Regeneron Reports Fourth Quarter and Full Year 2022 Financial and Operating Results

February 3, 2023

- *Fourth quarter 2022 revenues decreased 31% to $3.41 billion versus fourth quarter 2021; excluding REGEN-COV® and Ronapreve™[(a)(b)], revenues increased 14%*
- *Full year 2022 revenues decreased 24% to $12.17 billion versus full year 2021; excluding REGEN-COV and Ronapreve[(a)(b)], revenues increased 17%*
- *Fourth quarter 2022 EYLEA® U.S. net sales decreased 3% to $1.50 billion versus fourth quarter 2021; full year 2022 EYLEA U.S. net sales increased 8% to $6.26 billion versus 2021*
- *Fourth quarter 2022 Dupixent® global net sales (recorded by Sanofi) increased 38% to $2.45 billion versus fourth quarter 2021; full year 2022 Dupixent global net sales increased 40% to $8.68 billion versus 2021*
- *Fourth quarter 2022 GAAP diluted EPS of $10.50 and non-GAAP diluted EPS[(a)] of $12.56; includes unfavorable $0.21 impact from acquired IPR&D charge*
- *Aflibercept 8 mg BLA for neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME) submitted to FDA in December 2022*
- *FDA approved Libtayo® in combination with chemotherapy as first-line treatment for advanced non-small cell lung cancer (NSCLC)*
- *European Commission approved Dupixent for adults with prurigo nodularis and adults and adolescents with eosinophilic esophagitis (EoE*)
- *Allocated $3.4 billion to business development and share repurchases in 2022; new $3.0 billion share repurchase program authorized in January 2023*

TARRYTOWN, N.Y., Feb. 03, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2022 and provided a business update.

"In 2022, Regeneron reported record revenue for EYLEA, Dupixent and Libtayo and made exciting progress across the entire pipeline," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In the fourth quarter of 2022, we submitted our Biologics License Application for neovascular age-related macular degeneration and diabetic macular edema for aflibercept 8 mg, which could potentially reach patients in the third quarter of 2023. We also continued to expand the use of our commercial products with the U.S. FDA approval of Libtayo in combination with chemotherapy for non-small cell lung cancer and the European Commission approval of Dupixent for prurigo nodularis. In 2023, we remain committed to achieving the full potential of our diverse commercial- and clinical-stage portfolio, with a particular focus on aflibercept 8 mg, Dupixent in a variety of type 2 allergic diseases, and our promising oncology and hematology assets."

Financial Highlights

	Three Months Ended December 31,			Year Ended December 31,		
($ in millions, except per share data)	**2022**	**2021**	**% Change**	**2022**	**2021**	**% Change**
Total revenues	$ 3,414	$ 4,952	(31%)	$ 12,173	$ 16,072	(24%)
Total revenues excluding REGEN-COV and Ronapreve[(a)(b)]	$ 3,018	$ 2,654	14%	$ 11,546	$ 9,882	17%
GAAP net income	$ 1,197	$ 2,229	(46%)	$ 4,338	$ 8,075	(46%)
GAAP net income per share - diluted	$ 10.50	$ 19.69	(47%)	$ 38.22	$ 71.97	(47%)
Non-GAAP net income[(a)]	$ 1,449	$ 2,677	(46%)	$ 5,164	$ 8,454	(39%)
Non-GAAP net income per share - diluted[(a)]	$ 12.56	$ 23.42	(46%)	$ 44.98	$ 74.35	(40%)

"We were pleased with our fourth-quarter and full-year 2022 financial performance, highlighted by revenue growth of 14% and 17%, respectively, when excluding contributions from REGEN-COV and Ronapreve, demonstrating the commercial strength and increasing diversity of our business," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "In January 2023, our Board of Directors authorized a new $3.0 billion share repurchase program, enabling us to continue returning capital directly to shareholders. This year, we look forward to driving long-term shareholder value through continued investment in R&D, excellent commercial execution and strategic business development."

