Regeneron Reports Fourth Quarter and Full Year 2020 Financial and Operating Results

February 5, 2021

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- *Fourth quarter 2020 revenues increased 30% to $2.42 billion versus fourth quarter 2019[4]*
- *Fourth quarter 2020 EYLEA® U.S. net sales increased 10% to $1.34 billion versus fourth quarter 2019 and full year 2020 EYLEA U.S. net sales increased 7% versus 2019*
- *Fourth quarter 2020 Dupixent® global net sales[2], which are recorded by Sanofi, increased 56% to $1.17 billion versus fourth quarter 2019 and full year 2020 Dupixent global net sales increased 75% versus 2019*
- *Fourth quarter 2020 GAAP diluted EPS was $10.24 and non-GAAP diluted EPS[1] was $9.53*
- *REGEN-COV ™antibody cocktail for COVID-19 received FDA Emergency Use Authorization; new agreement signed with U.S. government to purchase up to 1.25 million additional doses*
- *Positive interim data reported from Phase 3 trial with REGEN-COV used as passive vaccine to prevent COVID-19*

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial results for the fourth quarter and full year 2020 and provided a business update.

"In 2020, the Regeneron team rapidly mobilized our significant scientific, development, manufacturing, and operational capabilities to bring our monoclonal antibody cocktail, REGEN-COV, to patients with COVID-19 through an Emergency Use Authorization," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In 2021, in addition to our ongoing work on COVID-19, we expect further diversified growth driven by continued EYLEA momentum, expanded approvals and increased market penetration for Dupixent, and new launches for Libtayo in oncology. We anticipate U.S. regulatory action for Libtayo in both non-small cell lung cancer and basal cell carcinoma within the next month – and anticipate additional readouts later this year from across our oncology pipeline, including the bispecific platform."

Financial Highlights

	Three Months Ended December 31,			Year Ended December 31,		
($ in millions, except per share data)	2020	2019	% Change	2020	2019	% Change
Total revenues[4]	$ 2,423	$ 1,864	30%	$ 8,497	$ 6,558	30%
GAAP net income	$ 1,149	$ 792	45%	$ 3,513	$ 2,116	66%
GAAP net income per share - diluted	$ 10.24	$ 6.93	48%	$ 30.52	$ 18.46	65%
Non-GAAP net income[1]	$ 1,080	$ 858	26%	$ 3,666	$ 2,827	30%
Non-GAAP net income per share - diluted[1]	$ 9.53	$ 7.50	27%	$ 31.47	$ 24.67	28%

"In 2020, Regeneron delivered double-digit top- and bottom-line growth and significant shareholder value despite the unprecedented circumstances of a global pandemic," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "As we look ahead into 2021 and beyond, our business momentum and strong balance sheet give us confidence as we invest in R&D for long-term growth and execute on our capital allocation priorities."

Business Highlights

Key Pipeline Progress

Regeneron has approximately 30 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 November 2020, the European Commission (EC) extended the marketing authorization in the European Union (EU) to include children 6 to 11 years of age with severe atopic dermatitis who are candidates for systemic therapy.
- 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. A supplemental Biologics License Application (sBLA) was subsequently submitted and a submission in the EU is planned by the end of the first quarter of 2021.
- Phase 3 studies in chronic inducible urticaria, chronic sinusitis without nasal polyposis, and allergic fungal rhinosinusitis were initiated.

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

- In November 2020, REGEN-COV received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). REGEN-COV is authorized for the treatment of mild to moderate COVID-19 in certain patients at high risk for progressing to severe COVID-19 and/or hospitalization.
- In January 2021, the Company announced a second agreement with the U.S. government to manufacture and deliver REGEN-COV. The U.S. government has agreed to acquire up to 1.25 million additional doses at the lowest treatment dose authorized or approved by the FDA for the indication authorized under the EUA, resulting in payments to the Company of up to $2.625 billion in the aggregate. The U.S. government is obligated to purchase all filled and finished doses of drug product delivered by June 30, 2021, and may accept doses through September 30, 2021 at its discretion. A number of factors may impact available filled and finished supply by June 30, 2021, including manufacturing considerations and authorized dose levels. The agreement is in addition to the July 2020 agreement with the

U.S. government for approximately 300,000 doses.

