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, 2020 (August 5, 2020)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of incorporation or organization)	(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, 2020, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 30, 2020. 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, 2020, Reporting Second Quarter 2020 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, 2020 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 2020 Financial and Operating Results

- *Second quarter 2020 revenues increased 24% to $1.95 billion versus second quarter 2019[4]*
- *Second quarter 2020 EYLEA® U.S. net sales were $1.11 billion*
- *Second quarter 2020 Dupixent® global net sales[2], which are recorded by Sanofi, were $945 million*
- *Second quarter 2020 GAAP diluted EPS was $7.61 and non-GAAP diluted EPS[1] was $7.16*
- *Initiated Phase 2 and Phase 3 clinical trials of REGN-COV2 for the treatment and prevention of COVID-19*
- *FDA approved Dupixent for children aged 6 to 11 years with moderate-to-severe atopic dermatitis*
- *Dupixent eosinophilic esophagitis trial met co-primary endpoints and a second confirmatory Phase 3 trial in chronic obstructive pulmonary disease (COPD) was initiated*
- *Completed secondary offering of approximately 13 million shares of common stock held by Sanofi and purchased 9.8 million shares from Sanofi*

Tarrytown, New York (August 5, 2020) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2020 and provided a business update.

"I'm very proud of how the Regeneron team has continued to drive important progress for patients, despite the significant challenges of the COVID-19 pandemic," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We have advanced REGN-COV2, our antibody cocktail for COVID-19, into late-stage clinical studies in record time and are working to ensure supply is available later this year. We are continuing to drive strong performance with our marketed medicines, including EYLEA, Dupixent, and Libtayo, while also advancing research, development, and regulatory progress across a number of therapeutic areas including cancer, Type 2 inflammatory diseases, pain, and rare diseases."

"Regeneron's business continues to be resilient during these times, delivering double digit top- and bottom-line growth in the second quarter," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "Our strong balance sheet, improved competitive outlook, increasingly diversified commercial portfolio, and robust pipeline position Regeneron well for sustained long-term growth."

Financial Highlights

($ in millions, except per share data)	Q2 2020	Q2 2019	% Change
Total revenues[4]	$ 1,952	$ 1,578	24 %
GAAP net income	$ 897	$ 193	365 %
GAAP net income per share - diluted	$ 7.61	$ 1.68	353 %
Non-GAAP net income[1]	$ 854	$ 690	24 %
Non-GAAP net income per share - diluted[1]	$ 7.16	$ 6.02	19 %

Business Highlights

Key Pipeline Progress

Regeneron has more than 20 product candidates in clinical development, including five marketed products for which it is investigating additional indications. Updates from the clinical pipeline include:

EYLEA® (aflibercept) Injection

- Phase 3 studies exploring less frequent dosing intervals using a high-dose formulation of aflibercept in neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME) were initiated.
- In April 2020, the European Commission approved the EYLEA pre-filled syringe.

Dupixent® (dupilumab)

- In May 2020, the U.S. Food and Drug Administration (FDA) approved Dupixent as the first biologic medicine for children aged 6 to 11 years with moderate-to-severe atopic dermatitis.
- In June 2020, the National Medical Products Administration (NMPA) in China approved Dupixent for adults with moderate-to-severe atopic dermatitis.
- In May 2020, the Company and Sanofi announced positive results from Part A of the Phase 3 trial in patients 12 years and older with eosinophilic esophagitis (EoE). The trial met both of its co-primary endpoints, as well as all key secondary endpoints.
- A Phase 3 study in pediatric patients with EoE was initiated.
- In June 2020, the FDA approved a 300 mg single-dose pre-filled pen for Dupixent.
- An ongoing Phase 3 trial in chronic obstructive pulmonary disease (COPD) patients with evidence of Type 2 inflammation met a blinded, stringent early efficacy threshold for continuation. Based on this result, a second confirmatory Phase 3 trial in COPD was initiated.

