Regeneron Reports Third Quarter 2020 Financial and Operating Results

November 5, 2020

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- *Third quarter 2020 revenues increased 32% to $2.29 billion versus third quarter 2019[4]*
- *Third quarter 2020 EYLEA® U.S. net sales increased 11% to $1.32 billion versus third quarter 2019*
- *Third quarter 2020 Dupixent® global net sales[2], which are recorded by Sanofi, increased 69% to $1.07 billion versus third quarter 2019*
- *Third quarter 2020 GAAP diluted EPS was $7.39 and non-GAAP diluted EPS[1] was $8.36*
- *REGN-COV2 trial in the COVID-19 outpatient setting met primary and key secondary endpoints*
- *FDA accepted for priority review Libtayo® (cemiplimab-rwlc) for both advanced non-small cell lung cancer and basal cell carcinoma*
- *FDA approved Inmazeb ™ for Ebola (Zaire ebolavirus)*

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2020 and provided a business update.

"Last week, Regeneron achieved an important milestone in the fight against COVID-19 with prospective Phase 2/3 results showing REGN-COV2 significantly reduced virus levels and the need for further medical attention in non-hospitalized patients; we have shared these important data with regulatory authorities," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Even with our intense commitment to fighting COVID-19, Regeneron continues to deliver across all aspects of our business. This quarter we had robust top- and bottom-line growth driven by EYLEA in retinal diseases and Dupixent in atopic dermatitis and asthma. In 2021, we look forward to important potential launches including for our PD-1 inhibitor Libtayo in non-small cell lung cancer and advanced basal cell carcinoma. Lastly, we are proud that our novel antibody cocktail REGN-EB3 recently became the first FDA-approved treatment for Ebola, underscoring the potential of antibody therapies to address deadly infectious diseases."

"We continue to invest in our promising pipeline while delivering meaningful revenue and earnings growth. Our revenue base is becoming more diversified with increasing contribution from Dupixent and Libtayo," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "This is evidenced by Dupixent achieving in excess of $1 billion in global net sales this quarter."

Financial Highlights

($ in millions, except per share data)	Q3 2020	Q3 2019	% Change
Total revenues[4]	$ 2,294	$ 1,744	32 %
GAAP net income	$ 842	$ 670	26 %
GAAP net income per share - diluted	$ 7.39	$ 5.86	26 %
Non-GAAP net income[1]	$ 961	$ 762	26 %
Non-GAAP net income per share - diluted[1]	$ 8.36	$ 6.67	25 %

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:

Dupixent® (dupilumab)

- In October 2020, the Company and Sanofi announced that a Phase 3 trial met its primary and all key secondary endpoints in children aged 6 to 11 years with uncontrolled moderate-to-severe asthma. Regulatory submissions in the United States and European Union (EU) are planned by the first quarter of 2021.
- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Dupixent, recommending to extend the approval in the EU to include children aged 6 to 11 years with severe atopic dermatitis who are candidates for systemic therapy.
- The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for the treatment of patients 12 years and older with eosinophilic esophagitis (EoE).

REGN-COV2, a dual antibody therapy to SARS-CoV-2 virus

- In October 2020, the Company submitted a request to the FDA for an Emergency Use Authorization (EUA) for REGN-COV2 in patients with mild-to-moderate COVID-19 who are at risk for poor outcomes.
- In October 2020, the Company announced positive results from an ongoing Phase 2/3 seamless trial in the COVID-19 outpatient setting showing REGN-COV2 met the primary and key secondary endpoints. REGN-COV2 significantly reduced viral load and patient medical visits (hospitalizations, emergency room, urgent care visits, and/or physician office/telemedicine visits). In September 2020, the Company also reported the first data from a descriptive analysis in this trial.
- In October 2020, the Independent Data Monitoring Committee (IDMC) for the REGN-COV2 treatment trials for COVID-19 recommended that the current hospitalized patient trial be modified. Specifically, based on a potential safety signal and an unfavorable risk/benefit profile at this time, the IDMC recommended that further enrollment of patients requiring high-flow oxygen or mechanical ventilation be placed on hold pending collection and analysis of further data on patients already enrolled. The IDMC also recommended continuing

enrollment of hospitalized patients requiring either no or low-flow oxygen as the risk/benefit remains acceptable in these cohorts. Finally, the IDMC recommended continuation of the outpatient trial (described further above) without modification.
- In September 2020, the Company and the University of Oxford announced that the RECOVERY Phase 3 open-label trial in the United Kingdom will evaluate REGN-COV2. This trial, which is being coordinated by researchers at the University of Oxford, is in patients hospitalized with COVID-19 and will compare the effects of adding REGN-COV2 to the usual standard-of-care versus standard-of-care on its own. The RECOVERY IDMC is aware of the IDMC recommendations made in connection with the REGN-COV2 treatment trials (described above), and will be discussing the impact, if any, on the RECOVERY trial.

