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 5, 2021 (August 5, 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 August 5, 2021, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 30, 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 August 5, 2021, Reporting Second 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: August 5, 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 Second Quarter 2021 Financial and Operating Results

- *Second quarter 2021 revenues increased 163% to $5.14 billion versus second quarter 2020 including $2.76 billion attributable to REGEN-COV™(2); revenues excluding REGEN-COV(1)(2) increased 22%*
- *Second quarter 2021 EYLEA® U.S. net sales increased 28% versus second quarter 2020 to a record $1.42 billion*
- *Second quarter 2021 Dupixent® global net sales(3), which are recorded by Sanofi, increased 59% to $1.50 billion versus second quarter 2020*
- *Second quarter 2021 GAAP diluted EPS was $27.97 and non-GAAP diluted EPS(1) was $25.80*
- *FDA updated REGEN-COV Emergency Use Authorization (EUA) with lower dose, subcutaneous administration, and post-exposure prophylaxis*
- *REGEN-COV Phase 3 RECOVERY trial in hospitalized patients with severe COVID-19 met primary outcome*
- *Reported that Dupixent significantly improved itch and hives in patients with chronic spontaneous urticaria, marking the fifth disease to show positive pivotal results*
- *Phase 3 trial of Libtayo® combined with chemotherapy stopped early due to significant improvement in overall survival in patients with first-line advanced non-small cell lung cancer*

Tarrytown, New York (August 5, 2021) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2021 and provided a business update.

"Regeneron had outstanding performance in the second quarter during which we delivered to the U.S. government the entire order for our COVID-19 antibody cocktail and recognized record global sales from our EYLEA and Dupixent franchises," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We continue to advance Dupixent's potential to help new patient groups, with recent positive Phase 3 data in chronic spontaneous urticaria and additional late-stage read-outs expected later this year in prurigo nodularis, eosinophilic esophagitis, and pediatric atopic dermatitis. With today's positive Phase 3 results in combination with chemotherapy in non-small cell lung cancer, Libtayo yet again demonstrates its potential to be a leading checkpoint inhibitor. We also progressed our genetics medicines platform, with landmark clinical data alongside our collaborator Intellia using a CRISPR therapeutic and the discovery of a promising new obesity target from the Regeneron Genetics Center."

Financial Highlights

($ in millions, except per share data)	Q2 2021	Q2 2020	% Change
Total revenues	$ 5,139	$ 1,952	163%
GAAP net income	$ 3,099	$ 897	245%
GAAP net income per share - diluted	$ 27.97	$ 7.61	268%
Non-GAAP net income[(1)]	$ 2,895	$ 854	239%
Non-GAAP net income per share - diluted[(1)]	$ 25.80	$ 7.16	260%

"Regeneron performed exceptionally well in the second quarter with the core business on a strong growth trajectory as we invest in our diverse and differentiated pipeline for long-term and sustainable growth," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron.

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

- Enrollment in the Phase 3 studies for high-dose formulation in diabetic macular edema (DME) and neovascular age-related macular degeneration (wet AMD) was completed.
- Enrollment in the Phase 3 study for retinopathy of prematurity (ROP) was also completed.

Dupixent® (dupilumab)

- The Company and Sanofi announced a Phase 3 trial in patients with moderate-to-severe chronic spontaneous urticaria (CSU) met its primary and all key secondary endpoints at 24 weeks. The trial showed that adding Dupixent to standard-of-care antihistamines significantly reduced itch and hives for biologic-naive patients, compared to antihistamines alone in the first of two trials of this clinical program.
- In June 2021, the U.S. Food and Drug Administration (FDA) approved a 200 mg single-dose pre-filled pen for Dupixent.

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

- In the second quarter of 2021, the Company fulfilled its second agreement with the U.S. government to manufacture and deliver 1.25 million doses of REGEN-COV at the lowest treatment dose authorized by the FDA, and recognized $2.59 billion of REGEN-COV sales.
- In June 2021, the FDA updated the REGEN-COV EUA by lowering the dose to 1,200 mg and permitting administration by subcutaneous injection when intravenous infusion is not feasible.