REGN-COV2

- The Company initiated clinical trials of REGN-COV2, its investigational two-antibody "cocktail" for the treatment and prevention of COVID-19.
- Following review from the Independent Data Monitoring Committee (IDMC) of REGN-COV2 Phase 1 safety results, a Phase 3 trial to evaluate REGN-COV2's ability to prevent infection among uninfected people who have had close exposure to a COVID-19 patient (such as the patient's housemate) was initiated and is being run jointly with the National Institute of Allergy and Infectious Diseases (NIAID). In addition, REGN-COV2 moved into the Phase 2/3 portion of two adaptive Phase 1/2/3 trials testing the cocktail's ability to treat hospitalized and non-hospitalized patients with COVID-19. The Company plans to report initial virology and biomarker results from the REGN-COV2 treatment trials in September 2020.

- Two papers were published in *Science* describing the creation of REGN-COV2 and highlighting the potential of REGN-COV2 to diminish the risk of viral escape by effectively binding to the virus's critical spike protein in two separate, non-overlapping locations.
- Non-human primate data were provided as a pre-review publication online for REGN-COV2 showing that treatment with this antibody cocktail can prevent SARS-CoV-2 infection as well as treat infected animals by accelerating viral elimination.
- The Company announced an agreement with the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense whereby the Company was awarded a $450 million contract to manufacture and supply filled and finished REGN-COV2 to the U.S. Government. The agreement provides for the Company to manufacture a fixed number of bulk lots beginning in the summer of 2020 and fill/finish and storage activities starting in the third quarter of 2020.

Kevzara® (sarilumab)
- The Company and Sanofi reported that the Regeneron-led U.S. Phase 3 study of Kevzara 400 mg in COVID-19 patients requiring mechanical ventilation did not meet its primary and key secondary endpoints. Based on the results, the U.S.-based trial has been stopped.

Oncology Program
- In April 2020, the Company and Sanofi announced that the primary endpoint was met in the Phase 3 trial of Libtayo® (cemiplimab) as monotherapy in first-line non-small cell lung cancer (NSCLC). In May 2020, the Company and Sanofi also announced that Libtayo demonstrated clinically-meaningful and durable responses in a pivotal, single-arm, open-label trial in patients with advanced basal cell carcinoma. The data from these trials will form the basis of regulatory submissions in the U.S. and European Union (EU) this year.
- In May 2020, the Company and Sanofi announced new, longer-term data for Libtayo from a pivotal Phase 2 trial in advanced cutaneous squamous cell carcinoma (CSCC). These results demonstrate both longer durability and higher complete response rates than previously reported. Updated data from this trial have also been incorporated into the U.S. label.
- A publication in *Science Translational Medicine* featured scientific findings highlighting the benefit demonstrated in preclinical research in combining the Company's novel class of CD28 costimulatory bispecific antibodies with Libtayo. In 2020, the Company plans to enroll patients in clinical trials investigating three different CD28 costimulatory bispecific candidates. Regeneron's first costimulatory bispecific trial, investigating the combination of PSMAxCD28 (REGN5678) and Libtayo for prostate cancer, is underway and has treated patients in several dose-escalation cohorts.

Praluent® (alirocumab)
- The Company submitted a supplemental Biologics License Application (sBLA) for homozygous familial hypercholesterolemia (HoFH) in adults.

Evinacumab, an antibody to ANGPTL3
- The Company completed the rolling BLA submission and a Marketing Authorization Application (MAA) was also submitted for HoFH.

Fasinumab, an antibody to NGF

- Two Phase 3 trials, FACT OA1 and FACT OA2, achieved the co-primary endpoints for fasinumab 1 mg monthly, demonstrating significant improvements in pain and physical function over placebo at week 16 and week 24, respectively. Fasinumab 1 mg monthly also showed nominally significant benefits in physical function in both trials and pain in one trial, when compared to the maximum FDA-approved prescription doses of non-steroidal anti-inflammatory drugs for osteoarthritis.
- The FACT OA1 trial included an additional treatment arm, fasinumab 1 mg every two months, which showed numerical benefit over placebo, but did not reach statistical significance.
- In initial safety analyses from the Phase 3 trials, there was an increase in arthropathies reported with fasinumab. In a sub-group of patients from one Phase 3 long-term safety trial, there was an increase in joint replacement with fasinumab 1 mg monthly treatment during the off-drug follow-up period, although this increase was not seen in the other trials to date. Additional longer-term safety data from the ongoing trials are being collected and are expected to be reported early next year.