Oncology Program

- The FDA accepted for priority review, with a target action date of February 28, 2021, the supplemental Biologics License Application (sBLA) for Libtayo® (cemiplimab) as monotherapy to treat patients with first-line locally advanced or metastatic non-small cell lung cancer (NSCLC) with ≥50% PD-L1 expression. A regulatory application for Libtayo as monotherapy in first-line NSCLC was also submitted in the EU.
- The FDA accepted for priority review, with a target action date of March 3, 2021, the sBLA for Libtayo for the treatment of patients with locally advanced or metastatic basal cell carcinoma (BCC). A regulatory application for Libtayo in advanced BCC was also submitted in the EU.
- Patient enrollment in the Libtayo Phase 3 first-line NSCLC chemotherapy combination study was completed.
- The Company and Sanofi presented positive data from pivotal trials for Libtayo monotherapy in first-line NSCLC and Libtayo monotherapy in BCC at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.
- A Phase 2 study of REGN5458, a bispecific antibody targeting BCMA and CD3, was initiated in multiple myeloma.

Inmazeb ™(atoltivimab, maftivimab, and odesivimab-ebgn)

- In October 2020, the FDA approved Inmazeb (REGN-EB3) for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including newborns of mothers who have tested positive for the infection.

Praluent® (alirocumab)

- The FDA accepted for review the sBLA for homozygous familial hypercholesterolemia (HoFH) in adults, with a target action date of April 4, 2021.

Evinacumab, an antibody to ANGPTL3

- The FDA accepted for priority review the BLA for HoFH, with a target action date of February 11, 2021. An MAA for HoFH has also been submitted in the EU.
- The *New England Journal of Medicine* (NEJM) published positive results from the Phase 3 trial in HoFH, showing that adding evinacumab to other lipid-lowering therapies cut bad cholesterol levels in half in patients with HoFH, including the most difficult to treat patients who had nearly non-existent LDL-receptor activity.

Corporate and Business Development Update

- In July 2020, the Company announced an agreement whereby the Company was awarded a $450 million contract to manufacture and supply REGN-COV2 to the U.S. government. The Company commenced delivery of REGN-COV2 drug product under the agreement during the third quarter of 2020. The Company continues to ramp up production for REGN-COV2 and now expects to have approximately 80,000 doses available by the end of November, approximately 200,000 total doses ready by the first week of January 2021, and approximately 300,000 total doses ready by the end of January 2021.
- In August 2020, the Company entered into a collaboration agreement with Roche to develop, manufacture, and distribute REGN-COV2. Each company has committed to dedicate a certain amount of manufacturing capacity to REGN-COV2 each year, and the collaboration is expected to substantially increase supply of REGN-COV2. Under the terms of the agreement, Regeneron will distribute and record sales for REGN-COV2 in the United States and Roche will be responsible for distribution outside the United States.
- In July 2020, the U.S. Department of Health and Human Services (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 Inmazeb, pursuant to which Regeneron expects to deliver a pre-specified number of treatment doses over the course of approximately six years.
- In August 2020, the Company issued and sold $2.0 billion aggregate principal amount of senior unsecured notes. See further details in the "*Other Financial Information*" section below.

Third Quarter 2020 Financial Results

Effective January 1, 2020, Regeneron 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 32% to $2.294 billion in the third quarter of 2020, compared to $1.744 billion in the third quarter of 2019.

EYLEA® net product sales in the United States increased to $1.318 billion in the third quarter of 2020, compared to $1.188 billion in the third quarter of 2019. 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 $653 million in the third quarter of 2020, compared to $469 million in the third quarter of 2019. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which increased to $213 million in

the third quarter of 2020 from $94 million in the third quarter of 2019. The change in the Company's share of profits from commercialization of antibodies was primarily driven by higher Dupixent profits. In addition, in the third quarter of 2020, the Company earned the first $50 million sales-based milestone from Sanofi, upon annual sales of antibodies outside the United States exceeding $1.0 billion on a rolling twelve-month basis.

Refer to Table 4 for a summary of collaboration revenue.

Other revenues in the third quarter of 2020 include recognition of revenue in connection with the Company's agreements with BARDA related to funding of certain REGN-COV2 and Inmazeb development activities.