- In July 2021, based on positive Phase 3 data announced in April 2021 which were recently published in the *New England Journal of Medicine*, the FDA also expanded the EUA to include post-exposure prophylaxis in people at high risk for progression to severe COVID-19, who are not fully vaccinated or are not expected to mount an adequate response to vaccination, and who have been exposed to a SARS-CoV-2 infected individual or are at high risk of exposure to an infected individual because of infection occurring in the same institutional setting (such as in nursing homes or prisons). For people who are not expected to mount an adequate immune response to vaccination, REGEN-COV can also now be administered monthly for the duration of ongoing exposure to SARS-CoV-2.
- In July 2021, Japan's Ministry of Health, Labour and Welfare (MHLW) approved the casirivimab and imdevimab antibody cocktail to treat patients with mild to moderate COVID-19, making Japan the first country to grant a full approval for the antibody cocktail.
- Positive results were announced from the Phase 3 UK-based RECOVERY trial in hospitalized COVID-19 patients, demonstrating that adding REGEN-COV to usual care reduced the risk of death by 20% in seronegative patients (patients who had not mounted a natural antibody response on their own against SARS-CoV-2), compared to seronegative patients receiving usual care alone. The Company has requested that the EUA be further expanded to include appropriate hospitalized patients.

Libtayo® (cemiplimab)
- In June 2021, the European Commission (EC) approved Libtayo for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC).
- In June 2021, the EC also approved Libtayo for the treatment of metastatic or locally advanced basal cell carcinoma (BCC).
- In August 2021, the Company and Sanofi announced that the Phase 3 trial of Libtayo in combination with platinum-doublet chemotherapy was stopped early after meeting its overall survival primary endpoint in patients with advanced NSCLC. These data are planned to form the basis of regulatory submissions in the United States and European Union (EU).

Odronextamab, a CD20xCD3 bispecific antibody
- The Company is resuming enrollment of patients with follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL), following amendment of trial protocols and the FDA's lifting of the partial clinical hold, in its monotherapy trials of odronextamab.

Fianlimab, an antibody to LAG-3
- Positive data from the Phase 1 trial in combination with Libtayo in advanced melanoma were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting; the Company intends to initiate a Phase 3 study in 2022.

REGN1908-1909, a multi-antibody therapy to Fel d 1
- The Company initiated a Phase 3 study in cat allergic asthmatics.

Genetics Medicines

- Intellia Therapeutics, Inc. and the Company announced positive interim data from the Phase 1 study of NTLA-2001, a CRISPR/Cas9 therapeutic for *TTR* gene knockout in people living with hereditary transthyretin amyloidosis with polyneuropathy (ATTRv-PN). These are the first-ever clinical data supporting safety and efficacy of *in vivo* CRISPR genome editing in humans and provide proof of concept for the ongoing multi-target collaboration between the companies.
- The Regeneron Genetics Center published their discovery of *GPR75* gene mutations that protect against obesity. This target is the focus of a small molecule collaboration agreement with AstraZeneca announced in July 2021, under which the companies will equally share research and development costs and any potential future profits.

Corporate Updates

The Company intends to invest approximately $1.8 billion over six years to expand its research, preclinical manufacturing, and support facilities at the Company's Tarrytown, New York campus.

Second Quarter 2021 Financial Results

Revenues

Total revenues increased by 163% to $5.139 billion in the second quarter of 2021, compared to $1.952 billion in the second quarter of 2020. Total revenues excluding (i) REGEN-COV (casirivimab and imdevimab) net product sales in the United States and (ii) the Company's share of gross profits in connection with Roche's sales of casirivimab and imdevimab outside the United States, increased by 22% to $2.379 billion in the second quarter of 2021, compared to the second quarter of 2020(1).

