Regeneron Reports Fourth Quarter and Full Year 2021 Financial and Operating Results

February 4, 2022

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- *Fourth quarter 2021 revenues increased 104% to $4.95 billion versus fourth quarter 2020 including $2.30 billion attributable to REGEN-COV®[2]; revenues excluding REGEN-COV[1] increased 17%*
- *Full year 2021 revenues increased 89% to $16.07 billion compared to full year 2020 including $6.19 billion attributable to REGEN-COV[2]; revenues excluding REGEN-COV[1] increased 19%*
- *Fourth quarter 2021 EYLEA® U.S. net sales increased 15% to $1.55 billion versus fourth quarter 2020 and full year 2021 EYLEA U.S. net sales increased 17% versus 2020*
- *Fourth quarter 2021 Dupixent® global net sales[3], which are recorded by Sanofi, increased 51% to $1.77 billion versus fourth quarter 2020 and full year 2021 Dupixent global net sales increased 53% versus 2020*
- *Fourth quarter 2021 GAAP diluted EPS was $19.69 and non-GAAP diluted EPS[1] was $23.72*

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

"In 2021, Regeneron delivered strong results across our core business with impressive EYLEA and Dupixent growth, while also helping address the ongoing pandemic by delivering REGEN-COV to millions of patients," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "For 2022, we remain focused on building on EYLEA's success, expanding approvals and patient reach for Dupixent, pursuing new indications for Libtayo, and reading out data from our oncology pipeline – all while continuing to progress our diversified earlier-stage pipeline. We also remain committed to our efforts to fight the COVID-19 pandemic and address the significant need for effective treatments and preventative approaches to SARS-CoV-2. Given the lack of efficacy of REGEN-COV against the Omicron variant, we are working hard to develop next generation antibodies that are active against Omicron and all other variants of concern."

Financial Highlights

	Three Months Ended December 31,			Year Ended December 31,		
($ in millions, except per share data)	2021	2020	% Change	2021	2020	% Change
Total revenues	$ 4,952	$ 2,423	104%	$ 16,072	$ 8,497	89%
GAAP net income	$ 2,229	$ 1,149	94%	$ 8,075	$ 3,513	130%
GAAP net income per share - diluted	$ 19.69	$ 10.24	92%	$ 71.97	$ 30.52	136%
Non-GAAP net income[1]	$ 2,712	$ 1,080	151%	$ 8,488	$ 3,666	132%
Non-GAAP net income per share - diluted[1]	$ 23.72	$ 9.53	149%	$ 74.66	$ 31.47	137%

"In 2021, Regeneron delivered solid top- and bottom-line growth driven by strong execution within our core business," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "With growth continuing across our existing portfolio and investments in our R&D engine supported by our strong balance sheet, we are well positioned for sustainable long-term growth."

Business Highlights

Key Pipeline Progress

Regeneron has over 30 product candidates in clinical development, including a number of marketed products for which it is investigating additional indications. Updates from the clinical pipeline in the fourth quarter of 2021 and 2022 to date include:

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 January 2022, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending to extend the approval of Dupixent in the European Union (EU) for the treatment of severe asthma in children aged 6 to 11 years old. A final decision from the European Commission (EC) regarding the regulatory application is expected in the coming months.
- The *New England Journal of Medicine* published positive results from the Phase 3 trial in children aged 6 to 11 years with moderate-to-severe asthma.
- A supplemental Biologics License Application (sBLA) for Dupixent for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis was submitted. A regulatory submission is also expected to be completed in the EU in the coming months.

- In January 2022, the Company and Sanofi announced positive results from a second Phase 3 trial in adults with uncontrolled prurigo nodularis. The trial met its primary and key secondary endpoints, showing that Dupixent significantly reduced itch and skin lesions compared to placebo at 24 weeks. Regulatory submissions are expected to commence in the first half of 2022.