- In February 2021, the European Medicines Agency (EMA) announced it had commenced a Rolling Review of data for the casirivimab and imdevimab antibody cocktail. Data on the safety, tolerability, and efficacy of the antibody cocktail will be shared with the EMA as they become available in the coming months.
- In October 2020, the Company announced additional positive results from an ongoing Phase 2/3 seamless trial in the COVID-19 outpatient setting showing that REGEN-COV significantly reduced viral load and COVID-19 medical visits (hospitalizations, emergency room, urgent care visits, and/or physician office/telemedicine visits). Initial clinical data from this trial were published in the *New England Journal of Medicine* (NEJM) in December 2020.
- A Phase 2 dose-ranging treatment study in non-hospitalized patients with COVID-19 was initiated and a lower 1,200 mg dose is being evaluated in the ongoing outpatient trial.
- In December 2020, the Company announced initial encouraging data from an ongoing Phase 1/2/3 trial in seronegative hospitalized COVID-19 patients requiring low-flow oxygen. The Phase 3 program in hospitalized patients will continue based on passing a futility analysis evaluating the risk of death or receiving mechanical ventilation and demonstrating positive reductions in viral load. In October 2020, the Independent Data Monitoring Committee (IDMC) for this trial recommended that, based on a potential safety signal and an unfavorable risk/benefit profile at this time, further enrollment of patients requiring high-flow oxygen or mechanical ventilation be placed on hold.
- The United Kingdom-based RECOVERY trial continues to evaluate REGEN-COV in hospitalized patients and has enrolled more than 6,000 patients in the cohort randomizing patients 1:1 to receive REGEN-COV or placebo.
- In January 2021, the Company announced positive initial results from an ongoing Phase 3 trial evaluating REGEN-COV used as a passive vaccine for the prevention of COVID-19 in people at high risk of infection (due to household exposure to a COVID-19 patient). An exploratory analysis was conducted on the first approximately 400 evaluable individuals enrolled in the trial, who were randomized to receive passive vaccination with REGEN-COV (1,200 mg via subcutaneous injections) or placebo.
- In January 2021, the Company announced that preclinical studies showed that the REGEN-COV antibody cocktail retains its potent neutralizing ability against circulating SARS-CoV-2 variants identified in the United Kingdom, South Africa, and Brazil. Both antibodies in the cocktail retained their potency against the UK variant (B.1.1.7); imdevimab retained its potency against the South African variant (B.1.351), while casirivimab potency was reduced but still comparable to that of other single antibodies in development against the original virus. The REGEN-COV antibody cocktail was prospectively designed so that if variants arose affecting one component, the other component could compensate and still allow for potent neutralizing activity. In fact, as reported in *Science* in June 2020, Regeneron scientists predicted the key mutation that has since appeared in the South African and Brazil variants, and further showed that this mutation would lower potency of the casirivimab component, but be compensated for by the imdevimab component.

Libtayo® (cemiplimab)

- The FDA accepted for priority review, with a target action date of February 28, 2021, the sBLA for Libtayo 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.

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.

REGN5458, a bispecific antibody targeting BCMA and CD3

- In December 2020, the Company announced updated data from the Phase 1 portion of a Phase 1/2 trial in patients with relapsed or refractory (R/R) multiple myeloma. The results continued to show deep and durable responses in patients with heavily-pretreated multiple myeloma and were shared in an oral presentation at the virtual 2020 American Society of Hematology (ASH) Annual Meeting.