COVID-19 Business Impact Update

- Regeneron maintains adequate market supply for all commercialized products. The Company's raw material supplies and contract manufacturing support have also remained stable.
- The Company continues to evaluate the impact of the COVID-19 pandemic on an individual clinical trial basis and expects fully-recruited clinical studies to remain generally on track. After briefly pausing new enrollment in certain studies due to the pandemic, enrollment in both new and ongoing clinical studies started to resume as regions relaxed their restrictions and healthcare resources started to become more available for non-COVID-19 activities. However, there has been a resurgence of COVID-19 cases in many regions across the world, and any resurgence in the regions in which the Company or its collaborators conduct clinical trials may require the Company to adjust its expectations relating to the impacted studies.

Corporate and Business Development Update

- The Company and Sanofi entered into an agreement, effective April 1, 2020, to restructure its collaboration for Praluent. In the United States, the Company is now solely responsible for the development and commercialization of Praluent and records net product sales. The Company does not owe Sanofi royalties on net product sales of Praluent in the United States. Sanofi has sole responsibility for the development and commercialization of Praluent outside the United States, and pays the Company a 5% royalty on Praluent net product sales.
- In May 2020, a secondary offering of approximately 13 million shares of the Company's common stock held by Sanofi was completed. Concurrent with the secondary offering, the Company purchased approximately 9.8 million shares directly from Sanofi for an aggregate purchase amount of $5 billion. Pursuant to the offering and purchase, Sanofi disposed of all but 400,000 shares of the Company's common stock that it retained as of the closing date of such transactions.

- In May 2020, the Company expanded its existing collaboration with Intellia Therapeutics, Inc. to provide the Company with rights to develop products for additional *in vivo* CRISPR/Cas9-based therapeutic targets and for the companies to jointly develop potential products for the treatment of hemophilia A and B. In addition, the Company also received non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products. In connection with the agreement, the Company made a $70 million up-front payment and purchased Intellia common stock for $30 million.
- In July 2020, HHS exercised its option under the existing agreement for the treatment of Ebola virus infection to provide additional funding for the manufacture and supply of REGN-EB3. REGN-EB3 is currently under priority review by the FDA, with a target action date of October 25, 2020. Contingent on FDA approval, Regeneron expects to deliver an established number of treatment doses over the course of approximately six years.

Second Quarter 2020 Financial Results

Effective January 1, 2020, Regeneron has implemented changes in the presentation of its financial statements related to certain reimbursements and other payments for products developed and commercialized with collaborators. The Company made these changes in presentation to better reflect the nature of the Company’s costs incurred and revenues earned pursuant to arrangements with collaborators and to enhance the comparability of Regeneron's financial statements with industry peers. The change in presentation has been applied retrospectively. See note (4) below for further information.

Revenues

Total revenues increased by 24% to $1.952 billion in the second quarter of 2020, compared to $1.578 billion in the second quarter of 2019.

EYLEA net product sales in the United States were $1.114 billion in the second quarter of 2020, compared to $1.160 billion in the second quarter of 2019. EYLEA's second quarter 2020 net product sales in the United States were negatively impacted by the COVID-19 pandemic. Overall distributor inventory levels for EYLEA in the United States remained within the Company's one-to-two-week targeted range.

Total revenues also include Sanofi and Bayer collaboration revenues[(2)] of $513 million in the second quarter of 2020, compared to $353 million in the second quarter of 2019. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which increased to $172 million in the second quarter of 2020 from $39 million in the second quarter of 2019. The change in the Company's share of profits from collaboration antibodies was primarily driven by higher Dupixent profits.

Refer to Table 4 for a summary of collaboration revenue.