Business Highlights

Key Pipeline Progress
Regeneron has approximately 35 product candidates in clinical development, including a number of marketed products for which it is investigating additional indications. Updates from the clinical pipeline include:

Aflibercept 8 mg

- A Biologics License Application (BLA) for the treatment of wet AMD and DME was submitted to the U.S. Food and Drug Administration (FDA) in December 2022. The Company is utilizing a priority review voucher in connection with the submission.

EYLEA (aflibercept) Injection

- In December 2022, the European Commission (EC) approved EYLEA for the treatment of retinopathy of prematurity (ROP) in preterm infants. The supplemental BLA (sBLA) for EYLEA to treat ROP in preterm infants is currently under review by the FDA, with a target action date of February 11, 2023.

Dupixent (dupilumab)

- In December 2022, the EC approved Dupixent for the treatment of adult patients with moderate-to-severe prurigo nodularis who are candidates for systemic therapy, making Dupixent the first and only targeted medicine specifically indicated to treat prurigo nodularis in Europe.
- In January 2023, the EC also approved Dupixent for the treatment of adults and adolescents with EoE, making Dupixent the first and only targeted medicine specifically indicated to treat EoE in Europe.
- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Dupixent to treat children aged 6 months to 5 years with severe atopic dermatitis. The EC decision is expected in the coming months.
- An sBLA for the treatment of adult and adolescent patients with chronic spontaneous urticaria (CSU) was submitted.

Oncology Programs
Libtayo (cemiplimab)

- In November 2022, the FDA approved Libtayo in combination with platinum-based chemotherapy for the first-line treatment of adult patients with advanced NSCLC.
- In November 2022, the EC approved Libtayo as a monotherapy for the treatment of adult patients with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy. In December 2022, the Ministry of Health, Labour and Welfare (MHLW) in Japan also approved Libtayo in advanced or recurrent cervical cancer.

Fianlimab, an antibody to LAG-3

- A Phase 3 study in first-line adjuvant melanoma was initiated.

Linvoseltamab, a bispecific antibody targeting BCMA and CD3

- The Company announced positive initial data from a pivotal Phase 2 expansion cohort evaluating linvoseltamab at the 200 mg dose in patients with heavily pre-treated, relapsed/refractory multiple myeloma. The results were presented at the American Society of Hematology (ASH) Annual Meeting and Exposition.

Odronextamab, a bispecific antibody targeting CD20 and CD3

- Positive data were also presented at ASH from two cohorts of a pivotal Phase 2 trial studying odronextamab in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL).

Other Programs

- A BLA for pozelimab, an antibody to C5, for the treatment of CD55-deficient protein-losing enteropathy (CHAPLE) was submitted.
- The FDA accepted for priority review the sBLA for Kevzara® (sarilumab) to treat polymyalgia rheumatica (PMR), with a target action date of February 28, 2023.
- The FDA accepted for priority review the sBLA for Evkeeza® (evinacumab) as an adjunct to other lipid-lowering therapies to treat children aged 5 to 11 years with homozygous familial hypercholesterolemia (HoFH), with a target action date of March 30, 2023.

Corporate and Business Development Updates

- In November 2022, the Company and CytomX Therapeutics, Inc. entered into a license and collaboration agreement to create conditionally-activated investigational bispecific cancer therapies utilizing CytomX's Probody® therapeutic platform and Regeneron's *Veloci-Bi*® bispecific antibody development platform. Under the terms of the agreement, the Company made an upfront payment of $30 million and will be responsible for funding development and commercial activities, and CytomX will be eligible to receive future target nomination payments and preclinical, clinical, and commercial milestone

payments as well as royalties on global net sales.

- The Company was included on the Dow Jones Sustainability World Index (DJSI World) for the fourth consecutive year and on the Dow Jones Sustainability North America Index (DJSI North America) for the third year.