Odronextamab, a CD20xCD3 bispecific antibody

- In December 2020, updated results from the Phase 1 trial in R/R follicular lymphoma, diffuse large B-cell lymphoma, and other B-cell non-Hodgkin lymphomas were shared in an oral presentation at ASH and included patient follow-up data of up to 3 years.
- In December 2020, the Company announced it was pausing new enrollment of patients with B-cell non-Hodgkin lymphomas (B-NHL) in its trials in compliance with an FDA partial clinical hold. The FDA requested that the Company amend the trial protocols in order to further reduce the incidence of ≥Grade 3 cytokine release syndrome (CRS) during step-up dosing. The Company is working with the FDA to amend the protocol, with the goal of resuming patient enrollment within the first half of 2021.

Additional Bispecific Antibodies

- In addition to REGN5458 and odronextamab, the Company has advanced two CD3 bispecifics into clinical trials including MUC16xCD3 (REGN4018), which is being studied in ovarian cancer.
- Three costimulatory CD28 bispecifics are now in clinical trials targeting prostate cancer, ovarian cancer, and other solid tumors.
- Also in clinical development is the first of a third class of bispecifics, METxMET (REGN5093), in non-small cell lung cancer driven by MET mutations and/or amplifications.

Itepekimab, an antibody to IL-33

- The Company and Sanofi have initiated a Phase 3 program in chronic obstructive pulmonary disease (COPD).

REGN5713-5714-5715, a multi-antibody therapy to Betv1

- A Phase 3 study in birch allergy was recently initiated. REGN5713-5714-5715 is designed to treat allergic inflammatory conditions caused by the allergen Betv1, which is the main allergen responsible for birch pollen allergies. Birch pollen allergy is one of the most common causes of seasonal allergies that occur in the spring, and is also believed to trigger "oral allergy syndrome" food reactions to related allergens found in fruits and nuts such as apples, pears, and cherries.

Select 2021 Milestones

Programs	Milestones
EYLEA	- Report results from Phase 2 study for high-dose formulation in neovascular age-related macular degeneration (wet AMD)
Dupixent	- FDA decision on sBLA and MAA submission for asthma in pediatrics (6–11 years of age) - Report results from Part B of the Phase 3 study in adults and adolescents with eosinophilic esophagitis (EoE) - Report results from Phase 3 study in prurigo nodularis
REGEN-COV (casirivimab and imdevimab)	- Report additonal data from Phase 3 portion of COVID-19 study in non-hospitalized patients - Report results for lower 1,200 mg dose in Phase 3 portion of COVID-19 study in non-hospitalized patients - Report additional data from Phase 3 portion of COVID-19 prevention study in household contacts - Data to be reported from Phase 3 United Kingdom-based RECOVERY trial in hospitalized patients - Report data from Phase 2 dose-ranging virology study in non-hospitalized patients - Submit BLA and MAA for COVID-19
Libtayo	- FDA decision on sBLA (target action date of February 28, 2021) and EC decision on regulatory submission for first-line NSCLC, monotherapy - Interim analysis from Phase 3 study in first-line NSCLC, chemotherapy combination - FDA decision on sBLA (target action date of March 3, 2021) and EC decision on regulatory submission for advanced BCC - Interim analysis from Phase 3 study in cervical cancer
REGN5458 (BCMA and CD3 Bispecific Antibody)	- Complete patient enrollment in potentially pivotal Phase 2 study in multiple myeloma - Initiate pivotal trials in earlier lines of multiple myeloma therapy
Odronextamab (CD20 and CD3 Bispecific Antibody)	- Complete patient enrollment in potentially pivotal Phase 2 study in B-NHL - Initiate Phase 3 program
Praluent	- FDA decision on sBLA for homozygous familial hypercholesterolemia (HoFH) in adults (target action date of April 4, 2021)
Evkeeza™ (evinacumab) (ANGPTL3 Antibody)	- FDA decision on BLA (target action date of February 11, 2021) and EC decision on MAA for HoFH
Fasinumab (NGF Antibody)	- Report additional longer-term safety results from Phase 3 studies in osteoarthritis pain of the knee or hip - Continue discussions with regulatory authorities and determine next steps for the program

Fourth Quarter and Full Year 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 30% to $2.423 billion in the fourth quarter of 2020, compared to $1.864 billion in the fourth quarter of 2019. Full year 2020 total revenues increased 30% to $8.497 billion, compared to $6.558 billion for the full year 2019.

