Regeneron Reports Fourth Quarter and Full Year 2023 Financial and Operating Results

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- *Fourth quarter 2023 revenues increased 1% to $3.43 billion versus fourth quarter 2022; excluding Ronapreve™[a][b], revenues increased 14%*
- *Full year 2023 revenues increased 8% to $13.12 billion versus full year 2022; excluding Ronapreve[a], revenues increased 12%*
- *Fourth quarter 2023 Dupixent® global net sales (recorded by Sanofi) increased 31% to $3.22 billion versus fourth quarter 2022; full year 2023 Dupixent global net sales increased 33% to $11.59 billion versus 2022*
- *Fourth quarter 2023 U.S. net sales for EYLEA® HD and EYLEA® were $1.46 billion, including $123 million from EYLEA HD; full year 2023 U.S. net sales for EYLEA HD and EYLEA were $5.89 billion, including $166 million from EYLEA HD following its August 2023 FDA approval*
- *Fourth quarter 2023 Libtayo® global net sales increased 44% to $244 million versus fourth quarter 2022; full year 2023 Libtayo global net sales increased 50% to $869 million versus 2022[f]*
- *Fourth quarter 2023 GAAP diluted EPS of $10.19 and non-GAAP diluted EPS[a] of $11.86; includes unfavorable $0.21 impact from acquired IPR&D charge*
- *Dupixent sBLA for chronic obstructive pulmonary disease (COPD) with type 2 inflammatory phenotype and linvoseltamab BLA for multiple myeloma submitted to FDA*

TARRYTOWN, N.Y., Feb. 02, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2023 and provided a business update.

"2023 marked another year of exceptional accomplishments for Regeneron as we further diversified our revenue base and made important progress in our robust R&D pipeline," said Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron. "In 2024, we plan to build on this momentum with continued growth of our breakthrough products Dupixent and EYLEA HD while we bring additional new therapies to market and advance our growing pipeline. Lastly, I want to congratulate our Chief Financial Officer, Bob Landry, on the occasion of his retirement and thank him for his significant contributions to Regeneron during his ten years with the Company."

Financial Highlights

	Three Months Ended December 31,			Year Ended December 31,		
($ in millions, except per share data)	2023	2022	% Change	2023	2022	% Change
Total revenues	$ 3,434	$ 3,414	1%	$ 13,117	$ 12,173	8%
Total revenues excluding Ronapreve[a][b]	$ 3,436	$ 3,018	14%	$ 12,906	$ 11,546	12%
GAAP net income	$ 1,160	$ 1,197	(3%)	$ 3,954	$ 4,338	(9%)
GAAP net income per share - diluted	$ 10.19	$ 10.50	(3%)	$ 34.77	$ 38.22	(9%)
Non-GAAP net income[a]	$ 1,366	$ 1,449	(6%)	$ 5,045	$ 5,164	(2%)
Non-GAAP net income per share - diluted[a]	$ 11.86	$ 12.56	(6%)	$ 43.79	$ 44.98	(3%)

"We were pleased with our fourth-quarter and full-year 2023 financial performance, highlighted by revenue growth of 14% and 12%, respectively, when excluding contributions from Ronapreve, reflecting continued strength across our business," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "In 2024, we plan to continue investing heavily in internal R&D, driving commercial execution with targeted promotion, and prudently deploying capital to business development and share repurchases, all of which is expected to better position the Company to deliver sustainable growth and long-term value to shareholders."

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:

EYLEA HD (aflibercept) 8 mg

- In January 2024, the European Commission (EC) and Japan's Ministry of Health, Labour and Welfare (MHLW) each approved EYLEA 8 mg (known as EYLEA HD in the United States) for the treatment of patients with wet age-related macular degeneration (wAMD) and diabetic macular edema (DME).
- In January 2024, the United States Centers for Medicare & Medicaid Services (CMS) assigned a permanent and product-specific J-code (J0177) for EYLEA HD. Under the Healthcare Common Procedure Coding System (HCPCS) process, the

EYLEA HD J-code will become effective on April 1, 2024. J-codes are permanent reimbursement codes used by government payers and commercial insurers in the United States to facilitate billing for Medicare Part B treatments, which must be administered by a healthcare professional. J-codes simplify and streamline the billing and reimbursement processes, allowing for efficient claims processing.