Select 2023 Milestones

Programs	Milestones
Aflibercept 8 mg	- FDA decision on BLA for wet AMD and DME (third quarter 2023) - Report two-year data from PULSAR (wet AMD) and PHOTON (DME) Phase 3 studies (third quarter 2023)
EYLEA (aflibercept)	- FDA decision on sBLA for ROP (target action date of February 11, 2023)
Dupixent (dupilumab)	- EC decision on regulatory submission for atopic dermatitis in pediatrics (6 months–5 years of age) (first half 2023) - Submit sBLA for EoE in pediatrics (mid-2023) - FDA decision on sBLA for CSU in adults and adolescents (second half 2023) - Report results from first Phase 3 study in COPD and Phase 3 study in chronic inducible urticaria - cold (first half 2023)
Solid Organ Oncology	- Initiate Phase 3 study for fianlimab (in combination with Libtayo) in perioperative melanoma (mid-2023) - Initiate Phase 2/3 studies for fianlimab (in combination with Libtayo) in first-line advanced NSCLC (first half 2023) and Phase 2 study in perioperative NSCLC (second half 2023) - Report additional results from Phase 1/2 study of REGN5678 (PSMA and CD28 bispecific antibody) in combination with Libtayo in prostate cancer (2023) - Report initial data across solid organ oncology, including for CD3 bispecifics and CD28 costimulatory bispecifics (2023) - EC decision on regulatory submission for Libtayo (in combination with chemotherapy) in advanced NSCLC (first half 2023)
Odronextamab (CD20 and CD3 Bispecific Antibody)	- Initiate Phase 3 studies in FL and DLBCL, including earlier lines of therapy (first half 2023) - Submit BLA for relapsed/refractory FL and DLBCL (second half 2023)
Linvoseltamab (BCMA and CD3 Bispecific Antibody)	- Initiate Phase 3 study in multiple myeloma, including earlier lines of therapy (first half 2023) - Submit BLA for relapsed/refractory multiple myeloma (second half 2023)
Pozelimab (C5 Antibody)	- FDA decision on BLA for CHAPLE (second half 2023)

Fourth Quarter 2022 Financial Results

Revenues

($ in millions)	Q4 2022	Q4 2021	% Change	FY 2022	FY 2021	% Change
Net product sales:						
EYLEA - U.S.	$ 1,496	$ 1,547	(3%)	$ 6,265	$ 5,792	8%
Libtayo - U.S.	110	81	36%	375	306	23%
Libtayo - ROW**	42	—	*	73	—	*
Praluent® - U.S.	36	40	(10%)	130	170	(24%)
REGEN-COV - U.S.	—	2,298	(100%)	—	5,828	(100%)
Evkeeza - U.S.	15	9	67%	48	19	153%
Inmazeb® - U.S.	—	—	— %	3	—	*
ARCALYST® - U.S.***	—	—	*	—	2	*
Total net product sales	1,699	3,975	(57%)	6,894	12,117	(43%)
Collaboration revenue:						
Sanofi	836	518	61%	2,856	1,902	50%
Bayer	355	372	(5%)	1,431	1,409	2%
Roche	396	—	*	627	362	73%
Other revenue	128	87	47%	365	282	29%
Total revenues	$ 3,414	$ 4,952	(31%)	$ 12,173	$ 16,072	(24%)
Total revenues excluding REGEN-COV and Ronapreve[a]	$ 3,018	$ 2,654	14%	$ 11,546	$ 9,882	17%

* Percentage not meaningful.

** Rest of world (ROW). Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States. Excluded from this line item is approximately $17 million and $34 million of net product sales recorded by Sanofi in the fourth quarter and second half of 2022, respectively, in connection with sales in certain markets (Sanofi will record net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 is sold through to the end customers).

*** 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.

Net product sales of EYLEA in the U.S. in the fourth quarter of 2022 were negatively impacted by (i) a short-term shift to off-label use of compounded bevacizumab, (ii) a temporary closing in the fourth quarter of 2022 of a not-for-profit fund that provides patient co-pay assistance, and (iii) an increase in sales-related deductions. Volumes of U.S. EYLEA in the fourth quarter of 2022 increased compared to the fourth quarter of 2021.

There were no sales of REGEN-COV in the U.S. during 2022 as the Company had completed its final deliveries of drug product under its agreements with the U.S. government as of December 31, 2021.