Antibodies to SARS-CoV-2 virus

- In the fourth quarter of 2021, the Company completed its final deliveries of drug product under its agreement with the U.S. government, delivering an additional 1.1 million doses of REGEN-COV®, and recognizing $2.30 billion of REGEN-COV sales.
- In November 2021, the European Commission approved the casirivimab and imdevimab(2) antibody cocktail for people aged 12 years and older for the treatment of non-hospitalized patients with confirmed COVID-19 who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID-19, and to prevent COVID-19.
- In November 2021, the Company announced additional positive results from a Phase 3 COVID-19 prevention trial jointly run with the National Institute of Allergy and Infectious Diseases (NIAID), showing that a single dose of REGEN-COV reduced the risk of contracting COVID-19 by 81.6% during the pre-specified follow-up period (months 2–8), maintaining the previously reported 81.4% risk reduction during the first month after administration (the primary endpoint).
- Based on laboratory data that showed markedly decreased binding to the Omicron spike protein, REGEN-COV is highly unlikely to be active against the Omicron variant. In January 2022, the FDA revised the Emergency Use Authorization (EUA) for REGEN-COV to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as Omicron (B.1.1.529) that is not susceptible to the treatment. With this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions, since Omicron is currently the dominant variant across the United States. If, in the future, patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to REGEN-COV, then the limitation on use may be revised in these areas.
- The Company continues to progress "next generation" antibodies that are active against Omicron, Delta (B.1.617.2), and other variants of concern. Pending regulatory discussions, new therapeutic candidates could enter clinical development in the coming months.

Oncology Programs

- The FDA accepted the sBLA for Libtayo® (cemiplimab), in combination with chemotherapy, to treat patients with advanced non-small cell lung cancer (NSCLC), with a target action date of September 19, 2022. A regulatory application was also submitted in the EU.
- In January 2022, the Company and Sanofi announced the voluntary withdrawal of the sBLA for Libtayo as a second-line treatment for patients with advanced cervical cancer. The decision was made after the companies and the FDA were not able to align on certain post-marketing studies. Discussions with regulatory authorities outside of the United States are ongoing.
- In December 2021, the Company announced results for higher dose level cohorts from the Phase 1 portion of the REGN5458 Phase 1/2 trial in patients with multiple myeloma, which were presented at the American Society of Hematology (ASH) Annual Meeting. The results showed a 75% overall response rate in patients treated with the highest dose levels studied. REGN5458 is a bispecific antibody targeting BCMA and CD3. The Company expects to complete enrollment in a potentially pivotal Phase 2 trial in multiple myeloma in the first quarter of 2022.
- The Company has additional CD3 bispecifics in clinical development, including a Phase 1 study of REGN4336, a bispecific antibody targeting PSMA and CD3, which was recently initiated in prostate cancer.
- The Company has ongoing clinical development for three costimulatory CD28 bispecifics targeting prostate cancer, ovarian cancer, and other solid tumors.
- In NSCLC, the Company is in dose expansion for REGN5093, which is a METxMET bispecific targeting cancers driven by MET mutations and/or amplifications. The Company is also studying REGN5093-M114, its first bispecific antibody-drug conjugate, in MET-altered advanced NSCLC.

Pozelimab

- A Phase 3 study of pozelimab, an antibody to C5, in combination with Alnylam's cemdisiran, an siRNA therapeutic, in paroxysmal nocturnal hemoglobinuria (PNH) was initiated.

Business Development Update

- In January 2022, the Company entered into a license and collaboration agreement for Ultragenyx Pharmaceutical Inc. to develop and commercialize Evkeeza® in countries outside of the United States.

Select 2022 Milestones

Programs	Milestones
Aflibercept 8 mg	- Report results from Phase 3 studies in neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME)
Dupixent (dupilumab)	- Complete rolling sBLA submission for eosinophilic esophagitis (EoE) in adults and adolescents - Report results from additional Phase 3 study for chronic spontaneous urticaria (CSU) - FDA decision on sBLA for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis
Antibodies to SARS-CoV-2 virus	- FDA decision on BLA (target action date of April 13, 2022) for COVID-19 treatment of non-hospitalized patients and prevention - Submit sBLA for COVID-19 treatment of hospitalized patients - Initiate "next generation" monoclonal antibody clinical study
Libtayo (cemiplimab)	- FDA decision on sBLA (target action date of September 19, 2022) and EC decision on regulatory submission for NSCLC, chemotherapy combination
REGN5458 (BCMA and CD3 Bispecific Antibody)	- Report results from potentially pivotal Phase 2 study in multiple myeloma - Initiate Phase 1 and Phase 3 studies exploring combinations with standard of care and additional combination studies
Odronextamab (CD20 and CD3 Bispecific Antibody)	- Report additional results from potentially pivotal Phase 2 study in B-cell non-Hodgkin lymphoma (B-NHL) - Initiate OLYMPIA Phase 3 program and additional combination studies
Solid Tumor Bispecific Antibodies	- Report results from REGN4018 (MUC16 and CD3 bispecific antibody) Phase 1 study in platinum-resistant ovarian cancer - Report results from REGN5678 (PSMA and CD28 bispecific antibody) Phase 1 study in prostate cancer - Report results from REGN5093 (bispecific antibody targeting two distinct MET epitopes) Phase 1 study in MET-altered advanced NSCLC

