Regeneron Reports Third Quarter 2021 Financial and Operating Results

November 4, 2021

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- *Third quarter 2021 revenues increased 51% to $3.45 billion versus third quarter 2020 including $804 million attributable to REGEN-COV®(2)*
- *Third quarter 2021 EYLEA® U.S. net sales increased 12% versus third quarter 2020 to $1.47 billion*
- *Third quarter 2021 Dupixent® global net sales(3), which are recorded by Sanofi, increased 55% to $1.66 billion versus third quarter 2020*
- *Third quarter 2021 GAAP diluted EPS was $14.33 and non-GAAP diluted EPS(1) was $15.37*
- *Positive results reported from four Phase 3 Dupixent studies; FDA expanded approval of Dupixent to include children aged 6 to 11 years with asthma*

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2021 and provided a business update.

"Regeneron had another strong quarter of core business growth, with EYLEA and Dupixent reaching more patients than ever and progress made across our diverse pipeline," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We secured a new U.S. government supply agreement and are delivering an additional 1.4 million doses of REGEN-COV. Our Biologics License Application for REGEN-COV as treatment and prophylaxis was accepted by the FDA for priority review, with a mid-April 2022 action date. During the third quarter, we announced positive data from Phase 3 trials of Dupixent in chronic spontaneous urticaria and pediatric atopic dermatitis. We also recently announced positive data from Phase 3 trials of Dupixent in eosinophilic esophagitis and prurigo nodularis, and that the FDA approval in pediatric asthma was extended to children as young as six. Finally, our abstracts that will be released today for the American Society of Hematology (ASH) Annual Meeting highlight programs across the hematology portfolio, including our BCMA and C5 antibodies."

Financial Highlights

($ in millions, except per share data)	Q3 2021	Q3 2020	% Change
Total revenues	$ 3,453	$ 2,294	51%
GAAP net income	$ 1,632	$ 842	94%
GAAP net income per share - diluted	$ 14.33	$ 7.39	94%
Non-GAAP net income(1)	$ 1,773	$ 961	84%
Non-GAAP net income per share - diluted(1)	$ 15.37	$ 8.36	84%

"Regeneron performed extremely well in the third quarter with strong top- and bottom-line growth driven by an increasingly diversified core business," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We are approaching the end of 2021 with positive momentum as we continue to invest in our broad pipeline to drive sustained long-term growth."

Business Highlights

Key Pipeline Progress

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

EYLEA® (aflibercept) Injection

- In August 2021, the Company announced that an ongoing Phase 2 trial evaluating an 8 mg dose of aflibercept in patients with neovascular age-related macular degeneration (wet AMD) met its primary safety and efficacy endpoints. The high-dose aflibercept formulation is currently also being evaluated in two large Phase 3 trials in wet AMD and diabetic macular edema (DME), which are expected to report results in the second half of 2022.

Dupixent® (dupilumab)

- In October 2021, the U.S. Food and Drug Administration (FDA) approved Dupixent for children aged 6 to 11 years with moderate-to-severe asthma.
- In July 2021, the Company and Sanofi announced that 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.
- In October 2021, the Company and Sanofi announced that a second Phase 3 trial in adults and adolescents with eosinophilic esophagitis (EoE) met its co-primary endpoints in patients taking Dupixent 300 mg weekly, showing significant improvements in clinical (Dysphagia Symptom Questionnaire) and histologic disease measures compared to placebo. A rolling supplemental Biologics License Application (sBLA) has been initiated for adults and adolescents with EoE.

- In October 2021, the Company and Sanofi announced that a Phase 3 trial in adults with uncontrolled prurigo nodularis met its primary and all key secondary endpoints, showing that Dupixent significantly reduced itch and skin lesions compared to placebo in this investigational setting. Results from an additional Phase 3 trial in prurigo nodularis are expected to be reported in the first half of 2022.
- In August 2021, the Company and Sanofi announced that a Phase 3 trial in children aged 6 months to 5 years with moderate-to-severe atopic dermatitis met its primary and all secondary endpoints, and the companies expect to complete regulatory submissions in the United States and European Union (EU) in the coming months.