Sanofi collaboration revenue increased 61% to $836 million in the fourth quarter of 2022, compared to the fourth quarter of 2021, and increased 50% to $2.856 billion for the full year 2022, compared to the full year 2021. This increase was primarily due to the Company's share of profits from commercialization of antibodies, which were $619 million and $388 million in the fourth quarter of 2022 and 2021, respectively, and $2.082 billion and $1.363 billion for full year 2022 and 2021, respectively. The change in the Company's share of profits from commercialization of antibodies was driven by profits associated with higher Dupixent sales. In addition, during 2022 the Company earned two $50 million sales-based milestones (including one in the fourth quarter of 2022) from Sanofi based upon sales of antibodies outside the U.S. on a rolling twelve-month basis, compared to earning one $50 million sales-based milestone in 2021 (in the third quarter of 2021).

Sanofi and Bayer collaboration revenue (and specifically, the share of profits the Company earned in connection with commercialization of products) was adversely impacted in 2022 by the U.S. dollar strengthening against foreign currencies, including the Japanese yen and the euro.

The Company recorded Roche collaboration revenue during full year 2022 and 2021 in connection with payments from Roche attributable to global gross profits from sales of Ronapreve. Roche collaboration revenue increased in the fourth quarter of 2022, compared to the fourth quarter of 2021, as no Roche collaboration revenue was recorded during the fourth quarter of 2021 since the Company owed a payment to Roche (which was recorded to Cost of goods sold) in connection with global gross profits of REGEN-COV and Ronapreve.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

($ in millions)	GAAP Q4 2022	GAAP Q4 2021	% Change	Non-GAAP[(a)] Q4 2022	Non-GAAP[(a)] Q4 2021	% Change
Research and development (R&D)**	$ 1,043	$ 738	41%	$ 911	$ 635	43%
Acquired in-process research and development (IPR&D)**	$ 30	$ 48	(38%)	*	*	n/a
Selling, general, and administrative (SG&A)	$ 661	$ 560	18%	$ 579	$ 495	17%
Cost of goods sold (COGS)	$ 302	$ 812	(63%)	$ 126	$ 559	(77%)
Cost of collaboration and contract manufacturing (COCM)	$ 238	$ 171	39%	*	*	n/a
Other operating (income) expense, net	$ (7)	$ (16)	(56%)	*	*	n/a

	GAAP FY 2022	GAAP FY 2021	% Change	Non-GAAP[(a)] FY 2022	Non-GAAP[(a)] FY 2021	% Change
Research and development**	$ 3,593	$ 2,860	26%	$ 3,169	$ 2,544	25%
Acquired in-process research and development**	$ 255	$ 48	431%	*	*	n/a
Selling, general, and administrative	$ 2,116	$ 1,825	16%	$ 1,853	$ 1,606	15%
Cost of goods sold	$ 800	$ 1,773	(55%)	$ 507	$ 1,470	(66%)
Cost of collaboration and contract manufacturing	$ 760	$ 664	14%	*	*	n/a
Other operating (income) expense, net	$ (90)	$ (46)	96%	*	*	n/a

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

** Certain reclassifications have been made to prior period amounts to conform with the current period's presentation. See note (f) below for additional information.

- GAAP and non-GAAP R&D expenses increased in the fourth quarter and full year of 2022, compared to the same periods in the prior year, driven by the impact of the 2022 amendments to the Sanofi collaboration agreements, additional costs incurred in connection with the Company's late-stage pipeline, an increase in clinical manufacturing activities, and higher headcount and headcount-related costs. The increase for the full year of 2022, compared to full year 2021, was partly offset by lower costs incurred in connection with development activities for REGEN-COV and fasinumab.
- Acquired IPR&D for full year 2022 included a $195 million charge related to the Company's acquisition of Checkmate Pharmaceuticals, Inc., a $30 million up-front payment in connection with the Company's collaboration agreement with CytomX (fourth quarter 2022), and a $20 million opt-in payment in connection with a product candidate under the Company's collaboration agreement with Adicet Bio, Inc. Acquired IPR&D for the fourth quarter and full year of 2021

included $34 million in aggregate up-front payments in connection with the Company's collaboration agreement with Nykode Therapeutics.