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

($ in millions)	Q2 2021	Q2 2020
EYLEA	$ 1,425	$ 1,114
Libtayo	78	63
Praluent®	42	47
REGEN-COV	2,591	—
Evkeeza®	2	—
ARCALYST®	— *	3
Total net product sales in the U.S.	$ 4,138	$ 1,227

* 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.

Net product sales of EYLEA in the United States increased in the second quarter of 2021, compared to the second quarter of 2020, primarily due to higher sales volume as well as a favorable comparison given the adverse impact of the COVID-19 pandemic on U.S. EYLEA demand during the second quarter of 2020.

The Company fulfilled its second agreement with the U.S. government and delivered 1.25 million doses of REGEN-COV. Other than $34 million of expected REGEN-COV net product sales in the third quarter of 2021 related to this agreement, the Company does not anticipate recording any additional net product sales of REGEN-COV in the United States during the third quarter of 2021. U.S. net product sales of REGEN-COV in the fourth quarter of 2021 will be dependent upon acceleration of COVID-19 cases and related drug utilization.

Total revenues also include collaboration revenues[3] of $955 million in the second quarter of 2021, compared to $513 million in the second quarter of 2020. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which were $328 million in the second quarter of 2021, compared to $172 million in the second quarter of 2020. The change in the Company's share of profits from commercialization of antibodies was driven by higher Dupixent profits. In the second quarter of 2021, the Company also recorded Roche collaboration revenue of $168 million in connection with the Company's share of gross profits from Roche's sales of the casirivimab and imdevimab antibody cocktail outside the United States.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue decreased in the second quarter of 2021, compared to the second quarter of 2020, primarily due to lower amounts recognized in connection with the Company's agreements with the Biomedical Advanced Research Development Authority (BARDA) related to funding of certain development activities for antibodies for the treatment of COVID-19.

Operating Expenses

	GAAP			Non-GAAP[1]		
($ in millions)	**Q2 2021**	**Q2 2020**	**% Change**	**Q2 2021**	**Q2 2020**	**% Change**
Research and development (R&D)	$ 714	$ 722	(1%)	$ 643	$ 580	11%
Selling, general, and administrative (SG&A)	$ 415	$ 348	19%	$ 365	$ 301	21%
Cost of goods sold (COGS)	$ 539	$ 103	423%	$ 514	$ 93	453%
Cost of collaboration and contract manufacturing (COCM)	$ 154	$ 173	(11%)	*	*	n/a
Other operating (income) expense, net	$ (31)	$ (50)	(38%)	*	*	n/a

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

- GAAP R&D expenses in the second quarter of 2020 included $85 million in up-front payments in connection with the collaboration agreement with Intellia. The decrease in GAAP R&D expenses in the second quarter of 2021 was offset primarily by higher costs incurred in connection with development activities related to REGEN-COV, which also drove the increase in non-GAAP R&D expenses.
- The increase in GAAP and non-GAAP SG&A expenses in the second quarter of 2021 was primarily due to higher headcount-related costs, an increase in commercialization-related expenses for EYLEA and Libtayo, and costs associated with educational campaigns related to COVID-19.
- The increase in COGS in the second quarter of 2021 was primarily due to the recognition of manufacturing costs in connection with product sales of REGEN-COV in the United States. In addition, the Company recognized higher inventory write-offs and reserves in the second quarter of 2021, compared to the second quarter of 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 unrealized and realized gains on equity securities of $409 million in the second quarter of 2021, compared to $228 million in the second quarter of 2020.

In the second quarter of 2021, the Company's GAAP effective tax rate was 17.4%, compared to 2.4% in the second quarter of 2020. The increase in the second quarter 2021 GAAP effective tax rate, compared to the second quarter of 2020, was primarily due to the significant positive impact of stock-based compensation in the second quarter of 2020. In the second quarter of 2021, the non-GAAP effective tax rate was 17.0%, compared to 0.9% in the second quarter of 2020.