EYLEA® net product sales in the United States increased to $1.343 billion in the fourth quarter of 2020, compared to $1.222 billion in the fourth quarter of 2019. Full year 2020 EYLEA net product sales in the United States increased to $4.947 billion, compared to $4.644 billion for the full year 2019. Overall distributor inventory levels for EYLEA in the United States remained within the Company's one-to-two-week targeted range.

Net product sales of REGEN-COV were $146 million in the fourth quarter of 2020 and $186 million for the full year of 2020.

Total revenues also include Sanofi and Bayer collaboration revenues(2) of $678 million in the fourth quarter and $2.373 billion for the full year 2020, compared to $482 million in the fourth quarter and $1.549 billion for the full year 2019. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which were $230 million and $785 million in the fourth quarter and full year 2020, respectively, compared to $104 million and $209 million in the fourth quarter and full year 2019, respectively. 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 fourth quarter and full year of 2020, compared to the same periods in the prior year, increased primarily due to recognition of revenue of $43 million and $187 million, respectively, in connection with the Company's agreement with the Biomedical Advanced Research Development Authority (BARDA) related to funding of certain development activities for antibodies related to the treatment of COVID-19. Other revenues for the full year of 2020 also increased due to recognition of revenue in connection with the Company's agreement with BARDA related to funding of certain Inmazeb development activities and Sanofi's reimbursement for manufacturing commercial supplies of Praluent.

Operating Expenses

	GAAP		%	Non-GAAP(1)		%
($ in millions)	Q4 2020	Q4 2019	Change	Q4 2020	Q4 2019	Change
Research and development (R&D)	$ 745	$ 552	35%	$ 675	$ 450	50%

Selling, general, and administrative (SG&A)	$ 304	$ 452	(33%)	$ 381	$ 311	23%
Cost of goods sold (COGS)	$ 180	$ 109	65%	$ 166	$ 93	78%
Cost of collaboration and contract manufacturing (COCM)	$ 174	$ 113	54%	*	*	n/a
Other operating (income) expense, net	$ (145)	$ (38)	282%	*	*	n/a

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

	GAAP		%	Non-GAAP[(1)]		%
($ in millions)	2020	2019	Change	2020	2019	Change
Research and development	$ 2,735	$ 2,450	12%	$ 2,411	$ 1,770	36%
Selling, general, and administrative	$ 1,346	$ 1,342	— %	$ 1,280	$ 1,069	20%
Cost of goods sold	$ 492	$ 362	36%	$ 451	$ 316	43%
Cost of collaboration and contract manufacturing	$ 628	$ 403	56%	*	*	n/a
Other operating (income) expense, net	$ (280)	$ (209)	34%	*	*	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 fourth quarter and full year 2020, compared to the same periods in the prior year, were primarily due to additional costs incurred in connection with COVID-19 related development activities. The higher GAAP and non-GAAP R&D expenses for full year 2020 were also due to additional costs incurred in connection with the Company's earlier-stage pipeline, higher headcount and headcount-related costs, and an increase in clinical manufacturing activities. GAAP R&D expenses for full year 2020 included $85 million of up-front payments in connection with the Intellia collaboration agreement, and GAAP R&D expenses for full year 2019 included a $400 million up-front payment in connection with the Alnylam collaboration agreement.
- The change in GAAP and non-GAAP SG&A expenses in the fourth quarter and full year 2020, compared to the same periods in the prior year, was primarily due to an increase in commercialization-related costs for EYLEA and Libtayo, higher headcount-related costs, and, effective April 1, 2020, no longer receiving Praluent-related cost reimbursements from Sanofi for Regeneron-incurred expenses. GAAP SG&A expenses for the fourth quarter and full year 2020 were also positively impacted by a reversal of $121 million in accruals for litigation-related loss contingencies in the fourth quarter of 2020 as a result of the October 2020 ruling by the Technical Board of Appeal of the European Patent Office and its impact on certain patent infringement actions in Europe relating to Praluent. In addition, in the fourth quarter of 2019, the Company recorded a $35 million GAAP SG&A charge related to employee separation costs, as the Company eliminated certain commercialization activities and related headcount in connection with the restructuring of the antibody agreement with Sanofi.
- The increase in COGS in the fourth quarter and full year 2020, compared to the same periods in the prior year, was primarily due to the recognition of manufacturing costs in connection with the initiation of product sales of REGEN-COV (which commenced in the third quarter of 2020) and Praluent in the United States (which were recorded by Sanofi prior to April 1, 2020), as well as higher product sales of Libtayo and EYLEA in the United States. These increases were partly offset by lower period costs for the Company's Limerick commercial manufacturing facility and lower inventory write-downs and reserves.
- The increase in COCM in the fourth quarter and full year 2020, compared to the same periods in the prior year, was primarily due to the recognition of manufacturing costs associated with Dupixent and recognition of costs in connection with manufacturing ex-U.S. commercial supplies of Praluent for Sanofi. In addition, COCM increased for full year 2020 due to process validation costs in connection with manufacturing Inmazeb under our BARDA 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. The increase in other operating income in the fourth quarter and full year 2020 was primarily due to the recognition of cumulative catch-up adjustments of $100 million, net, arising from an update to the estimate of the stage of completion for certain collaboration programs.