Other revenues in the second quarter of 2020 include recognition of revenue in connection with the Company's agreements with BARDA related to funding of certain development activities for REGN-EB3 for the treatment of Ebola and antibodies for the treatment of COVID-19.

Operating Expenses

	GAAP			Non-GAAP[(1)]		
($ in millions)	**Q2 2020**	**Q2 2019**	**% Change**	**Q2 2020**	**Q2 2019**	**% Change**
Research and development (R&D)	$ 722	$ 886	(19 %)	$ 580	$ 426	36 %
Selling, general, and administrative (SG&A)	$ 348	$ 295	18 %	$ 301	$ 252	19 %
Cost of goods sold (COGS)	$ 103	$ 67	54 %	$ 93	$ 58	60 %
Cost of collaboration and contract manufacturing (COCM)	$ 173	$ 79	119 %	*	*	n/a
Other operating (income) expense, net	$ (50)	$ (64)	(22 %)	*	*	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. GAAP R&D expenses in the second quarter of 2019 included a $400 million up-front payment in connection with the collaboration agreement with Alnylam Pharmaceuticals, Inc. Non-GAAP R&D expenses increased in the second quarter of 2020 principally due to additional costs incurred in connection with COVID-19 related development activities, higher headcount and headcount-related costs, and an increase in clinical manufacturing activities.
- The higher GAAP and non-GAAP SG&A expenses in the second quarter of 2020 were primarily due to higher headcount-related costs, higher contributions to independent not-for-profit patient assistance organizations, and the Company no longer receiving Praluent-related cost reimbursements from Sanofi.

- The increase in cost of collaboration and contract manufacturing in the second quarter of 2020 was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent, process validation costs in connection with manufacturing REGN-EB3 under the BARDA Ebola agreement, and recognition of costs in connection with manufacturing ex-U.S. commercial supplies of Praluent for Sanofi under the new agreement.
- 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 gains on equity securities of $228 million in the second quarter of 2020, compared to net unrealized losses of $117 million in the second quarter of 2019. GAAP other income (expense), net, also includes the recognition of net realized gains on sales of debt securities.

In the second quarter of 2020, the Company's GAAP effective tax rate was 2.4%, compared to 14.1% in the second quarter of 2019. The GAAP effective tax rate for the second quarter of 2020 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation, and, to a lesser extent, 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 second quarter of 2020, the non-GAAP effective tax rate was 0.9%, compared to 19.1% in the second quarter of 2019. The Company expects its full year 2020 GAAP effective tax rate to be 9–11% and its non-GAAP effective tax rate to be 10–12% (see financial guidance table below).

GAAP net income per diluted share was $7.61 in the second quarter of 2020, compared to GAAP net income per diluted share of $1.68 in the second quarter of 2019. Non-GAAP net income per diluted share was $7.16 in the second quarter of 2020, compared to non-GAAP net income per diluted share of $6.02 in the second quarter of 2019. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

As described above, during the second quarter of 2020, the Company purchased 9,806,805 shares of Common Stock from Sanofi and recorded the cost of the shares received, or $5 billion, as Treasury Stock.

The Company generated $943 million of net cash provided by operating activities in the second quarter of 2020, compared to $188 million in the second quarter of 2019, which led to $814 million in free cash flow for the second quarter of 2020, compared to $94 million for the second quarter of 2019.

2020 Financial Guidance[(3)]

The Company's full year 2020 financial guidance consists of the following components:

	GAAP	Non-GAAP[(1)]
R&D	$2.605 billion–$2.725 billion *(previously $2.150 billion–$2.310 billion)*	$2.270 billion–$2.370 billion *(previously $1.900 billion–$2.040 billion)*
SG&A	$1.400 billion–$1.480 billion *(previously $1.380 billion–$1.500 billion)*	$1.210 billion–$1.270 billion *(previously $1.190 billion–$1.290 billion)*
COGS	$490 million–$540 million *(previously $350 million–$420 million)*	$445 million–$485 million *(previously $295 million–$355 million)*
COCM[(5)]	$600 million–$660 million *(previously $600 million–$700 million)*	*
Other operating (income) expense, net	($180) million–($205) million *(previously ($175) million–($205) million)*	*
Capital expenditures	$540 million–$590 million *(previously $510 million–$590 million)*	*
Effective tax rate (ETR)	9–11% *(previously 10–12%)*	10–12% *(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 2020 GAAP to Non-GAAP financial guidance is included below:

(In millions)	Projected Range	
	Low	**High**
GAAP R&D	$ 2,605	$ 2,725
R&D: Non-cash share-based compensation expense	(250)	(270)
R&D: Up-front payments related to license and collaboration agreements	(85)	(85)
Non-GAAP R&D	$ 2,270	$ 2,370
GAAP SG&A	$ 1,400	$ 1,480
SG&A: Non-cash share-based compensation expense	(160)	(180)
SG&A: Litigation contingencies and restructuring-related expenses	(30)	(30)
Non-GAAP SG&A	$ 1,210	$ 1,270
GAAP COGS	$ 490	$ 540
COGS: Non-cash share-based compensation expense	(44)	(54)
COGS: Other	(1)	(1)
Non-GAAP COGS	$ 445	$ 485
GAAP ETR	9 %	11 %
Income tax effect of GAAP to non-GAAP reconciling items and other	1 %	1 %
Non-GAAP ETR	10 %	12 %

(1) This press release uses non-GAAP R&D, non-GAAP SG&A, non-GAAP COGS, non-GAAP other income (expense) net, non-GAAP effective tax rate, non-GAAP net income, non-GAAP net income per share, 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 equity investments) 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 2020 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(4) Applicable amounts previously reported for the three and six months ended June 30, 2019 and as of December 31, 2019 have been revised to reflect a change in presentation of cost reimbursements from collaborators who are not deemed to be the Company's customers from collaboration revenue to a reduction of the corresponding operating expense. The Company also changed the presentation of amounts recognized in connection with up-front and development milestone payments received from collaboration revenue to Other operating income, as well as the presentation of the corresponding balance sheet accounts. The revisions were reclassifications only and had no impact on the Company's previously reported GAAP and non-GAAP net income and net income per share. Refer to the Company's Form 10-Q for the quarterly period ended June 30, 2020 (Note 1 of the Notes to Condensed Consolidated Financial Statements) for further details.

(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 second quarter 2020 financial and operating results on Wednesday, August 5, 2020, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International). 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 seven FDA-approved treatments and numerous product candidates in development, 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, 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 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 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), fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, REGN-COV2, Regeneron's oncology programs (including its costimulatory bispecific portfolio), Regeneron's 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 product candidates in patients, including serious complications or side effects in connection with the use of Regeneron’s Products and 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 without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, evinacumab, fasinumab, REGN-COV2, and REGN5678; 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, and Kevzara), 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 product candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), on the commercial success of Regeneron's Products and 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 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 COGS, 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), to be cancelled or terminated without any further product success; 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, and Praluent), 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, 2019 and its Form 10-Q for the quarterly period ended June 30, 2020. 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 any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

Non-GAAP Financial Measures

This press release and/or the financial results attached to this press release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of such non-GAAP financial measures.

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Contact Information:

Justin Holko
Investor Relations
914-847-7786
justin.holko@regeneron.com

Hala Mirza
Corporate Communications
914-847-3422
hala.mirza@regeneron.com

TABLE 1

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

	June 30, 2020	December 31, 2019*
Assets:		
Cash and marketable securities	$ 5,731.8	$ 6,471.1
Accounts receivable - trade, net	1,991.0	2,100.0
Accounts receivable - Sanofi and other	820.3	685.6
Inventories	1,640.9	1,415.5
Property, plant, and equipment, net	3,031.4	2,890.4
Deferred tax assets	774.0	824.2
Other assets	439.3	418.4
Total assets	$ 14,428.7	$ 14,805.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 2,589.1	$ 2,514.2
Debt	1,500.0	—
Deferred revenue	566.3	487.4
Finance lease liabilities	715.9	713.9
Stockholders' equity	9,057.4	11,089.7
Total liabilities and stockholders' equity	$ 14,428.7	$ 14,805.2

* Certain revisions have been made to the previously reported December 31, 2019 amounts. See note (4) above.