- GAAP and non-GAAP SG&A expenses increased in the fourth quarter and full year of 2022, compared to the same periods in the prior year, primarily due to an increase in commercialization-related expenses for Libtayo (as effective July 1, 2022, the Company became solely responsible for the commercialization of Libtayo worldwide), higher contributions to an independent not-for-profit patient assistance organization, and higher headcount and headcount-related costs, partly offset by educational campaigns related to COVID-19 that did not recur during 2022.
- GAAP and non-GAAP COGS decreased in the fourth quarter and full year of 2022, compared to the same periods in the prior year, primarily due to the Company recognizing U.S. REGEN-COV net product sales (and corresponding cost of goods sold) during 2021 and a 2021 payment of $260 million owed by the Company in connection with global gross profits under its Roche collaboration agreement; such transactions did not recur in 2022. GAAP and non-GAAP COGS also decreased in 2022 since effective July 1, 2022, following the acquisition of Libtayo worldwide rights, the Company is no longer obligated to pay Sanofi for their share of U.S. Libtayo gross profits.

  GAAP COGS also decreased in the fourth quarter and full year of 2022 due to lower inventory write-offs and reserves. Non-GAAP COGS excluded certain charges related to REGEN-COV (primarily inventory write-offs and reserves) of $134 million and $197 million in the fourth quarter and full year of 2022, respectively, and $232 million in each of the fourth quarter and full year of 2021.
- Other operating (income) expense, net, for full year 2022 included the recognition of $44 million (an increase to other operating income) as a result of discontinuing further clinical development of fasinumab related to the Company's Teva and Mitsubishi Tanabe Pharma collaborative arrangements.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized gains on equity securities of $81 million in the fourth quarter of 2022, compared to $138 million of net unrealized losses in the fourth quarter of 2021. GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $40 million for full year 2022, compared to net unrealized gains of $386 million for full year 2021.

In the fourth quarter and full year 2022, the Company's GAAP effective tax rate (ETR) was 9.6% and 10.7%, respectively, compared to 11.0% and 13.4% in the fourth quarter and full year 2021, respectively. The GAAP ETR in the fourth quarter and full year 2022, compared to the same periods in the prior year, included a higher benefit from the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate (including the impact from REGEN-COV income earned in the U.S. during 2021). In the fourth quarter and full year 2022, the non-GAAP ETR was 11.3% and 12.1%, respectively, compared to 12.6% and 13.5% in the fourth quarter and full year 2021, respectively.

GAAP net income per diluted share was $10.50 in the fourth quarter of 2022, compared to $19.69 in the fourth quarter of 2021. GAAP net income per diluted share was $38.22 for the full year 2022, compared to $71.97 for full year 2021. Non-GAAP net income per diluted share was $12.56 in the fourth quarter of 2022, compared to $23.42 in the fourth quarter of 2021. Non-GAAP net income per diluted share was $44.98 for the full year 2022, compared to $74.35 for the full year 2021. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

During the full year 2022, the Company repurchased shares of common stock under its share repurchase program, and recorded the cost of the shares, or $2.100 billion, as Treasury Stock. As of December 31, 2022, $745 million remained available for share repurchases under the program. In January 2023, the Company's board of directors authorized a new share repurchase program to repurchase up to an additional $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.

2023 Financial Guidance[(c)]

The Company's full year 2023 financial guidance consists of the following components:

	2023 Guidance
GAAP R&D	$4.200–$4.435 billion
Non-GAAP R&D[(a)]	$3.725–$3.925 billion
GAAP SG&A	$2.460–$2.650 billion
Non-GAAP SG&A[(a)]	$2.130–$2.280 billion
GAAP gross margin on net product sales[(d)]	88%–90%
Non-GAAP gross margin on net product sales[(a)(d)]	90%–92%
COCM[(e)]*	$720–$800 million
Capital expenditures*	$825–$950 million
GAAP effective tax rate	10%–12%
Non-GAAP effective tax rate[(a)]	11%–13%

* 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 2023 GAAP to non-GAAP financial guidance is included below:

($ in millions)	Projected Range Low	High
GAAP R&D	$ 4,200	$ 4,435
Stock-based compensation expense	470	500
Acquisition-related integration costs	5	10
Non-GAAP R&D	$ 3,725	$ 3,925
GAAP SG&A	$ 2,460	$ 2,650
Stock-based compensation expense	310	330
Acquisition-related integration costs	20	40
Non-GAAP SG&A	$ 2,130	$ 2,280
GAAP gross margin on net product sales	88%	90%
Stock-based compensation expense	1%	1%
Intangible asset amortization expense	1%	1%
Non-GAAP gross margin on net product sales	90%	92%
GAAP ETR	10%	12%
Income tax effect of GAAP to non-GAAP reconciling items	1%	1%
Non-GAAP ETR	11%	13%