Other Financial Information

GAAP other income (expense), net, includes the recognition of net gains on equity securities of $60 million in the fourth quarter and $222 million for the full year 2020, compared to net gains of $189 million in the fourth quarter and $118 million for the full year 2019. 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, for which the associated interest expense is included in GAAP and non-GAAP other income (expense), net.

GAAP income tax expense was $75 million and the effective tax rate was 6.2% in the fourth quarter of 2020, compared to $98 million and 11.0% in the fourth quarter of 2019. GAAP income tax expense was $297 million and the effective tax rate was 7.8% for the full year 2020, compared to $313 million and 12.9% for the full year 2019. The GAAP effective tax rate for the fourth quarter and full year 2020 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation, federal tax credits for research activities, and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate. In the fourth quarter and full year 2020, the non-GAAP effective tax rate was 7.7% and 9.1%, respectively, compared to 10.6% and 14.6% in the fourth quarter and full year 2019, respectively.

GAAP net income per diluted share was $10.24 in the fourth quarter of 2020, compared to GAAP net income per diluted share of $6.93 in the fourth quarter of 2019. GAAP net income per diluted share was $30.52 for the full year 2020, compared to GAAP net income per diluted share of $18.46 for full year 2019. Non-GAAP net income per diluted share was $9.53 in the fourth quarter of 2020, compared to non-GAAP net income per diluted share of $7.50 in the fourth quarter of 2019. Non-GAAP net income per diluted share was $31.47 for the full year 2020, compared to non-GAAP net income per diluted share of $24.67 for the full year 2019. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

During 2020, the Company repurchased 1.6 million shares of its common stock under the Company's share repurchase program. As of December 31, 2020, the Company had repurchased the entire $1.0 billion it was authorized to repurchase under the program.

In January 2021, the Company's board of directors authorized a new share repurchase program to repurchase up to $1.5 billion of the Company's common stock.

Repurchases may be made from time to time at management's discretion through a variety of methods. The program has no time limit and can be discontinued at any time.

Net cash provided by operating activities in the fourth quarter of 2020 was $1.231 billion, compared to $787 million in the fourth quarter of 2019, resulting in $1.070 billion in free cash flow for the fourth quarter of 2020, compared to $648 million for the fourth quarter of 2019. Net cash provided by operating activities for the full year 2020 was $2.618 billion, compared to $2.430 billion in net cash provided by operating activities for the full year 2019, resulting in $2.004 billion in free cash flow for the full year 2020, compared to $2.000 billion for the full year 2019.