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

- In September 2021, the Company announced an agreement to supply the U.S. government with an additional 1.4 million doses of REGEN-COV (of which over 300,000 doses were delivered during the third quarter of 2021). Pursuant to the agreement, the U.S. government is obligated to purchase REGEN-COV doses delivered by January 31, 2022, resulting in aggregate payments to the Company of up to $2.940 billion. Roche will supply a portion of the doses to Regeneron to fulfill Regeneron's agreement with the U.S. government.
- The FDA accepted for priority review the BLA for COVID-19 treatment in non-hospitalized patients and as prophylaxis in certain individuals, with a target action date of April 13, 2022. A Marketing Authorization Application (MAA) for COVID-19 treatment in infected non-hospitalized patients or as prophylaxis was also submitted in the EU.
- In September 2021, the Company announced that a Phase 3 trial in patients hospitalized with COVID-19 met its primary endpoint, showing REGEN-COV significantly reduced viral load. The FDA is currently reviewing the Company's request to expand the Emergency Use Authorization (EUA) to include treatment in hospital settings, and the Company plans to submit a BLA and MAA for this patient population in the coming months.
- The *New England Journal of Medicine* published positive detailed results from the Phase 3 trial that assessed the ability of REGEN-COV to treat COVID-19 in infected high-risk non-hospitalized patients.

Oncology Programs

- The FDA accepted for priority review, with a target action date of January 30, 2022, the sBLA for Libtayo® (cemiplimab) to treat patients with recurrent or metastatic cervical cancer whose disease progressed on or after chemotherapy. The MAA in the EU is expected to be submitted by the end of the year.
- Positive data from the Phase 3 trial of Libtayo, in combination with chemotherapy, in patients with advanced non-small cell lung cancer, were presented at the European Society for Medical Oncology Virtual Congress 2021. These results will form the basis of regulatory submissions, which are planned in the United States and EU in the coming months.
- A Phase 1 study of REGN5093-M114, a bispecific antibody-drug conjugate targeting two distinct MET epitopes, was initiated in MET-altered advanced non-small cell lung cancer.

Pozelimab, an antibody to C5

- A Phase 3 study of pozelimab in combination with cemdisiran, a siRNA therapeutic, in myasthenia gravis was initiated.

REGN5713-5714-5715, a multi-antibody therapy to Bet v 1

- The initial Phase 3 study in birch allergic patients with allergic rhinoconjunctivitis met its primary endpoint with a reduction in the combined allergic rhinitis symptom and medication score. The Company is currently evaluating further development plans, including an additional Phase 3 study during an upcoming birch pollen season.

Third Quarter 2021 Financial Results

Revenues

Total revenues increased by 51% to $3.453 billion in the third quarter of 2021, compared to $2.294 billion in the third 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 sales of casirivimab and imdevimab pursuant to the Roche collaboration agreement, increased by 18% to $2.649 billion in the third quarter of 2021, compared to the third quarter of 2020[1].

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

($ in millions)	Q3 2021	Q3 2020	% Change
EYLEA	$ 1,473	$ 1,318	12 %
Libtayo	78	72	8 %
Praluent®	45	49	(8) %
REGEN-COV	677	40	**
Evkeeza®	7	—	**
ARCALYST®	— *	3	**

Total net product sales in the U.S.	$ 2,280	$ 1,482	54 %

* 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.
** Percentage not meaningful

During the third quarter of 2021, the Company commenced deliveries of REGEN-COV under its September 2021 supply agreement with the U.S. government (as described above).

Total revenues also include collaboration revenues[3] of $1.074 billion in the third quarter of 2021, compared to $653 million in the third quarter of 2020. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which were $387 million in the third quarter of 2021, compared to $213 million in the third quarter of 2020. The change in the Company's share of profits from commercialization of antibodies was driven by higher Dupixent profits. In addition, in both the third quarter of 2021 and 2020, the Company earned $50 million sales-based milestones from Sanofi based upon sales of antibodies outside the United States on a rolling twelve-month basis. In the third quarter of 2021, the Company also recorded Roche collaboration revenue of $127 million in connection with the true-up payment owed from Roche in connection with global gross profits from sales of the casirivimab and imdevimab antibody cocktail.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue decreased in the third quarter of 2021, compared to the third 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 COVID-19 antibodies, and, to a lesser extent, Inmazeb®.

Operating Expenses

	GAAP			Non-GAAP[1]		
($ in millions)	Q3 2021	Q3 2020	% Change	Q3 2021	Q3 2020	% Change
Research and development (R&D)	$ 665	$ 685	(3%)	$ 592	$ 629	(6%)
Selling, general, and administrative (SG&A)	$ 445	$ 327	36%	$ 391	$ 291	34%
Cost of goods sold (COGS)	$ 239	$ 131	82%	$ 224	$ 122	84%
Cost of collaboration and contract manufacturing (COCM)	$ 214	$ 143	50%	*	*	n/a
Other operating expense (income), net	$ 42	$ (45)	(193%)	*	*	n/a

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

- The increase in SG&A expenses in the third quarter of 2021 was primarily due to higher headcount-related costs and an increase in commercialization-related expenses for EYLEA, including direct-to-consumer advertising.
- The increase in COGS in the third quarter of 2021 was primarily due to the recognition of manufacturing costs in connection with product sales of REGEN-COV in the United States.
- The increase in COCM in the third quarter of 2021 was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent.
- Other operating expense (income), 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. The decrease in other operating income in the third quarter of 2021 was primarily due to the recognition of a cumulative catch-up adjustment of $67 million arising from an update to the estimate of the total R&D costs expected to be incurred under the Sanofi Immuno-oncology collaboration agreement.