Fourth Quarter and Full Year 2021 Financial Results

Revenues

Total revenues increased by 104% to $4.952 billion in the fourth quarter of 2021, compared to $2.423 billion in the fourth quarter of 2020. Full year 2021 total revenues increased 89% to $16.072 billion, compared to $8.497 billion for the full year 2020. Total revenues excluding (i) REGEN-COV (casirivimab and imdevimab) net product sales in the United States and (ii) true-up payments recorded to collaboration revenue in connection with global gross profits from sales of the casirivimab and imdevimab antibody cocktail pursuant to the Roche collaboration agreement, increased by 17% to $2.654 billion in the fourth quarter of 2021, compared to the fourth quarter of 2020, and increased by 19% to $9.882 billion for the full year 2021, compared to the full year 2020(1).

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

($ in millions)	Q4 2021	Q4 2020	% Change	FY 2021	FY 2020	% Change
EYLEA®	$ 1,547	$ 1,343	15%	$ 5,792	$ 4,947	17%
Libtayo	81	74	9%	306	271	13%
Praluent®	40	55	(27%)	170	151	13%
REGEN-COV	2,298	146	**	5,828	186	**
Evkeeza	9	—	**	19	—	**
ARCALYST®	— *	4	**	2 *	13	**
Total net product sales in the U.S.	$ 3,975	$ 1,622	145%	$ 12,117	$ 5,568	118%

* 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 fourth quarter of 2021, the Company completed its final deliveries of REGEN-COV under its agreement with the U.S. government.

Total revenues also include collaboration revenues(3) of $890 million in the fourth quarter and $3.673 billion for the full year 2021, compared to $678 million in the fourth quarter and $2.373 billion for the full year 2020. Sanofi collaboration revenue increased primarily due to the Company's share of profits from commercialization of antibodies, which were $388 million and $1.363 billion in the fourth quarter and full year 2021, respectively, compared to $230 million and $785 million in the fourth quarter and full year 2020, respectively. The change in the Company's share of profits from commercialization of antibodies was driven by higher Dupixent profits. The Company also recorded Roche collaboration revenue of $362 million for the full year 2021 in connection with the true-up payment from Roche attributable to global gross profits from sales of the casirivimab and imdevimab antibody cocktail. No Roche collaboration revenue was recorded during the fourth quarter of 2021, as the Company owed a true-up payment to Roche in connection with global gross profits from sales of the antibody cocktail, which was recorded to Cost of goods sold.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue decreased in the fourth quarter and full year of 2021, compared to the same periods of 2020, primarily due to lower amounts

recognized in connection with the Company's agreement with the Biomedical Advanced Research Development Authority (BARDA) related to funding of certain development activities for COVID-19 antibodies.

Operating Expenses

	GAAP		%	Non-GAAP[(1)]		%
($ in millions)	Q4 2021	Q4 2020	Change	Q4 2021	Q4 2020	Change
Research and development (R&D)	$ 786	$ 745	6%	$ 639	$ 675	(5%)
Selling, general, and administrative (SG&A)	$ 560	$ 304	84%	$ 495	$ 381	30%
Cost of goods sold (COGS)	$ 812	$ 180	351%	$ 559	$ 166	237%
Cost of collaboration and contract manufacturing (COCM)	$ 171	$ 174	(2%)	*	*	n/a
Other operating (income) expense, net	$ (16)	$ (145)	(89%)	*	*	n/a

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

	GAAP		%	Non-GAAP[(1)]		%
($ in millions)	FY 2021	FY 2020	Change	FY 2021	FY 2020	Change
Research and development	$ 2,908	$ 2,735	6%	$ 2,548	$ 2,411	6%
Selling, general, and administrative	$ 1,825	$ 1,346	36%	$ 1,606	$ 1,280	25%
Cost of goods sold	$ 1,773	$ 492	260%	$ 1,470	$ 451	226%
Cost of collaboration and contract manufacturing	$ 664	$ 628	6%	*	*	n/a
Other operating (income) expense, net	$ (46)	$ (280)	(84%)	*	*	n/a