Dupixent (dupilumab)

- The Company and Sanofi announced that based on results from an interim analysis, the second Phase 3 trial (NOTUS) in patients with uncontrolled COPD and evidence of type 2 inflammation met its primary endpoint and showed that Dupixent significantly reduced exacerbations by 34% (confirming positive results from the replicate Phase 3 BOREAS trial). The NOTUS trial also confirmed that treatment with Dupixent led to rapid and significant improvements in lung function by 12 weeks and were sustained at 52 weeks. In December 2023, a supplemental Biologics License Application (sBLA) was submitted to the U.S. Food and Drug Administration (FDA) based on the results of these two trials. A regulatory application has also been submitted in the European Union (EU).
- In January 2024, the FDA approved Dupixent for the treatment of children aged 1 to 11 years (weighing at least 15 kg) with eosinophilic esophagitis (EoE), making Dupixent the first and only medicine specifically indicated to treat these patients. A regulatory application has also been submitted in the EU.

Oncology Programs

- The Company presented updated positive data from the pivotal trial of linvoseltamab, a bispecific antibody targeting BCMA and CD3, in patients with relapsed/refractory multiple myeloma at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition.
- A BLA for linvoseltamab in relapsed/refractory multiple myeloma was submitted to the FDA in December 2023 and a regulatory application is also under review in the EU.
- The Company presented updated data for odronextamab, a bispecific antibody targeting CD20 and CD3, in patients with relapsed/refractory follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) at the 65th ASH Annual Meeting and Exposition. A BLA for odronextamab in relapsed/refractory FL and DLBCL is currently under review by the FDA, with a target action date of March 31, 2024, and a regulatory application is also under review in the EU.
- The Company presented, at European Society for Medical Oncology Immuno-Oncology (ESMO IO) Congress 2023, initial Phase 1 dose-escalation data for REGN5668, a costimulatory bispecific antibody targeting MUC16 and CD28, in combination with Libtayo (cemiplimab) that showed encouraging initial activity in patients with recurrent ovarian cancer.

Other Programs

- The EC approved Evkeeza® (evinacumab) as an adjunct to other lipid-lowering therapies to treat children with homozygous familial hypercholesterolemia (HoFH), which extended the approved indication to children as young as 5 years of age.
- A Phase 3 study was initiated for NTLA-2001, a TTR gene knockout using CRISPR/Cas9, in transthyretin (ATTR) amyloidosis with cardiomyopathy (ATTR-CM).
- The FDA granted Breakthrough Therapy designation to mibavademab, an agonist antibody to leptin receptor (LEPR), for generalized lipodystrophy (for which a Phase 2 study is ongoing).

Corporate and Business Development Updates

- In the Company's ongoing patent infringement lawsuit against Mylan Pharmaceuticals Inc., a wholly-owned subsidiary of Viatris Inc., and Biocon Biologics Inc. concerning Mylan's filing for FDA approval of an aflibercept 2 mg biosimilar (now owned by Biocon), the United States District Court for the Northern District of West Virginia issued a decision finding that (i) the asserted claims of one of the Company's formulation patents (U.S. Patent No. 11,084,865) were valid and infringed by Mylan and (ii) the asserted claims of two of the Company's methods of treatment patents (U.S. Patent Nos. 10,888,601 and 11,253,572) were infringed by Mylan but were invalid as obvious.
- In January 2024, the Company entered into an agreement with 2seventy bio, Inc. to acquire full development and commercialization rights to its preclinical and clinical stage cell therapy pipeline and will assume ongoing program, infrastructure, and personnel costs related to these programs. The transaction is expected to close in the first half of 2024 subject to certain customary closing conditions.
- The Company announced its inclusion on the Dow Jones Sustainability World Index (DJSI World) for the fifth consecutive year, alongside its fourth consecutive inclusion on the Dow Jones Sustainability North America Index (DJSI North America).