Operating Expenses

	GAAP		%	Non-GAAP[1]		
($ in millions)	Q3 2020	Q3 2019	Change	Q3 2020	Q3 2019	% Change
Research and development (R&D)	$ 685	$ 526	30%	$ 629	$ 466	35%
Selling, general, and administrative (SG&A)	$ 327	$ 304	8%	$ 291	$ 264	10%
Cost of goods sold (COGS)	$ 131	$ 116	13%	$ 122	$ 100	22%
Cost of collaboration and contract manufacturing (COCM)	$ 143	$ 110	30%	*	*	n/a
Other operating (income) expense, net	$ (45)	$ (51)	(12%)	*	*	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 third quarter of 2020 were primarily 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 third quarter of 2020 were primarily due to commercialization-related costs for EYLEA and Praluent, and higher headcount-related costs.
- The increase in cost of collaboration and contract manufacturing in the third quarter of 2020 was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent and recognition of costs in connection with manufacturing ex-U.S. commercial supplies of Praluent for Sanofi.
- 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 losses on equity securities of $37 million in the third quarter of 2020, compared to net gains of $3 million in the third quarter of 2019.

In the third quarter of 2020, the Company's GAAP effective tax rate was 15.6%, compared to 12.9% in the third quarter of 2019. The GAAP effective tax rate for the third 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 third quarter of 2020, the non-GAAP effective tax rate was 16.3%, compared to 13.6% in the third quarter of 2019.

GAAP net income per diluted share was $7.39 in the third quarter of 2020, compared to GAAP net income per diluted share of $5.86 in the third quarter of 2019. Non-GAAP net income per diluted share was $8.36 in the third quarter of 2020, compared to non-GAAP net income per diluted share of $6.67 in the third quarter of 2019. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

In August 2020, the Company issued and sold $1.250 billion aggregate principal amount of 1.750% senior unsecured notes due 2030 and $750 million aggregate principal amount of 2.800% senior unsecured notes due 2050. Net proceeds to the Company from the issuance and sale of the notes were used in part to repay the $1.5 billion bridge loan facility, which was previously entered into in May 2020 in connection with the Company's purchase of shares of its common stock held by Sanofi.

Net cash used in operating activities in the third quarter of 2020 was $254 million, compared to $557 million in net cash provided by operating activities in the third quarter of 2019, which led to $(408) million in free cash flow for the third quarter of 2020, compared to $436 million for the third quarter of 2019. The decrease in cash from operating activities primarily resulted from an increase in trade accounts receivable in connection with extending payment terms to certain of the Company's EYLEA customers due to the COVID-19 pandemic.

2020 Financial Guidance[3]

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

	GAAP	Non-GAAP[1]
R&D	$2.750 billion–$2.820 billion *(previously $2.605 billion–$2.725 billion)*	$2.420 billion–$2.470 billion *(previously $2.270 billion–$2.370 billion)*
SG&A	$1.425 billion–$1.475 billion *(previously $1.400 billion–$1.480 billion)*	$1.235 billion–$1.265 billion *(previously $1.210 billion–$1.270 billion)*
COGS	$485 million–$525 million *(previously $490 million–$540 million)*	$440 million–$470 million *(previously $445 million–$485 million)*
COCM[5]	$595 million–$625 million *(previously $600 million–$660 million)*	*

Other operating (income) expense, net	($180) million–($200) million *(previously ($180) million–($205) million)*	*
Capital expenditures	$570 million–$600 million *(previously $540 million–$590 million)*	*
Effective tax rate (ETR)	9–11%	10–12%

* 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:

	Projected Range	
(In millions)	**Low**	**High**
GAAP R&D	$ 2,750	$ 2,820
R&D: Non-cash share-based compensation expense	(245)	(265)
R&D: Up-front payments related to license and collaboration agreements	(85)	(85)
Non-GAAP R&D	$ 2,420	$ 2,470
GAAP SG&A	$ 1,425	$ 1,475
SG&A: Non-cash share-based compensation expense	(160)	(180)
SG&A: Litigation contingencies and restructuring-related expenses	(30)	(30)
Non-GAAP SG&A	$ 1,235	$ 1,265
GAAP COGS	$ 485	$ 525
COGS: Non-cash share-based compensation expense	(44)	(54)
COGS: Other	(1)	(1)
Non-GAAP COGS	$ 440	$ 470
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 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 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 nine months ended September 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 September 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 third quarter 2020 financial and operating results on Thursday, November 5, 2020, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International), conference ID 1535889. 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 eight 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 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 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), Inmazeb ™(atoltivimab, maftivimab, and odesivimab-ebgn), fasinumab, evinacumab, 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, Inmazeb, evinacumab, fasinumab, REGN-COV2, REGN5458, and REGN6569; 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, 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 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), as well as Regeneron's agreement with Roche relating to REGN-COV2, 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, 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 September 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 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)