Other Financial Information

In the third quarter of 2021, the Company's GAAP effective tax rate was 10.2%, compared to 15.6% in the third quarter of 2020. The decrease in the third quarter 2021 GAAP effective tax rate, compared to the third quarter of 2020, was due in part to the positive impact of stock-based compensation in the third quarter of 2021. In the third quarter of 2021, the non-GAAP effective tax rate was 10.8%, compared to 16.3% in the third quarter of 2020.

GAAP net income per diluted share was $14.33 in the third quarter of 2021, compared to GAAP net income per diluted share of $7.39 in the third quarter of 2020. Non-GAAP net income per diluted share was $15.37 in the third quarter of 2021, compared to non-GAAP net income per diluted share of $8.36 in the third 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 nine months of 2021 was $4.709 billion, compared to $1.387 billion in the first nine months of 2020, resulting in $4.312 billion in free cash flow[1] for the first nine months of 2021, compared to $934 million for the first nine months of 2020. The increase in free cash flow was primarily due to the Company's collection of amounts due from the U.S. government in connection with REGEN-COV sales in 2021.

2021 Financial Guidance[4]

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

	GAAP	Non-GAAP[1]
R&D	$2.845 billion–$2.915 billion *(previously $2.950 billion–$3.075 billion)*	$2.550 billion–$2.600 billion *(previously $2.650 billion–$2.750 billion)*

SG&A	$1.760 billion–$1.830 billion *(previously $1.730 billion–$1.830 billion)*	$1.560 billion–$1.610 billion *(previously $1.540 billion–$1.620 billion)*
Gross margin on net product sales[5]	Approximately 87.5% *(previously 87–88%)*	Approximately 88% *(previously 88–89%)*
COCM[6]	$670 million–$700 million *(previously $630 million–$680 million)*	*
Other operating (income) expense, net	($50) million–($60) million *(previously ($135) million–($155) million)*	*
Capital expenditures	$545 million–$575 million *(previously $590 million–$640 million)*	*
Effective tax rate (ETR)	14–15% *(previously 14–16%)*	14–15% *(previously 14–16%)*

* 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:

	Projected Range	
($ in millions)	**Low**	**High**
GAAP R&D	$ 2,845	$ 2,915
R&D: Non-cash share-based compensation expense	(295)	(315)
Non-GAAP R&D	$ 2,550	$ 2,600
GAAP SG&A	$ 1,760	$ 1,830
SG&A: Non-cash share-based compensation expense	(194)	(214)
SG&A: Litigation contingencies and other	(6)	(6)
Non-GAAP SG&A	$ 1,560	$ 1,610
GAAP gross margin on net product sales	Approximately 87.5%	Approximately 87.5%
Non-cash share-based compensation expense	< 1%	< 1%
Non-GAAP gross margin on net product sales	Approximately 88%	Approximately 88%
GAAP ETR	14%	15%
Income tax effect of GAAP to non-GAAP reconciling items and other	< 1%	< 1%
Non-GAAP ETR	14%	15%

(1) This press release uses non-GAAP R&D, non-GAAP SG&A, non-GAAP gross margin on net product sales, non-GAAP other income (expense) net, non-GAAP effective tax rate, non-GAAP net income, non-GAAP net income per share, total revenues excluding REGEN-COV, and free cash flow, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP). These non-GAAP financial measures are computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items.

The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate from period to period based on factors that are not within the Company's control (such as the Company's stock price on the dates share-based grants are issued or changes in the fair value of the Company's investments in equity securities) or items that are not associated with normal, recurring operations (such as restructuring-related expenses). 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 casirivimab and imdevimab antibody cocktail is known as REGEN-COV in the United States and Ronapreve™ in other countries. The Company records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States.