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

- GAAP and non-GAAP R&D expenses in the fourth quarter of 2021, compared to the fourth quarter of 2020, included lower costs incurred in connection with REGEN-COV development activities, 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. Non-GAAP R&D expenses in the fourth quarter of 2021 excluded $44 million of aggregate up-front payments, primarily in connection with the collaboration agreement with Nykode Therapeutics.
- GAAP and non-GAAP R&D expenses for full year 2021, compared to full year 2020, included higher headcount and headcount related costs, an increase in facilities-related expenses, and lower costs incurred in connection with development activities for fasinumab and Kevzara (for the treatment of COVID-19). Non-GAAP R&D expenses for full year 2020 excluded $85 million of up-front payments in connection with the Intellia collaboration agreement.
- The increase in GAAP and non-GAAP SG&A expenses in the fourth quarter and full year 2021, compared to the same periods in the prior year, was primarily due to an increase in commercialization-related expenses for EYLEA, including direct-to-consumer advertising, educational campaigns related to COVID-19, and higher headcount-related costs. Non-GAAP SG&A expenses in the fourth quarter and full year 2020 excluded the reversal of accruals for Praluent litigation-related loss contingencies.
- The increase in GAAP and non-GAAP COGS in the fourth quarter and full year 2021, compared to the same periods in the prior year, was primarily due to the recognition of manufacturing costs in connection with product sales of REGEN-COV in the United States, in addition to a $260 million fourth quarter 2021 true-up payment owed to Roche in connection with global gross profits under the Company's collaboration agreement described above. Additionally, during the fourth quarter of 2021, the Company recorded a $232 million charge to write down its REGEN-COV inventory as a result of data that showed REGEN-COV was highly unlikely to be active against the Omicron variant and the FDA revision of the EUA for REGEN-COV, pursuant to which REGEN-COV was no longer authorized for use in any U.S. states, territories, or jurisdictions.
- Other operating (income) expense, net, for full year 2021 included the recognition of a cumulative catch-up adjustment of $67 million, which was recorded as a reduction to other operating income, 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 operating (income) expense, net, in the fourth quarter and full year 2020 included the recognition of cumulative catch-up adjustments of $100 million, which was recorded as an increase to other operating income, arising from an update to the estimate of total R&D costs expected to be incurred for certain collaboration programs.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $138 million in the fourth quarter of 2021, compared to $62 million of net unrealized gains in the fourth quarter of 2020. GAAP other income (expense) included the recognition of net unrealized gains on equity securities of $386 million for full year 2021, compared to $196 million for full year 2020.

In the fourth quarter and full year 2021, the Company's GAAP effective tax rate was 11.0% and 13.4%, respectively, compared to 6.2% and 7.8% in the fourth quarter and full year 2020, respectively. The increase in the fourth quarter and full year 2021 GAAP effective tax rate, compared to the same periods in the prior year, was due in part to the impact of higher REGEN-COV sales in the United States. In the fourth quarter and full year 2021, the non-GAAP effective tax rate was 12.7% and 13.6%, respectively, compared to 7.7% and 9.1% in the fourth quarter and full year 2020, respectively.

GAAP net income per diluted share was $19.69 in the fourth quarter of 2021, compared to $10.24 in the fourth quarter of 2020. GAAP net income per diluted share was $71.97 for the full year 2021, compared to $30.52 for full year 2020. Non-GAAP net income per diluted share was $23.72 in the fourth quarter of 2021, compared to $9.53 in the fourth quarter of 2020. Non-GAAP net income per diluted share was $74.66 for the full year 2021, compared to $31.47 for the full year 2020. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

In November 2021, the Company's board of directors authorized a new share repurchase program to repurchase up to $3.0 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 for the full year 2021 was $7.081 billion, compared to $2.618 billion for the full year 2020, resulting in $6.529 billion in free cash flow for the full year 2021, compared to $2.004 billion for the full year 2020. The increase in free cash flow for the full year 2021 was primarily due to the Company's collection of amounts due from the U.S. government in connection with REGEN-COV sales.