2021 Financial Guidance[(3)]

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

	GAAP	Non-GAAP[(1)]
R&D	$3.000 billion–$3.175 billion	$2.700 billion–$2.850 billion
SG&A	$1.700 billion–$1.850 billion	$1.500 billion–$1.630 billion
Gross margin on net product sales[(5)]	86%–88%	87%–89%
COCM[(6)]	$670 million–$750 million	*
Other operating (income) expense, net	($150) million–($175) million	*
Capital expenditures	$600 million–$680 million	*
Effective tax rate (ETR)	11–13%	12–14%

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

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

	Projected Range	
($ in millions)	**Low**	**High**
GAAP R&D	$ 3,000	$ 3,175
R&D: Non-cash share-based compensation expense	(300)	(325)
Non-GAAP R&D	$ 2,700	$ 2,850
GAAP SG&A	$ 1,700	$ 1,850
SG&A: Non-cash share-based compensation expense	(200)	(220)
Non-GAAP SG&A	$ 1,500	$ 1,630
GAAP gross margin on net product sales	86%	88%
Non-cash share-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	87%	89%
GAAP ETR	11%	13%
Income tax effect of GAAP to non-GAAP reconciling items and other	1%	1%
Non-GAAP ETR	12%	14%

(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, and free cash flow, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP). These non-GAAP financial measures are computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items.
The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate from period to period based on factors that are not within the Company's control (such as the Company's stock price on the dates share-based grants are issued or changes in the fair value of the Company's investments in equity securities) or items that are not associated with normal, recurring operations (such as restructuring-related expenses, including employee separation costs). Management uses these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. With respect to free cash flows, the Company believes that this non-GAAP measure provides a further measure of the Company's operations' ability to generate cash flows. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the Company's historical GAAP to non-GAAP results is included in Table 3 of this press release.

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

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

(4) Applicable amounts previously reported for the three months and year ended December 31, 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) 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 fourth quarter and full year 2020 financial and operating results on Friday, February 5, 2021, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International), conference ID 1580376. 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, 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, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center®, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the Company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), Inmazeb ™(atoltivimab, maftivimab, and odesivimab-ebgn), fasinumab, Evkeeza ™(evinacumab), REGEN-COV ™(casirivimab and imdevimab), garetosmab, pozelimab, odronextamab, itepekimab, REGN5458, REGN5713-5714-5715, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; the likelihood and timing of achieving any of the anticipated milestones described in this press release; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, Inmazeb, Evkeeza, fasinumab, REGEN-COV, garetosmab, pozelimab, odronextamab, itepekimab, REGN5458, and REGN5713-5714-5715; 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 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 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), 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 (including the impact of the recently issued "most-favored-nation" interim final rule); 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 REGEN-COV, 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. 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)