GAAP net income per diluted share was $27.97 in the second quarter of 2021, compared to GAAP net income per diluted share of $7.61 in the second quarter of 2020. Non-GAAP net income per diluted share was $25.80 in the second quarter of 2021, compared to non-GAAP net income per diluted share of $7.16 in the second quarter of 2020. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

Net cash provided by operating activities in the first half of 2021 was $1.295 billion, compared to $1.641 billion in the first half of 2020, resulting in $1.031 billion in free cash flow for the first half of 2021, compared to $1.341 billion for the first half of 2020. The Company expects a significant increase in free cash flow in the third quarter of 2021 as the Company collected all amounts due from the U.S. government in connection with second quarter 2021 REGEN-COV sales in July 2021.

2021 Financial Guidance[(4)]

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

	GAAP	Non-GAAP[1]
R&D	$2.950 billion–$3.075 billion *(previously $3.000 billion–$3.175 billion)*	$2.650 billion–$2.750 billion *(previously $2.700 billion–$2.850 billion)*
SG&A	$1.730 billion–$1.830 billion *(previously $1.690 billion–$1.840 billion)*	$1.540 billion–$1.620 billion *(previously $1.500 billion–$1.630 billion)*
Gross margin on net product sales[5]	87–88% *(previously 86–88%)*	88–89% *(previously 87–89%)*
COCM[6]	$630 million–$680 million *(previously $660 million–$730 million)*	*
Other operating (income) expense, net	($135) million–($155) million *(previously ($150) million–($175) million)*	*
Capital expenditures	$590 million–$640 million *(previously $585 million–$650 million)*	*
Effective tax rate (ETR)	14–16% *(previously 12–14%)*	14–16% *(previously 13–15%)*

* 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	$ 2,950	$ 3,075
R&D: Non-cash share-based compensation expense	(300)	(325)
Non-GAAP R&D	$ 2,650	$ 2,750
GAAP SG&A	$ 1,730	$ 1,830
SG&A: Non-cash share-based compensation expense	(190)	(210)
Non-GAAP SG&A	$ 1,540	$ 1,620
GAAP gross margin on net product sales	87%	88%
Non-cash share-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	88%	89%
GAAP ETR	14%	16%
Income tax effect of GAAP to non-GAAP reconciling items and other	< 1%	< 1%
Non-GAAP ETR	14%	16%

(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). 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) 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. The Company records its share of gross profits from global sales within collaboration revenue.

(3) 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. 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 (if applicable) is adjusted on a prospective basis accordingly, if necessary.

(4) 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.

(5) 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.

(6) Corresponding reimbursements from collaborators and others for manufacturing of commercial supplies is recorded within revenues.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its second quarter 2021 financial and operating results on Thursday, August 5, 2021, at 8:30 AM Eastern Time. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International), conference ID 9098036. 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 and imdevimab),

garetosmab, pozelimab, odronextamab, itepekimab, 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; 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 June 30, 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)

	June 30, 2021	December 31, 2020
Assets:		
Cash and marketable securities	$ 7,811.1	$ 6,722.6
Accounts receivable, net	6,998.6	4,114.7
Inventories	1,983.9	1,916.6
Property, plant, and equipment, net	3,358.5	3,221.6
Deferred tax assets	746.6	858.9
Other assets	587.2	328.9
Total assets	$ 21,485.9	$ 17,163.3
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,090.3	$ 2,806.8
Finance lease liabilities	718.4	717.2
Deferred revenue	570.7	635.5
Long-term debt	1,979.2	1,978.5
Stockholders' equity	15,127.3	11,025.3
Total liabilities and stockholders' equity	$ 21,485.9	$ 17,163.3

