of Praluent in the United States. Also effective April 1, 2020, Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales. Previously, Sanofi recorded global net product sales of Praluent and the Company recorded its share of profits/losses in connection with 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, depending on the amount of manufactured product supplied by each party to the market.

[f] Regeneron records net product sales of Evkeeza in the United States.

[g] Effective April 1, 2021, Kiniksa records net product sales of ARCALYST in the United States and pays the Company a share of ARCALYST profits. Prior to April 1, 2021, Regeneron recorded net product sales of ARCALYST in the United States.

[h] Percentage not meaningful