(a) This press release uses non-GAAP R&D, non-GAAP SG&A, non-GAAP COGS, non-GAAP gross margin on net product sales, non-GAAP other income (expense), net, non-GAAP ETR, non-GAAP net income, non-GAAP net income per share, total revenues excluding REGEN-COV and Ronapreve, 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 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- or integration-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.

(b) The casirivimab and imdevimab antibody cocktail for COVID-19 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.

(c) The Company's 2023 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(d) 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.

(e) Corresponding reimbursements from collaborators and others for manufacturing of commercial supplies is recorded within revenues.

(f) Beginning with the first quarter of 2022, the Company added Acquired in-process research and development as a new line item to its Statements of Operations, which includes IPR&D acquired in connection with asset acquisitions as well as up-front/opt-in payments related to license and collaboration agreements. Amounts recorded in this line would have historically been recorded to Research and development expenses. Prior period amounts have been reclassified to conform with the current period's presentation.

Beginning with the first quarter of 2022, IPR&D expenses are no longer excluded in the determination of non-GAAP financial results. Prior period non-GAAP results have also been updated to reflect these changes.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2022 financial and operating results on

Friday, February 3, 2023, at 8:30 AM Eastern Time. Participants may access the conference call live via webcast, or register in advance and participate via telephone, on the "Investors and Media" page of Regeneron's website at www.regeneron.com. 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, develops, and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and 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 Regeneron, 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), aflibercept 8 mg, pozelimab, odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, 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 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, capital expenditures, and GAAP and non-GAAP ETR; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), 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, Praluent, and REGEN-COV® (casirivimab and imdevimab)), 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,	
	2022	**2021**
Assets:		
Cash and marketable securities	$ 14,334.1	$ 12,532.7
Accounts receivable, net	5,328.7	6,036.5
Inventories	2,401.9	1,951.3
Property, plant, and equipment, net	3,763.0	3,482.2
Intangible assets, net	915.5	6.7
Deferred tax assets	1,723.7	876.9
Other assets	747.6	548.5
Total assets	$ 29,214.5	$ 25,434.8
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,301.4	$ 3,451.0
Finance lease liabilities	720.0	719.7
Deferred revenue	547.7	515.3
Long-term debt	1,981.4	1,980.0
Stockholders' equity	22,664.0	18,768.8
Total liabilities and stockholders' equity	$ 29,214.5	$ 25,434.8

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,	
	2022	**2021***	**2022**	**2021***
Revenues:				
Net product sales	$ 1,699.3	$ 3,975.2	$ 6,893.7	$ 12,117.2
Collaboration revenue	1,587.4	890.3	4,914.1	3,673.3
Other revenue	127.7	86.2	365.1	281.2
	3,414.4	4,951.7	12,172.9	16,071.7
Expenses:				
Research and development	1,043.1	737.6	3,592.5	2,860.1
Acquired in-process research and development	30.0	48.0	255.1	48.0
Selling, general, and administrative	660.5	559.6	2,115.9	1,824.9
Cost of goods sold	302.2	811.7	800.0	1,773.1
Cost of collaboration and contract manufacturing	238.4	170.9	760.4	664.4
Other operating (income) expense, net	(6.6)	(15.8)	(89.9)	(45.6)
	2,267.6	2,312.0	7,434.0	7,124.9

Income from operations	1,146.8	2,639.7	4,738.9	8,946.8
Other income (expense):				
Other income (expense), net	195.3	(122.2)	179.3	436.3
Interest expense	(17.4)	(14.1)	(59.4)	(57.3)
	177.9	(136.3)	119.9	379.0
Income before income taxes	1,324.7	2,503.4	4,858.8	9,325.8
Income tax expense	127.6	274.4	520.4	1,250.5
Net income	$ 1,197.1	$ 2,229.0	$ 4,338.4	$ 8,075.3
Net income per share - basic	$ 11.19	$ 20.99	$ 40.51	$ 76.40
Net income per share - diluted	$ 10.50	$ 19.69	$ 38.22	$ 71.97
Weighted average shares outstanding - basic	107.0	106.2	107.1	105.7
Weighted average shares outstanding - diluted	114.0	113.2	113.5	112.2

* Certain reclassifications have been made to prior period amounts to conform with the current period's presentation. See note (f) above for additional information.