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,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Net product sales	$ 4,137.8	$ 1,226.9	$ 5,862.1	$ 2,463.6
Collaboration revenue	954.7	513.3	1,709.1	1,041.6
Other revenue	46.0	211.8	96.0	275.0
	5,138.5	1,952.0	7,667.2	3,780.2
Expenses:				
Research and development	714.2	722.0	1,457.1	1,305.9
Selling, general, and administrative	414.7	348.3	820.3	715.6
Cost of goods sold	539.4	102.5	722.6	181.3
Cost of collaboration and contract manufacturing	154.3	173.0	279.1	311.5
Other operating (income) expense, net	(31.3)	(50.2)	(71.8)	(90.6)
	1,791.3	1,295.6	3,207.3	2,423.7
Income from operations	3,347.2	656.4	4,459.9	1,356.5
Other income (expense):				
Other income (expense), net	420.0	272.2	574.9	246.8
Interest expense	(14.4)	(9.7)	(29.0)	(15.8)
	405.6	262.5	545.9	231.0
Income before income taxes	3,752.8	918.9	5,005.8	1,587.5
Income tax expense	653.9	21.6	791.7	65.6
Net income	$ 3,098.9	$ 897.3	$ 4,214.1	$ 1,521.9
Net income per share - basic	$ 29.51	$ 8.19	$ 40.06	$ 13.87
Net income per share - diluted	$ 27.97	$ 7.61	$ 38.07	$ 13.03
Weighted average shares outstanding - basic	105.0	109.6	105.2	109.7
Weighted average shares outstanding - diluted	110.8	117.9	110.7	116.8

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,	
	2021	**2020**	**2021**	**2020**
GAAP R&D	$ 714.2	$ 722.0	$ 1,457.1	$ 1,305.9
R&D: Non-cash share-based compensation expense	70.9	56.9	140.6	113.6
R&D: Up-front payments related to license and collaboration agreements	—	85.0	—	85.0
Non-GAAP R&D	$ 643.3	$ 580.1	$ 1,316.5	$ 1,107.3
GAAP SG&A	$ 414.7	$ 348.3	$ 820.3	$ 715.6
SG&A: Non-cash share-based compensation expense	49.6	38.2	100.4	78.5
SG&A: Litigation contingencies and other	—	8.7	—	28.9
Non-GAAP SG&A	$ 365.1	$ 301.4	$ 719.9	$ 608.2
GAAP COGS	$ 539.4	$ 102.5	$ 722.6	$ 181.3
COGS: Non-cash share-based compensation expense	25.0	8.4	35.4	17.2
COGS: Other	—	0.9	—	0.9
Non-GAAP COGS	$ 514.4	$ 93.2	$ 687.2	$ 163.2
GAAP other income (expense), net	$ 405.6	$ 262.5	$ 545.9	$ 231.0
Other income/expense: Gains on investments	(409.6)	(256.1)	(553.9)	(199.3)
Interest expense: Other	—	1.5	—	1.5
Non-GAAP other income (expense), net	$ (4.0)	$ 7.9	$ (8.0)	$ 33.2
GAAP net income	$ 3,098.9	$ 897.3	$ 4,214.1	$ 1,521.9
Total of GAAP to non-GAAP reconciling items above	(264.1)	(56.5)	(277.5)	126.3
Income tax effect of GAAP to non-GAAP reconciling items	60.2	13.6	67.6	(23.2)
Non-GAAP net income	$ 2,895.0	$ 854.4	$ 4,004.2	$ 1,625.0
Non-GAAP net income per share - basic	$ 27.57	$ 7.80	$ 38.06	$ 14.81
Non-GAAP net income per share - diluted	$ 25.80	$ 7.16	$ 35.72	$ 13.70
Shares used in calculating:				
Non-GAAP net income per share - basic	105.0	109.6	105.2	109.7
Non-GAAP net income per share - diluted	112.2	119.3	112.1	118.6
Effective tax rate reconciliation:				
GAAP effective tax rate	17.4%	2.4%	15.8%	4.1%
Income tax effect of GAAP to non-GAAP reconciling items	(0.4%)	(1.5%)	(0.5%)	1.1%
Non-GAAP effective tax rate	17.0%	0.9%	15.3%	5.2%
Free cash flow reconciliation:				
Net cash provided by operating activities	$ 626.7	$ 943.4	$ 1,295.2	$ 1,641.4
Capital expenditures	(148.5)	(129.9)	(263.8)	(300.0)
Free cash flow	$ 478.2	$ 813.5	$ 1,031.4	$ 1,341.4