	September 30, 2020	December 31, 2019*
Assets:		
Cash and marketable securities	$ 5,901.0	$ 6,471.1
Accounts receivable - trade, net	3,092.5	2,100.0
Accounts receivable - Sanofi and other	947.0	685.6

Inventories	1,801.6	1,415.5
Property, plant, and equipment, net	3,138.3	2,890.4
Deferred tax assets	804.2	824.2
Other assets	399.4	418.4
Total assets	$ 16,084.0	$ 14,805.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 2,664.0	$ 2,514.2
Long-term debt	1,978.3	—
Deferred revenue	599.7	487.4
Finance lease liabilities	716.5	713.9
Stockholders' equity	10,125.5	11,089.7
Total liabilities and stockholders' equity	$ 16,084.0	$ 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 September 30,		Nine Months Ended September 30,	
	2020	**2019***	**2020**	**2019***
Revenues:				
Net product sales	$ 1,482.2	$ 1,238.3	$ 3,945.8	$ 3,548.0
Sanofi collaboration revenue	353.3	175.0	869.3	232.8
Bayer collaboration revenue	299.9	293.6	825.5	834.8
Other revenue	158.6	36.8	433.6	78.5
	2,294.0	1,743.7	6,074.2	4,694.1
Expenses:				
Research and development	684.6	526.0	1,990.5	1,897.6
Selling, general, and administrative	326.9	304.4	1,042.5	890.1
Cost of goods sold	131.0	115.9	312.3	253.8
Cost of collaboration and contract manufacturing	143.0	109.6	454.5	289.6
Other operating (income) expense, net	(44.6)	(50.7)	(135.2)	(171.1)
	1,240.9	1,005.2	3,664.6	3,160.0
Income from operations	1,053.1	738.5	2,409.6	1,534.1
Other (expense) income, net	(54.8)	30.0	176.2	5.2
Income before income taxes	998.3	768.5	2,585.8	1,539.3
Income tax expense	156.2	98.9	221.8	215.5
Net income	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
Net income per share - basic	$ 7.98	$ 6.12	$ 21.83	$ 12.12
Net income per share - diluted	$ 7.39	$ 5.86	$ 20.36	$ 11.54
Weighted average shares outstanding - basic	105.5	109.4	108.3	109.2
Weighted average shares outstanding - diluted	113.9	114.2	116.1	114.7

* Certain revisions have been made to the previously reported September 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
GAAP R&D	$ 684.6	$ 526.0	$ 1,990.5	$ 1,897.6
R&D: Non-cash share-based compensation expense	55.9	60.0	169.5	178.0
R&D: Up-front payments related to license and collaboration agreements	—	—	85.0	400.0
Non-GAAP R&D	$ 628.7	$ 466.0	$ 1,736.0	$ 1,319.6

GAAP SG&A	$ 326.9	$ 304.4	$ 1,042.5	$ 890.1
SG&A: Non-cash share-based compensation expense	35.9	40.8	114.4	122.3
SG&A: Litigation contingencies and restructuring-related expenses	—	—	28.9	10.0
Non-GAAP SG&A	$ 291.0	$ 263.6	$ 899.2	$ 757.8
GAAP COGS	$ 131.0	$ 115.9	$ 312.3	$ 253.8
COGS: Non-cash share-based compensation expense	9.4	16.3	26.6	30.5
COGS: Other	—	—	0.9	—
Non-GAAP COGS	$ 121.6	$ 99.6	$ 284.8	$ 223.3
GAAP other income (expense), net	$ (54.8)	$ 30.0	$ 176.2	$ 5.2
Other income/expense: Losses (gains) on investments	37.2	(3.4)	(162.1)	70.7
Interest expense: Other	11.2	—	12.7	—
Non-GAAP other income (expense), net	$ (6.4)	$ 26.6	$ 26.8	$ 75.9
GAAP net income	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
Total of GAAP to non-GAAP reconciling items above	149.6	113.7	275.9	811.5
Income tax effect of GAAP to non-GAAP reconciling items	(30.5)	(21.5)	(53.7)	(165.8)
Non-GAAP net income	$ 961.2	$ 761.8	$ 2,586.2	$ 1,969.5
Non-GAAP net income per share - basic	$ 9.11	$ 6.96	$ 23.88	$ 18.04
Non-GAAP net income per share - diluted	$ 8.36	$ 6.67	$ 22.01	$ 17.16
Shares used in calculating:				
Non-GAAP net income per share - basic	105.5	109.4	108.3	109.2
Non-GAAP net income per share - diluted	115.0	114.2	117.5	114.8
Effective tax rate reconciliation:				
GAAP effective tax rate	15.6 %	12.9 %	8.6 %	14.0 %
Income tax effect of GAAP to non-GAAP reconciling items	0.7 %	0.7 %	1.0 %	2.2 %
Non-GAAP effective tax rate	16.3 %	13.6 %	9.6 %	16.2 %
Free cash flow reconciliation:				
Net cash (used in) provided by operating activities	$ (254.3)	$ 557.3	$ 1,387.1	$ 1,642.6
Capital expenditures	(153.2)	(121.7)	(453.2)	(290.6)
Free cash flow	$ (407.5)	$ 435.6	$ 933.9	$ 1,352.0