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,	
	2022	**2021***	**2022**	**2021***
GAAP R&D	$ 1,043.1	$ 737.6	$ 3,592.5	$ 2,860.1
R&D: Stock-based compensation expense	131.0	102.9	406.8	316.6
R&D: Acquisition-related integration costs	1.4	—	17.0	—
Non-GAAP R&D	$ 910.7	$ 634.7	$ 3,168.7	$ 2,543.5
GAAP SG&A	$ 660.5	$ 559.6	$ 2,115.9	$ 1,824.9
SG&A: Stock-based compensation expense	78.4	64.2	256.4	213.3
SG&A: Acquisition-related integration costs and other	3.5	—	6.6	5.6
Non-GAAP SG&A	$ 578.6	$ 495.4	$ 1,852.9	$ 1,606.0
GAAP COGS	$ 302.2	$ 811.7	$ 800.0	$ 1,773.1
COGS: Stock-based compensation expense	22.6	21.3	61.8	71.8
COGS: Intangible asset amortization expense	19.7	—	34.8	—
COGS: Charges related to REGEN-COV	133.7	231.7	196.6	231.7
Non-GAAP COGS	$ 126.2	$ 558.7	$ 506.8	$ 1,469.6
GAAP other income (expense), net	$ 177.9	$ (136.3)	$ 119.9	$ 379.0
Other income/expense: (Gains) losses on investments	(80.5)	137.6	36.8	(387.0)
Non-GAAP other income (expense), net	$ 97.4	$ 1.3	$ 156.7	$ (8.0)
GAAP net income	$ 1,197.1	$ 2,229.0	$ 4,338.4	$ 8,075.3
Total of GAAP to non-GAAP reconciling items above	309.8	557.7	1,016.8	452.0
Income tax effect of GAAP to non-GAAP reconciling items	(57.9)	(110.0)	(191.3)	(73.7)
Non-GAAP net income	$ 1,449.0	$ 2,676.7	$ 5,163.9	$ 8,453.6
Non-GAAP net income per share - basic	$ 13.54	$ 25.20	$ 48.22	$ 79.98
Non-GAAP net income per share - diluted	$ 12.56	$ 23.42	$ 44.98	$ 74.35

Shares used in calculating:

Non-GAAP net income per share - basic	107.0	106.2	107.1	105.7
Non-GAAP net income per share - diluted	115.4	114.3	114.8	113.7

* Prior period results have been revised to reflect certain changes to amounts excluded from non-GAAP results. See note (f) above for additional information.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue reconciliation:				
Total revenues	$ 3,414.4	$ 4,951.7	$ 12,172.9	$ 16,071.7
REGEN-COV net product sales in the United States	—	2,297.9	—	5,828.0
Global gross profit payment from Roche in connection with sales of Ronapreve	396.4	—	627.3	361.8
Total revenues excluding REGEN-COV and Ronapreve	$ 3,018.0	$ 2,653.8	$ 11,545.6	$ 9,881.9
Effective tax rate reconciliation:				
GAAP ETR	9.6%	11.0%	10.7%	13.4%
Income tax effect of GAAP to non-GAAP reconciling items	1.7%	1.6%	1.4%	0.1%
Non-GAAP ETR	11.3%	12.6%	12.1%	13.5%

	Year Ended December 31,	
	2022	**2021**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 5,014.9	$ 7,081.3
Capital expenditures	(590.1)	(551.9)
Free cash flow	$ 4,424.8	$ 6,529.4