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,	
	2020	**2019***	**2020**	**2019***
Revenues:				
Net product sales	$ 1,226.9	$ 1,205.3	$ 2,463.6	$ 2,309.7
Sanofi collaboration revenue	269.1	75.8	516.0	57.8
Bayer collaboration revenue	244.2	277.2	525.6	541.2
Other revenue	211.8	19.5	275.0	41.7
	1,952.0	1,577.8	3,780.2	2,950.4
Expenses:				
Research and development	722.0	885.5	1,305.9	1,371.6
Selling, general, and administrative	348.3	294.6	715.6	585.7
Cost of goods sold	102.5	67.0	181.3	137.9
Cost of collaboration and contract manufacturing	173.0	78.8	311.5	180.0
Other operating (income) expense, net	(50.2)	(63.7)	(90.6)	(120.4)
	1,295.6	1,262.2	2,423.7	2,154.8
Income from operations	656.4	315.6	1,356.5	795.6
Other income (expense), net	262.5	(90.9)	231.0	(24.8)
Income before income taxes	918.9	224.7	1,587.5	770.8
Income tax expense	21.6	31.6	65.6	116.6
Net income	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
Net income per share - basic	$ 8.19	$ 1.77	$ 13.87	$ 6.00
Net income per share - diluted	$ 7.61	$ 1.68	$ 13.03	$ 5.69
Weighted average shares outstanding - basic	109.6	109.2	109.7	109.1
Weighted average shares outstanding - diluted	117.9	114.6	116.8	115.0

* Certain revisions have been made to the previously reported June 30, 2019 amounts. See note (4) above.

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,	
	2020	**2019**	**2020**	**2019**
GAAP R&D	$ 722.0	$ 885.5	$ 1,305.9	$ 1,371.6
R&D: Non-cash share-based compensation expense	56.9	59.3	113.6	118.0
R&D: Up-front payments related to license and collaboration agreements	85.0	400.0	85.0	400.0
Non-GAAP R&D	$ 580.1	$ 426.2	$ 1,107.3	$ 853.6
GAAP SG&A	$ 348.3	$ 294.6	$ 715.6	$ 585.7
SG&A: Non-cash share-based compensation expense	38.2	37.7	78.5	81.5
SG&A: Litigation contingencies and restructuring-related expenses	8.7	5.0	28.9	10.0
Non-GAAP SG&A	$ 301.4	$ 251.9	$ 608.2	$ 494.2
GAAP COGS	$ 102.5	$ 67.0	$ 181.3	$ 137.9
COGS: Non-cash share-based compensation expense	8.4	8.8	17.2	14.2
COGS: Other	0.9	—	0.9	—
Non-GAAP COGS	$ 93.2	$ 58.2	$ 163.2	$ 123.7
GAAP other income (expense), net	$ 262.5	$ (90.9)	$ 231.0	$ (24.8)
Other income/expense: (Gains) losses on investments	(256.1)	116.9	(199.3)	74.1
Interest expense: Other	1.5	—	1.5	—
Non-GAAP other income (expense), net	$ 7.9	$ 26.0	$ 33.2	$ 49.3
GAAP net income	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
Total of GAAP to non-GAAP reconciling items above	(56.5)	627.7	126.3	697.8
Income tax effect of GAAP to non-GAAP reconciling items	13.6	(130.8)	(23.2)	(144.3)
Non-GAAP net income	$ 854.4	$ 690.0	$ 1,625.0	$ 1,207.7
Non-GAAP net income per share - basic	$ 7.80	$ 6.32	$ 14.81	$ 11.07
Non-GAAP net income per share - diluted	$ 7.16	$ 6.02	$ 13.70	$ 10.50
Shares used in calculating:				
Non-GAAP net income per share - basic	109.6	109.2	109.7	109.1
Non-GAAP net income per share - diluted	119.3	114.6	118.6	115.0
Effective tax rate reconciliation:				
GAAP effective tax rate	2.4 %	14.1 %	4.1 %	15.1 %
Income tax effect of GAAP to non-GAAP reconciling items	(1.5 %)	5.0 %	1.1 %	2.7 %
Non-GAAP effective tax rate	0.9 %	19.1 %	5.2 %	17.8 %
Free cash flow reconciliation:				
Net cash provided by operating activities	$ 943.4	$ 188.3	$ 1,641.4	$ 1,085.3
Capital expenditures	(129.9)	(94.6)	(300.0)	(168.9)
	$ 813.5	$ 93.7	$ 1,341.4	$ 916.4