2022 Financial Guidance[(4)]

The Company's full year 2022 financial guidance consists of the following components:

	GAAP	Non-GAAP[(1)]
R&D	$3.170 billion–$3.400 billion	$2.800 billion–$3.000 billion
SG&A	$1.890 billion–$2.030 billion	$1.650 billion–$1.770 billion
Gross margin on net product sales[(5)]	89%–91%	90%–92%
COCM[(6)]	$750 million–$830 million	*
Other operating (income) expense, net	($60) million–($80) million	*
Capital expenditures	$650 million–$730 million	*
Effective tax rate (ETR)	12%–14%	13%–15%

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

A reconciliation of full year 2022 GAAP to Non-GAAP financial guidance is included below:

	Projected Range	
($ in millions)	Low	High
GAAP R&D	$ 3,170	$ 3,400
R&D: Non-cash share-based compensation expense	(370)	(400)
Non-GAAP R&D	$ 2,800	$ 3,000
GAAP SG&A	$ 1,890	$ 2,030
SG&A: Non-cash share-based compensation expense	(240)	(260)
Non-GAAP SG&A	$ 1,650	$ 1,770
GAAP gross margin on net product sales	89%	91%
Non-cash share-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	90%	92%
GAAP ETR	12%	14%
Income tax effect of GAAP to non-GAAP reconciling items and other	1%	1%
Non-GAAP ETR	13%	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 (casirivimab and imdevimab), 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. A reconciliation of the Company's historical GAAP to non-GAAP results is included in Table 3 of this press release.

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.

(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. These estimates are revised, if necessary, in subsequent periods if the Company's actual share of the profits or losses differ from those estimates.

(4) The Company's 2022 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 fourth quarter and full year 2021 financial and operating results on Friday, February 4, 2022, 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/8706689. 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), aflibercept 8 mg, pozelimab, odronextamab, itepekimab, REGN5458, REGN5713-5714-5715, REGN1908-1909, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; the likelihood and timing of achieving any of the anticipated milestones described in this press release; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for

Regeneron's Products, including those listed above and/or otherwise discussed in this press release; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance, including GAAP and non-GAAP R&D, GAAP and non-GAAP SG&A, GAAP and non-GAAP gross margin on net product sales, COCM, other operating (income) expense, net, capital expenditures, and GAAP and non-GAAP effective tax rate; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's agreement with Roche relating to the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve™ in other countries), to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA, Dupixent, Praluent, and REGEN-COV), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil litigation initiated by the U.S. Attorney's Office for the District of Massachusetts), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission. 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.

Contact Information:

Mark Hudson	Christina Chan
Investor Relations	Corporate Communications
914-847-3482	914-847-8827
mark.hudson@regeneron.com	christina.chan@regeneron.com

TABLE 1

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

	December 31, 2021	December 31, 2020
Assets:		
Cash and marketable securities	$ 12,532.7	$ 6,722.6
Accounts receivable, net	6,036.5	4,114.7
Inventories	1,951.3	1,916.6
Property, plant, and equipment, net	3,482.2	3,221.6
Deferred tax assets	876.9	858.9
Other assets	555.2	328.9
Total assets	$ 25,434.8	$ 17,163.3
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,451.0	$ 2,806.8
Finance lease liabilities	719.7	717.2

Deferred revenue	515.3	635.5
Long-term debt	1,980.0	1,978.5
Stockholders' equity	18,768.8	11,025.3
Total liabilities and stockholders' equity	$ 25,434.8	$ 17,163.3

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,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Net product sales	$ 3,975.2	$ 1,621.8	$ 12,117.2	$ 5,567.6
Collaboration revenue	890.3	677.7	3,673.3	2,372.5
Other revenue	86.2	123.4	281.2	557.0
	4,951.7	2,422.9	16,071.7	8,497.1
Expenses:				
Research and development	785.6	744.5	2,908.1	2,735.0
Selling, general, and administrative	559.6	303.5	1,824.9	1,346.0
Cost of goods sold	811.7	179.6	1,773.1	491.9
Cost of collaboration and contract manufacturing	170.9	173.5	664.4	628.0
Other operating (income) expense, net	(15.8)	(145.2)	(45.6)	(280.4)
	2,312.0	1,255.9	7,124.9	4,920.5
Income from operations	2,639.7	1,167.0	8,946.8	3,576.6
Other income (expense):				
Other (expense) income, net	(122.2)	72.4	436.3	290.7
Interest expense	(14.1)	(14.8)	(57.3)	(56.9)
	(136.3)	57.6	379.0	233.8
Income before income taxes	2,503.4	1,224.6	9,325.8	3,810.4
Income tax expense	274.4	75.4	1,250.5	297.2
Net income	$ 2,229.0	$ 1,149.2	$ 8,075.3	$ 3,513.2
Net income per share - basic	$ 20.99	$ 10.90	$ 76.40	$ 32.65
Net income per share - diluted	$ 19.69	$ 10.24	$ 71.97	$ 30.52
Weighted average shares outstanding - basic	106.2	105.4	105.7	107.6
Weighted average shares outstanding - diluted	113.2	112.2	112.2	115.1