	December 31,	
	2020	**2019***
Assets:		
Cash and marketable securities	$ 6,722.6	$ 6,471.1
Accounts receivable - trade, net	3,111.5	2,100.0
Accounts receivable - Sanofi and other, net	1,003.2	685.6
Inventories	1,916.6	1,415.5
Property, plant, and equipment, net	3,221.6	2,890.4
Deferred tax assets	858.9	824.2
Other assets	328.9	418.4
Total assets	$ 17,163.3	$ 14,805.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 2,806.8	$ 2,514.2
Long-term debt	1,978.5	—
Deferred revenue	635.5	487.4
Finance lease liabilities	717.2	713.9
Stockholders' equity	11,025.3	11,089.7
Total liabilities and stockholders' equity	$ 17,163.3	$ 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 December 31,		Year Ended December 31,	
	2020	**2019***	**2020**	**2019***
Revenues:				
Net product sales	$ 1,621.8	$ 1,286.4	$ 5,567.6	$ 4,834.4
Sanofi collaboration revenue	317.1	170.8	1,186.4	403.6
Bayer collaboration revenue	360.6	310.8	1,186.1	1,145.6
Other revenue	123.4	95.5	557.0	174.0
	2,422.9	1,863.5	8,497.1	6,557.6
Expenses:				
Research and development	744.5	552.4	2,735.0	2,450.0
Selling, general, and administrative	303.5	451.8	1,346.0	1,341.9
Cost of goods sold	179.6	108.5	491.9	362.3
Cost of collaboration and contract manufacturing	173.5	113.2	628.0	402.8
Other operating (income) expense, net	(145.2)	(38.1)	(280.4)	(209.2)
	1,255.9	1,187.8	4,920.5	4,347.8
Income from operations	1,167.0	675.7	3,576.6	2,209.8
Other income (expense):				
Other income (expense), net	72.4	220.8	290.7	249.5
Interest expense	(14.8)	(6.7)	(56.9)	(30.2)
	57.6	214.1	233.8	219.3
Income before income taxes	1,224.6	889.8	3,810.4	2,429.1
Income tax expense	75.4	97.8	297.2	313.3
Net income	$ 1,149.2	$ 792.0	$ 3,513.2	$ 2,115.8
Net income per share - basic	$ 10.90	$ 7.25	$ 32.65	$ 19.38
Net income per share - diluted	$ 10.24	$ 6.93	$ 30.52	$ 18.46
Weighted average shares outstanding - basic	105.4	109.2	107.6	109.2
Weighted average shares outstanding - diluted	112.2	114.3	115.1	114.6

* Certain revisions have been made to the previously reported December 31, 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 December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
GAAP R&D	$ 744.5	$ 552.4	$ 2,735.0	$ 2,450.0
R&D: Non-cash share-based compensation expense	69.1	72.4	238.6	250.4
R&D: Up-front payments related to license and collaboration agreements	—	30.0	85.0	430.0
Non-GAAP R&D	$ 675.4	$ 450.0	$ 2,411.4	$ 1,769.6
GAAP SG&A	$ 303.5	$ 451.8	$ 1,346.0	$ 1,341.9
SG&A: Non-cash share-based compensation expense	38.6	45.4	153.0	167.7
SG&A: Litigation contingencies	(121.0)	60.0	(95.0)	70.0
SG&A: Restructuring-related expenses	5.2	35.2	8.1	35.2
Non-GAAP SG&A	$ 380.7	$ 311.2	$ 1,279.9	$ 1,069.0
GAAP COGS	$ 179.6	$ 108.5	$ 491.9	$ 362.3
COGS: Non-cash share-based compensation expense	13.8	15.7	40.4	46.2
COGS: Other	—	—	0.9	—
Non-GAAP COGS	$ 165.8	$ 92.8	$ 450.6	$ 316.1
GAAP other income (expense), net	$ 57.6	$ 214.1	$ 233.8	$ 219.3
Other income/expense: Gains on investments	(59.5)	(189.0)	(221.6)	(118.3)
Interest expense: Other	—	—	12.7	—
Non-GAAP other income (expense), net	$ (1.9)	$ 25.1	$ 24.9	$ 101.0
GAAP net income	$ 1,149.2	$ 792.0	$ 3,513.2	$ 2,115.8
Total of GAAP to non-GAAP reconciling items above	(53.8)	69.7	222.1	881.2
Income tax effect of GAAP to non-GAAP reconciling items	14.8	(4.1)	(38.9)	(169.9)
Income tax expense: Impact of sale of assets between foreign subsidiaries	(30.0)	—	(30.0)	—
Non-GAAP net income	$ 1,080.2	$ 857.6	$ 3,666.4	$ 2,827.1
Non-GAAP net income per share - basic	$ 10.25	$ 7.85	$ 34.07	$ 25.89
Non-GAAP net income per share - diluted	$ 9.53	$ 7.50	$ 31.47	$ 24.67
Shares used in calculating:				
Non-GAAP net income per share - basic	105.4	109.2	107.6	109.2
Non-GAAP net income per share - diluted	113.4	114.3	116.5	114.6
Effective tax rate reconciliation:				
GAAP effective tax rate	6.2 %	11.0 %	7.8 %	12.9 %
Income tax effect of GAAP to non-GAAP reconciling items	1.5 %	(0.4) %	1.3 %	1.7 %
Non-GAAP effective tax rate	7.7 %	10.6 %	9.1 %	14.6 %
Free cash flow reconciliation:				
Net cash provided by operating activities	$ 1,231.0	$ 787.4	$ 2,618.1	$ 2,430.0
Capital expenditures	(161.4)	(139.0)	(614.6)	(429.6)
Free cash flow	$ 1,069.6	$ 648.4	$ 2,003.5	$ 2,000.4