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 327.6	$ 171.9	$ 588.2	$ 342.8
Reimbursement for manufacturing of commercial supplies	110.9	100.6	216.5	180.7
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(3.5)	(6.4)	(9.6)	(12.6)
Reimbursement for manufacturing of commercial supplies	2.7	3.0	7.4	5.1
Total Sanofi collaboration revenue	437.7	269.1	802.5	516.0
Bayer collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	335.4	230.9	644.3	484.7
Reimbursement for manufacturing of commercial supplies	13.7	13.3	27.6	40.9
Total Bayer collaboration revenue	349.1	244.2	671.9	525.6
Roche collaboration revenue:				
Regeneron's share of gross profits in connection with sales of casirivimab and imdevimab	167.9	—	234.7	—
Total collaboration revenue	$ 954.7	$ 513.3	$ 1,709.1	$ 1,041.6

TABLE 5

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

	Three Months Ended June 30,						
	2021			2020			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,424.7	$ 903.8	$ 2,328.5	$ 1,113.7	$ 641.0	$ 1,754.7	33 %
Dupixent[b]	$ 1,146.6	$ 352.4	$ 1,499.0	$ 770.4	$ 174.6	$ 945.0	59 %
Libtayo[c]	$ 78.0	$ 38.9	$ 116.9	$ 63.3	$ 16.7	$ 80.0	46 %
Praluent[d]	$ 41.9	$ 57.5	$ 99.4	$ 47.2	$ 39.4	$ 86.6	15 %
REGEN-COV[e]	$ 2,591.2	$ 470.2	$ 3,061.4	—	—	—	(h)
Kevzara[b]	$ 30.7	$ 36.0	$ 66.7	$ 36.5	$ 31.8	$ 68.3	(2 %)
Evkeeza[f]	$ 2.0	—	$ 2.0	—	—	—	(h)
ARCALYST[g]	$ 7.7	—	$ 7.7	$ 2.7	—	$ 2.7	185 %
ZALTRAP[b]	$ 1.3	$ 22.2	$ 23.5	$ 1.7	$ 25.0	$ 26.7	(12 %)

	Six Months Ended June 30,						
	2021			2020			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 2,771.7	$ 1,728.1	$ 4,499.8	$ 2,285.7	$ 1,322.7	$ 3,608.4	25 %
Dupixent[b]	$ 2,108.1	$ 653.8	$ 2,761.9	$ 1,449.4	$ 350.8	$ 1,800.2	53 %
Libtayo[c]	$ 147.1	$ 70.6	$ 217.7	$ 125.0	$ 29.8	$ 154.8	41 %
Praluent[d]	$ 85.2	$ 118.8	$ 204.0	$ 82.3	$ 84.1	$ 166.4	23 %
REGEN-COV[e]	$ 2,853.4	$ 654.4	$ 3,507.8	—	—	—	(h)
Kevzara[b]	$ 61.4	$ 74.4	$ 135.8	$ 71.8	$ 56.6	$ 128.4	6 %
Evkeeza[f]	$ 2.5	—	$ 2.5	—	—	—	(h)
ARCALYST[g]	$ 9.9	—	$ 9.9	$ 5.7	—	$ 5.7	74 %
ZALTRAP[b]	$ 2.7	$ 45.2	$ 47.9	$ 3.2	$ 51.5	$ 54.7	(12 %)

[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, if any. Prior to April 1, 2021, Regeneron recorded net product sales of ARCALYST in the United States.

[h] Percentage not meaningful