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,	
	2021	**2020**	**2021**	**2020**
GAAP R&D	$ 785.6	$ 744.5	$ 2,908.1	$ 2,735.0
R&D: Non-cash share-based compensation expense	102.9	69.1	316.6	238.6
R&D: Up-front payments related to license and collaboration agreements	44.0	—	44.0	85.0
Non-GAAP R&D	$ 638.7	$ 675.4	$ 2,547.5	$ 2,411.4
GAAP SG&A	$ 559.6	$ 303.5	$ 1,824.9	$ 1,346.0
SG&A: Non-cash share-based compensation expense	64.2	38.6	213.3	153.0
SG&A: Litigation contingencies and other	—	(115.8)	5.6	(86.9)
Non-GAAP SG&A	$ 495.4	$ 380.7	$ 1,606.0	$ 1,279.9
GAAP COGS	$ 811.7	$ 179.6	$ 1,773.1	$ 491.9

COGS: Non-cash share-based compensation expense	21.3	13.8	71.8	40.4
COGS: REGEN-COV inventory reserve	231.7	—	231.7	—
COGS: Other	—	—	—	0.9
Non-GAAP COGS	$ 558.7	$ 165.8	$ 1,469.6	$ 450.6
GAAP other income (expense), net	$ (136.3)	$ 57.6	$ 379.0	$ 233.8
Other income/expense: Losses (gains) on investments	137.6	(59.5)	(387.0)	(221.6)
Interest expense: Other	—	—	—	12.7
Non-GAAP other income (expense), net	$ 1.3	$ (1.9)	$ (8.0)	$ 24.9
GAAP net income	$ 2,229.0	$ 1,149.2	$ 8,075.3	$ 3,513.2
Total of GAAP to non-GAAP reconciling items above	601.7	(53.8)	496.0	222.1
Income tax effect of GAAP to non-GAAP reconciling items	(119.2)	14.8	(82.9)	(38.9)
Income tax expense: Impact of sale of assets between foreign subsidiaries	—	(30.0)	—	(30.0)
Non-GAAP net income	$ 2,711.5	$ 1,080.2	$ 8,488.4	$ 3,666.4
Non-GAAP net income per share - basic	$ 25.53	$ 10.25	$ 80.31	$ 34.07
Non-GAAP net income per share - diluted	$ 23.72	$ 9.53	$ 74.66	$ 31.47
Shares used in calculating:				
Non-GAAP net income per share - basic	106.2	105.4	105.7	107.6
Non-GAAP net income per share - diluted	114.3	113.4	113.7	116.5

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION (Unaudited) *(continued)*

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue reconciliation:				
Total revenues	$ 4,951.7	$ 2,422.9	$ 16,071.7	$ 8,497.1
REGEN-COV net product sales in the United States	2,297.9	145.5	5,828.0	185.7
Global gross profit true-up payment from Roche in connection with sales of casirivimab and imdevimab	—	—	361.8	—
Total revenues excluding REGEN-COV (casirivimab and imdevimab)	$ 2,653.8	$ 2,277.4	$ 9,881.9	$ 8,311.4
Effective tax rate reconciliation:				
GAAP effective tax rate	11.0 %	6.2%	13.4%	7.8%
Income tax effect of GAAP to non-GAAP reconciling items	1.7%	1.5%	0.2%	1.3%
Non-GAAP effective tax rate	12.7%	7.7%	13.6%	9.1%

	Year Ended December 31,	
	2021	**2020**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 7,081.3	$ 2,618.1
Capital expenditures	(551.9)	(614.6)
Free cash flow	$ 6,529.4	$ 2,003.5

TABLE 4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 387.8	$ 229.6	$ 1,363.0	$ 785.2
Sales-based milestones earned	—	—	50.0	50.0
Reimbursement for manufacturing of commercial supplies	127.6	93.0	488.8	368.0
Immuno-oncology:				

Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(1.0)	(8.4)	(13.6)	(25.7)
Reimbursement for manufacturing of commercial supplies	3.5	2.9	14.0	8.9
Total Sanofi collaboration revenue	517.9	317.1	1,902.2	1,186.4
Bayer collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	353.9	335.3	1,349.2	1,107.9
Reimbursement for manufacturing of commercial supplies	18.5	25.3	60.1	78.2
Total Bayer collaboration revenue	372.4	360.6	1,409.3	1,186.1
Roche collaboration revenue:				
Global gross profit true-up payment from Roche in connection with sales of casirivimab and imdevimab	—	—	361.8	—
Total collaboration revenue	$ 890.3	$ 677.7	$ 3,673.3	$ 2,372.5

TABLE 5

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

Three Months Ended December 31,

	2021			2020			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,547.2	$ 933.5	$ 2,480.7	$ 1,343.2	$ 858.8	$ 2,202.0	13%
Dupixent[b]	$ 1,348.2	$ 425.6	$ 1,773.8	$ 925.6	$ 246.4	$ 1,172.0	51%
Libtayo[c]	$ 80.8	$ 40.2	$ 121.0	$ 74.1	$ 23.2	$ 97.3	24%
Praluent[d]	$ 40.0	$ 62.6	$ 102.6	$ 55.2	$ 45.7	$ 100.9	2%
REGEN-COV[e]	$ 2,297.9	$ 572.7	$ 2,870.6	$ 145.5	—	$ 145.5	(h)
Kevzara[b]	$ 42.0	$ 61.9	$ 103.9	$ 36.6	$ 34.9	$ 71.5	45%
Evkeeza[f]	$ 9.3	—	$ 9.3	—	—	—	(h)
ARCALYST[g]	$ 18.7	—	$ 18.7	$ 3.8	—	$ 3.8	392%
ZALTRAP[b]	$ 1.4	$ 20.3	$ 21.7	$ 0.9	$ 23.9	$ 24.8	(13%)

Year Ended December 31,

	2021			2020			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 5,792.3	$ 3,592.4	$ 9,384.7	$ 4,947.2	$ 2,961.5	$ 7,908.7	19%
Dupixent[b]	$ 4,713.0	$ 1,485.3	$ 6,198.3	$ 3,226.2	$ 818.6	$ 4,044.8	53%
Libtayo[c]	$ 306.3	$ 151.9	$ 458.2	$ 270.7	$ 77.5	$ 348.2	32%
Praluent[d]	$ 170.0	$ 251.1	$ 421.1	$ 186.0	$ 172.8	$ 358.8	17%
REGEN-COV[e]	$ 5,828.0	$ 1,745.9	$ 7,573.9	$ 185.7	—	$ 185.7	(h)
Kevzara[b]	$ 161.9	$ 176.1	$ 338.0	$ 141.6	$ 128.3	$ 269.9	25%
Evkeeza[f]	$ 18.4	—	$ 18.4	—	—	—	(h)
ARCALYST[g]	$ 40.7	—	$ 40.7	$ 13.1	—	$ 13.1	211%
ZALTRAP[b]	$ 5.3	$ 86.4	$ 91.7	$ 5.8	$ 97.9	$ 103.7	(12%)

[a] Regeneron records net product sales of EYLEA in the United States. Bayer records net product sales of EYLEA outside the United States. The Company records its share of profits/losses in connection with sales of EYLEA outside the United States.

[b] Sanofi records global net product sales of Dupixent, Kevzara, and ZALTRAP. The Company records its share of profits/losses in connection with global sales of Dupixent and Kevzara, and Sanofi pays the Company a percentage of net sales of ZALTRAP.

[c] Regeneron records net product sales of Libtayo in the United States and Sanofi records net product sales of Libtayo outside the United States. The parties equally share profits/losses in connection with global sales of Libtayo.

[d] Effective April 1, 2020, Regeneron records net product sales of Praluent in the United States. Also effective April 1, 2020, Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales. Previously, Sanofi recorded global net product sales of Praluent and the Company recorded its share of profits/losses in connection with such sales.

(e) Regeneron records net product sales of REGEN-COV in connection with its agreements with the U.S. government. Roche records net product sales of the antibody cocktail outside the United States and the parties share gross profits from global sales based on a pre-specified formula, depending on the amount of manufactured product supplied by each party to the market.

(f) Regeneron records net product sales of Evkeeza in the United States. Pursuant to a January 2022 agreement, Ultragenyx will record net product sales of Evkeeza outside of the United States and will pay the Company a percentage of such sales.

(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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