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019***	**2020**	**2019***
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 171.9	$ 38.8	$ 342.8	$ 11.0
Reimbursement for manufacturing of commercial supplies	100.6	43.9	180.7	58.4
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(6.4)	(6.9)	(12.6)	(11.6)
Reimbursement for manufacturing of commercial supplies	3.0	—	5.1	—
Total Sanofi collaboration revenue	$ 269.1	$ 75.8	$ 516.0	$ 57.8
Bayer collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 230.9	$ 269.0	$ 484.7	$ 518.3
Reimbursement for manufacturing of commercial supplies	13.3	8.2	40.9	22.9
Total Bayer collaboration revenue	$ 244.2	$ 277.2	$ 525.6	$ 541.2

* Certain revisions have been made to the previously reported June 30, 2019 amounts. See note (4) above.

TABLE 5

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

	Net Product Sales Recorded by Regeneron	Three Months Ended June 30,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA[a]	U.S.	$ 1,113.7	$ 641.0	$ 1,754.7	$ 1,160.3	$ 715.3	$ 1,875.6	(6 %)
Dupixent	(b)	$ 770.4	$ 174.6	$ 945.0	$ 454.7	$ 102.6	$ 557.3	70 %
Libtayo[b]	U.S.	$ 63.3	$ 16.7	$ 80.0	$ 40.8	—	$ 40.8	96 %
Praluent[c]	U.S.	$ 47.2	$ 39.4	$ 86.6	$ 26.5	$ 47.2	$ 73.7	18 %
Kevzara	(b)	$ 36.5	$ 31.8	$ 68.3	$ 34.2	$ 24.3	$ 58.5	17 %
ZALTRAP	(b)	$ 1.7	$ 25.0	$ 26.7	$ 1.3	$ 25.3	$ 26.6	— %
ARCALYST	U.S.	$ 2.7	—	$ 2.7	$ 4.2	—	$ 4.2	(36 %)

	Net Product Sales Recorded by Regeneron	Six Months Ended June 30,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA[a]	U.S.	$ 2,285.7	$ 1,322.7	$ 3,608.4	$ 2,234.4	$ 1,384.7	$ 3,619.1	— %
Dupixent	(b)	$ 1,449.4	$ 350.8	$ 1,800.2	$ 757.7	$ 173.3	$ 931.0	93 %
Libtayo[b]	U.S.	$ 125.0	$ 29.8	$ 154.8	$ 67.6	—	$ 67.6	129 %
Praluent[c]	U.S.	$ 82.3	$ 84.1	$ 166.4	$ 49.4	$ 88.2	$ 137.6	21 %
Kevzara	(b)	$ 71.8	$ 56.6	$ 128.4	$ 54.9	$ 37.3	$ 92.2	39 %
ZALTRAP	(b)	$ 3.2	$ 51.5	$ 54.7	$ 1.8	$ 49.3	$ 51.1	7 %
ARCALYST	U.S.	$ 5.7	—	$ 5.7	$ 7.7	—	$ 7.7	(26 %)

[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] Regeneron records net product sales of Libtayo in the United States. Sanofi records net product sales of Libtayo outside the United States and global net product sales of Dupixent, Kevzara, and ZALTRAP. The Company records its share of profits/losses in connection with (i) sales of Libtayo outside the United States, and (ii) global sales of Dupixent and Kevzara, within collaboration revenue (see Table 4). Sanofi pays the Company a percentage of net sales of ZALTRAP.

[c] 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. Refer to "Business Development Update" section above for further details.