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019***	**2020**	**2019***
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 212.8	$ 94.2	$ 555.6	$ 105.2
Sales-based milestone earned	50.0	—	50.0	—
Reimbursement for manufacturing of commercial supplies	94.3	85.4	275.0	143.8
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(4.7)	(4.6)	(17.3)	(16.2)
Reimbursement for manufacturing of commercial supplies	0.9	—	6.0	—
Total Sanofi collaboration revenue	$ 353.3	$ 175.0	$ 869.3	$ 232.8
Bayer collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 287.9	$ 275.0	$ 772.6	$ 793.3
Reimbursement for manufacturing of commercial supplies	12.0	18.6	52.9	41.5
Total Bayer collaboration revenue	$ 299.9	$ 293.6	$ 825.5	$ 834.8

* Certain revisions have been made to the previously reported September 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 September 30,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA[a]	U.S.	$ 1,318.3	$ 780.0	$ 2,098.3	$ 1,187.7	$ 730.2	$ 1,917.9	9 %
Dupixent	(b)	$ 851.2	$ 221.4	$ 1,072.6	$ 508.3	$ 124.8	$ 633.1	69 %
Libtayo[b]	U.S.	$ 71.6	$ 24.5	$ 96.1	$ 47.6	$ 3.9	$ 51.5	87 %
Praluent[c]	U.S.	$ 48.5	$ 43.0	$ 91.5	$ 33.5	$ 36.2	$ 69.7	31 %
Kevzara	(b)	$ 33.2	$ 36.8	$ 70.0	$ 36.5	$ 18.3	$ 54.8	28 %
REGN-COV2[d]	U.S.	$ 40.2	—	$ 40.2	—	—	—	(e)
ZALTRAP	(b)	$ 1.7	$ 22.5	$ 24.2	$ 3.1	$ 25.3	$ 28.4	(15) %
ARCALYST	U.S.	$ 3.6	—	$ 3.6	$ 3.0	—	$ 3.0	20 %

	Net Product Sales Recorded by Regeneron	Nine Months Ended September 30,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA[a]	U.S.	$ 3,604.0	$ 2,102.7	$ 5,706.7	$ 3,422.1	$ 2,114.9	$ 5,537.0	3 %
Dupixent	(b)	$ 2,300.6	$ 572.2	$ 2,872.8	$ 1,266.0	$ 298.1	$ 1,564.1	84 %
Libtayo[b]	U.S.	$ 196.6	$ 54.3	$ 250.9	$ 115.2	$ 3.9	$ 119.1	111 %
Praluent[c]	U.S.	$ 130.8	$ 127.1	$ 257.9	$ 82.9	$ 124.4	$ 207.3	24 %
Kevzara	(b)	$ 105.0	$ 93.4	$ 198.4	$ 91.4	$ 55.6	$ 147.0	35 %
REGN-COV2[d]	U.S.	$ 40.2	—	$ 40.2	—	—	—	(e)
ZALTRAP	(b)	$ 4.9	$ 74.0	$ 78.9	$ 4.9	$ 74.6	$ 79.5	(1) %
ARCALYST	U.S.	$ 9.3	—	$ 9.3	$ 10.7	—	$ 10.7	(13) %

[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.

[d] Regeneron records net product sales of REGN-COV2 in connection with our agreement with the U.S. government

[e] Percentage not meaningful

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