(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 third quarter 2021 financial and operating results on Thursday, November 4, 2021, at 8:30 AM Eastern Time. Participants may access the conference call live via webcast on the "Investors and Media" page of Regeneron's website at www.regeneron.com. To participate via telephone, please register in advance at http://www.directeventreg.com/registration/event/4979976. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the Company's website for at least 30 days.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading biotechnology company that invents 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 or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation EYLEA® (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) and its REGEN-COV supply agreement with the U.S. government, 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 September 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)

	September 30, 2021	December 31, 2020
Assets:		
Cash and marketable securities	$ 11,418.9	$ 6,722.6
Accounts receivable, net	5,452.0	4,114.7
Inventories	2,053.8	1,916.6
Property, plant, and equipment, net	3,395.7	3,221.6
Deferred tax assets	723.2	858.9
Other assets	627.9	328.9
Total assets	$ 23,671.5	$ 17,163.3
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,150.6	$ 2,806.8
Finance lease liabilities	719.0	717.2
Deferred revenue	564.3	635.5
Long-term debt	1,979.6	1,978.5
Stockholders' equity	17,258.0	11,025.3
Total liabilities and stockholders' equity	$ 23,671.5	$ 17,163.3

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,	
	2021	2020	2021	2020
Revenues:				
Net product sales	$ 2,279.9	$ 1,482.2	$ 8,142.0	$ 3,945.8
Collaboration revenue	1,073.9	653.2	2,783.0	1,694.8
Other revenue	99.0	158.6	195.0	433.6
	3,452.8	2,294.0	11,120.0	6,074.2
Expenses:				
Research and development	665.4	684.6	2,122.5	1,990.5
Selling, general, and administrative	445.0	326.9	1,265.3	1,042.5
Cost of goods sold	238.8	131.0	961.4	312.3
Cost of collaboration and contract manufacturing	214.4	143.0	493.5	454.5
Other operating expense (income), net	42.0	(44.6)	(29.8)	(135.2)

	1,605.6	1,240.9	4,812.9	3,664.6
Income from operations	1,847.2	1,053.1	6,307.1	2,409.6
Other income (expense):				
Other (expense) income, net	(16.4)	(28.5)	558.5	218.3
Interest expense	(14.2)	(26.3)	(43.2)	(42.1)
	(30.6)	(54.8)	515.3	176.2
Income before income taxes	1,816.6	998.3	6,822.4	2,585.8
Income tax expense	184.4	156.2	976.1	221.8
Net income	$ 1,632.2	$ 842.1	$ 5,846.3	$ 2,364.0
Net income per share - basic	$ 15.37	$ 7.98	$ 55.42	$ 21.83
Net income per share - diluted	$ 14.33	$ 7.39	$ 52.29	$ 20.36
Weighted average shares outstanding - basic	106.2	105.5	105.5	108.3
Weighted average shares outstanding - diluted	113.9	113.9	111.8	116.1

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,	
	2021	**2020**	**2021**	**2020**
GAAP R&D	$ 665.4	$ 684.6	$ 2,122.5	$ 1,990.5
R&D: Non-cash share-based compensation expense	73.1	55.9	213.7	169.5
R&D: Up-front payments related to license and collaboration agreements	—	—	—	85.0
Non-GAAP R&D	$ 592.3	$ 628.7	$ 1,908.8	$ 1,736.0
GAAP SG&A	$ 445.0	$ 326.9	$ 1,265.3	$ 1,042.5
SG&A: Non-cash share-based compensation expense	48.7	35.9	149.1	114.4
SG&A: Litigation contingencies and other	5.6	—	5.6	28.9
Non-GAAP SG&A	$ 390.7	$ 291.0	$ 1,110.6	$ 899.2
GAAP COGS	$ 238.8	$ 131.0	$ 961.4	$ 312.3
COGS: Non-cash share-based compensation expense	15.1	9.4	50.5	26.6
COGS: Other	—	—	—	0.9
Non-GAAP COGS	$ 223.7	$ 121.6	$ 910.9	$ 284.8
GAAP other (expense) income, net	$ (30.6)	$ (54.8)	$ 515.3	$ 176.2
Other income/expense: Losses (gains) on investments	29.3	37.2	(524.6)	(162.1)
Interest expense: Other	—	11.2	—	12.7
Non-GAAP other (expense) income, net	$ (1.3)	$ (6.4)	$ (9.3)	$ 26.8
GAAP net income	$ 1,632.2	$ 842.1	$ 5,846.3	$ 2,364.0
Total of GAAP to non-GAAP reconciling items above	171.8	149.6	(105.7)	275.9
Income tax effect of GAAP to non-GAAP reconciling items	(31.3)	(30.5)	36.3	(53.7)
Non-GAAP net income	$ 1,772.7	$ 961.2	$ 5,776.9	$ 2,586.2
Non-GAAP net income per share - basic	$ 16.69	$ 9.11	$ 54.76	$ 23.88
Non-GAAP net income per share - diluted	$ 15.37	$ 8.36	$ 50.99	$ 22.01
Shares used in calculating:				
Non-GAAP net income per share - basic	106.2	105.5	105.5	108.3
Non-GAAP net income per share - diluted	115.3	115.0	113.3	117.5
Effective tax rate reconciliation:				
GAAP effective tax rate	10.2%	15.6%	14.3%	8.6%
Income tax effect of GAAP to non-GAAP reconciling items	0.6%	0.7%	(0.3%)	1.0%
Non-GAAP effective tax rate	10.8%	16.3%	14.0%	9.6%
Free cash flow reconciliation:				
Net cash provided by (used in) operating activities	$ 3,413.6	$ (254.3)	$ 4,708.8	$ 1,387.1