TABLE 4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 619.0	$ 387.8	$ 2,082.0	$ 1,363.0
Sales-based milestones earned	50.0	—	100.0	50.0
Reimbursement for manufacturing of commercial supplies	166.9	127.6	633.7	488.8
Other	—	—	28.7	—
Immuno-oncology:				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	—	(1.0)	6.7	(13.6)
Reimbursement for manufacturing of ex-U.S. commercial supplies	—	3.5	4.6	14.0
Total Sanofi collaboration revenue	835.9	517.9	2,855.7	1,902.2
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	324.0	353.9	1,317.4	1,349.2
Reimbursement for manufacturing of ex-U.S. commercial supplies	31.1	18.5	91.4	60.1
One-time payment in connection with change in Japan arrangement	—	—	21.9	—
Total Bayer collaboration revenue	355.1	372.4	1,430.7	1,409.3
Other collaboration revenue:				

Global gross profit payment from Roche in connection with sales of REGEN-COV and Ronapreve	396.4	—	627.3	361.8
Other	—	—	0.4	—
Total collaboration revenue	$ 1,587.4	$ 890.3	$ 4,914.1	$ 3,673.3

TABLE 5

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

	Three Months Ended December 31,						
	2022			2021			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,496.4	$ 838.6	$ 2,335.0	$ 1,547.2	$ 883.2 *	$ 2,430.4	(4%)
Dupixent[b]	$ 1,936.3	$ 512.6	$ 2,448.9	$ 1,348.2	$ 425.6	$ 1,773.8	38%
Libtayo[c]	$ 110.0	$ 58.8	$ 168.8	$ 80.8	$ 40.2	$ 121.0	40%
Praluent[d]	$ 35.5	$ 97.9	$ 133.4	$ 40.0	$ 62.6	$ 102.6	30%
REGEN-COV[e]	$ —	$ 1,088.4	$ 1,088.4	$ 2,297.9	$ 572.7	$ 2,870.6	(62%)
Kevzara[b]	$ 46.6	$ 34.6	$ 81.2	$ 42.0	$ 61.9	$ 103.9	(22%)
Other products[f]	$ 16.6	$ 15.0	$ 31.6	$ 10.7	$ 20.3	$ 31.0	2%

	Year Ended December 31,						
	2022			2021			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 6,264.6	$ 3,382.8	$ 9,647.4	$ 5,792.3	$ 3,450.9 *	$ 9,243.2	4%
Dupixent[b]	$ 6,668.0	$ 2,013.2	$ 8,681.2	$ 4,713.0	$ 1,485.3	$ 6,198.3	40%
Libtayo[c]	$ 374.5	$ 203.5	$ 578.0	$ 306.3	$ 151.9	$ 458.2	26%
Praluent[d]	$ 130.0	$ 337.4	$ 467.4	$ 170.0	$ 251.1	$ 421.1	11%
REGEN-COV[e]	$ —	$ 1,769.6	$ 1,769.6	$ 5,828.0	$ 1,745.9	$ 7,573.9	(77%)
Kevzara[b]	$ 199.7	$ 158.3	$ 358.0	$ 161.9	$ 176.1	$ 338.0	6%
Other products[f]	$ 56.1	$ 69.1	$ 125.2	$ 25.9	$ 86.4	$ 112.3	11%

* Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits and losses based on sales from Bayer to its distributor in Japan. Previously, the Company received from Bayer a tiered percentage of sales based on sales by Bayer's distributor in Japan. Consequently, the prior year net product sales amount has been revised for comparability purposes.

[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 and Kevzara. The Company records its share of profits/losses in connection with global sales of Dupixent and Kevzara.

[c] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Included in this line item is approximately $17 million and $34 million of net product sales recorded by Sanofi in the fourth quarter and second half of 2022, respectively, in connection with sales in certain markets (Sanofi will record net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 is sold through to the end customers).

[d] Regeneron records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales.

[e] Regeneron records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States. The parties share gross profits from global sales of REGEN-COV and Ronapreve based on a pre-specified formula.

[f] Included in this line item are products which are sold by the Company and others. Refer to "Fourth Quarter 2022 Financial Results" section above for a complete listing of net product sales recorded by the Company. Not included in this line item are net product sales of ARCALYST subsequent to the first quarter of 2021, which are recorded by Kiniksa.

REGENERON

Source: Regeneron Pharmaceuticals, Inc.