TABLE 4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	**2019***	**2020**	**2019***
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 229.6	$ 104.1	$ 785.2	$ 209.3
Sales-based milestone earned	—	—	50.0	—
Reimbursement for manufacturing of commercial supplies	93.0	72.2	368.0	216.0
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(8.4)	(5.5)	(25.7)	(21.7)
Reimbursement for manufacturing of commercial supplies	2.9	—	8.9	—

Total Sanofi collaboration revenue	$ 317.1	$ 170.8	$ 1,186.4	$ 403.6
Bayer collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 335.3	$ 298.1	$ 1,107.9	$ 1,091.4
Reimbursement for manufacturing of commercial supplies	25.3	12.7	78.2	54.2
Total Bayer collaboration revenue	$ 360.6	$ 310.8	$ 1,186.1	$ 1,145.6

* Certain revisions have been made to the previously reported December 31, 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 December 31,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA[a]	U.S.	$ 1,343.2	$ 858.8	$ 2,202.0	$ 1,222.1	$ 782.5	$ 2,004.6	10 %
Dupixent	(b)	$ 925.6	$ 246.4	$ 1,172.0	$ 605.2	$ 146.3	$ 751.5	56 %
Libtayo[b]	U.S.	$ 74.1	$ 23.2	$ 97.3	$ 60.5	$ 14.2	$ 74.7	30 %
Praluent[c]	U.S.	$ 55.2	$ 45.7	$ 100.9	$ 43.1	$ 38.3	$ 81.4	24 %
Kevzara	(b)	$ 36.6	$ 34.9	$ 71.5	$ 37.6	$ 22.1	$ 59.7	20 %
REGEN-COV[d]	U.S.	$ 145.5	—	$ 145.5	—	—	—	(e)
ZALTRAP	(b)	$ 0.9	$ 23.9	$ 24.8	$ 2.4	$ 26.5	$ 28.9	(14) %
ARCALYST	U.S.	$ 3.8	—	$ 3.8	$ 3.8	—	$ 3.8	— %

	Net Product Sales Recorded by Regeneron	Year Ended December 31,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
EYLEA[a]	U.S.	$ 4,947.2	$ 2,961.5	$ 7,908.7	$ 4,644.2	$ 2,897.4	$ 7,541.6	5 %
Dupixent	(b)	$ 3,226.2	$ 818.6	$ 4,044.8	$ 1,871.2	$ 444.4	$ 2,315.6	75 %
Libtayo[b]	U.S.	$ 270.7	$ 77.5	$ 348.2	$ 175.7	$ 18.1	$ 193.8	80 %
Praluent[c]	U.S.	$ 186.0	$ 172.8	$ 358.8	$ 126.0	$ 162.7	$ 288.7	24 %
Kevzara	(b)	$ 141.6	$ 128.3	$ 269.9	$ 129.0	$ 77.7	$ 206.7	31 %
REGEN-COV[d]	U.S.	$ 185.7	—	$ 185.7	—	—	—	(e)
ZALTRAP	(b)	$ 5.8	$ 97.9	$ 103.7	$ 7.3	$ 101.1	$ 108.4	(4) %
ARCALYST	U.S.	$ 13.1	—	$ 13.1	$ 14.5	—	$ 14.5	(10) %

[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 REGEN-COV in connection with its agreements with the U.S. government.

[e] Percentage not meaningful