Capital expenditures	(133.2)	(153.2)	(397.0)	(453.2)
Free cash flow	$ 3,280.4	$ (407.5)	$ 4,311.8	$ 933.9

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 387.0	$ 212.8	$ 975.2	$ 555.6
Sales-based milestone earned	50.0	50.0	50.0	50.0
Reimbursement for manufacturing of commercial supplies	144.7	94.3	361.2	275.0
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(3.0)	(4.7)	(12.6)	(17.3)
Reimbursement for manufacturing of commercial supplies	3.1	0.9	10.5	6.0
Total Sanofi collaboration revenue	581.8	353.3	1,384.3	869.3
Bayer collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	351.0	287.9	995.3	772.6
Reimbursement for manufacturing of commercial supplies	14.0	12.0	41.6	52.9
Total Bayer collaboration revenue	365.0	299.9	1,036.9	825.5
Roche collaboration revenue:				
Global gross profit true-up payment owed from Roche in connection with sales of casirivimab and imdevimab	127.1	—	361.8	—
Total collaboration revenue	$ 1,073.9	$ 653.2	$ 2,783.0	$ 1,694.8

TABLE 5

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

	Three Months Ended September 30,						
	2021			2020			% Change (Total Sales)
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**	
EYLEA[a]	$ 1,473.4	$ 930.8	$ 2,404.2	$ 1,318.3	$ 780.0	$ 2,098.3	15 %
Dupixent[b]	$ 1,256.7	$ 406.2	$ 1,662.9	$ 851.2	$ 221.4	$ 1,072.6	55 %
Libtayo[c]	$ 78.4	$ 41.1	$ 119.5	$ 71.6	$ 24.5	$ 96.1	24 %
Praluent[d]	$ 44.8	$ 69.7	$ 114.5	$ 48.5	$ 43.0	$ 91.5	25 %
REGEN-COV[e]	$ 676.7	$ 518.8	$ 1,195.5	$ 40.2	—	$ 40.2	(h)
Kevzara[b]	$ 58.5	$ 39.3	$ 97.8	$ 33.2	$ 36.8	$ 70.0	40 %
Evkeeza[f]	$ 6.6	—	$ 6.6	—	—	—	(h)
ARCALYST[g]	$ 12.1	—	$ 12.1	$ 3.6	—	$ 3.6	236 %
ZALTRAP[b]	$ 1.2	$ 20.9	$ 22.1	$ 1.7	$ 22.5	$ 24.2	(9) %

	Nine Months Ended September 30,						
	2021			2020			% Change (Total Sales)
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**	
EYLEA[a]	$ 4,245.1	$ 2,658.9	$ 6,904.0	$ 3,604.0	$ 2,102.7	$ 5,706.7	21 %
Dupixent[b]	$ 3,364.8	$ 1,060.0	$ 4,424.8	$ 2,300.6	$ 572.2	$ 2,872.8	54 %
Libtayo[c]	$ 225.5	$ 111.7	$ 337.2	$ 196.6	$ 54.3	$ 250.9	34 %

Praluent[d]	$	130.0	$	188.5	$	318.5	$	130.8	$	127.1	$	257.9	23	%
REGEN-COV[e]	$	3,530.1	$	1,173.2	$	4,703.3	$	40.2		—	$	40.2	(h)	
Kevzara[b]	$	119.9	$	113.7	$	233.6	$	105.0	$	93.4	$	198.4	18	%
Evkeeza[f]	$	9.1		—	$	9.1		—		—		—	(h)	
ARCALYST[g]	$	22.0		—	$	22.0	$	9.3		—	$	9.3	137	%
ZALTRAP[b]	$	3.9	$	66.1	$	70.0	$	4.9	$	74.0	$	78.9	(11)	%

[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

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