Select Upcoming 2024 Milestones

Programs	Milestones
Ophthalmology	- Initiate pivotal retinal vein occlusion (RVO) study of EYLEA HD (mid-2024) to enable FDA submission - Initiate pivotal studies of pozelimab (C5 antibody) in combination with cemdisiran (siRNA therapy) in geographic atrophy (second half 2024)

Immunology & Inflammation	- EC decision on regulatory submission for Dupixent for EoE in children (1–11 years of age) (second half 2024) - sBLA acceptance for Dupixent in COPD with type 2 inflammatory phenotype (first quarter 2024) and FDA decision on sBLA (mid/second half 2024); EC decision on regulatory submission (second half 2024) - Report results from ongoing Phase 3 study for Dupixent in chronic spontaneous urticaria (CSU) in biologic-naïve patients (fourth quarter 2024) - Initiate Phase 1 study in severe food allergy following transient linvoseltamab treatment (in combination with Dupixent) (2024) - Complete enrollment of Phase 3 studies of itepekimab (IL-33 antibody) in COPD (second half 2024)
Solid Organ Oncology	- Conduct interim analysis from Phase 3 study of Libtayo in adjuvant cutaneous squamous cell carcinoma (CSCC) (second half 2024) - Report potentially pivotal initial results from Phase 2/3 study of fianlimab (LAG-3 antibody) in combination with Libtayo in first-line metastatic melanoma and initial combination data in first-line advanced non-small cell lung cancer (NSCLC) (second half 2024) - Initiate potentially pivotal Phase 2 study for fianlimab (in combination with Libtayo) in perioperative melanoma and Phase 2 study for fianlimab (in combination with Libtayo) in perioperative NSCLC (first half 2024) - Initiate dose-expansion cohorts of REGN7075 (EGFR and CD28 costimulatory bispecific antibody) in combination with Libtayo in EGFR-high tumors (first half 2024) - Initiate cohorts combining REGN5678 (PSMA and CD28 costimulatory bispecific antibody) and REGN4336 (PSMA and CD3 bispecific antibody) in metastatic castration-resistant prostate cancer and initiate REGN5678 monotherapy cohort in renal cell carcinoma (first half 2024)
Hematology	- FDA decision on BLA (target action date of March 31, 2024) and EC decision on regulatory submission (second half 2024) for odronextamab in relapsed/refractory FL and DLBCL - BLA acceptance for linvoseltamab in relapsed/refractory multiple myeloma (first quarter 2024) and FDA decision on BLA (second half 2024) - Initiate Phase 1 study of linvoseltamab in combination with CD38 and CD28 costimulatory bispecific antibody in multiple myeloma (2024) - Report Phase 2 results for REGN9933 (Factor XI antibody) in thrombosis (second half 2024)
Genetic Medicines	- Initiate Phase 1 study of Factor 9 gene insertion in hemophilia B (mid-2024) - Report additional data from Phase 1/2 study for DB-OTO (AAV-based gene therapy) in pediatrics with hearing loss (2024) - Initiate Phase 1 study of ALN-SOD (SOD1 siRNA) in amyotrophic lateral sclerosis (ALS) (2024)
Obesity	- Initiate Phase 2 study of semaglutide in combination with trevogrumab (anti-myostatin) with and without garetosmab (anti-Activin A) (mid-2024)

Fourth Quarter 2023 Financial Results

Revenues

($ in millions)	Q4 2023	Q4 2022	% Change	FY 2023	FY 2022	% Change
Net product sales:						
EYLEA HD - U.S.	$ 123	$ —	*	$ 166	$ —	*
EYLEA - U.S.	1,338	1,496	(11%)	5,720	6,265	(9%)
Total EYLEA HD and EYLEA - U.S.	1,461	1,496	(2%)	5,886	6,265	(6%)
Libtayo - Global**	244	152	61%	863	448	93%
Praluent® - U.S.	61	36	69%	182	130	40%
Evkeeza - U.S.	24	15	60%	77	48	60%
Inmazeb® - U.S.	62	—	*	70	3	*
Total net product sales	1,852	1,699	9%	7,078	6,894	3%
Collaboration revenue:						
Sanofi	993	836	19%	3,800	2,856	33%
Bayer	377	355	6%	1,487	1,431	4%
Other	—	396	(100%)	216	627	(66%)
Other revenue	212	128	66%	536	365	47%
Total revenues	$ 3,434	$ 3,414	1%	$ 13,117	$ 12,173	8%

* Percentage not meaningful

** Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States. Excluded from the full year 2023 is approximately $6 million of first quarter 2023 net product sales recorded by Sanofi in connection with sales in certain markets (Sanofi recorded net product sales in such markets during a transition period). Similarly, excluded from the fourth quarter and full year 2022 is approximately $17 million and $34 million, respectively, of net product sales recorded by Sanofi (see Table 5).

Net product sales of EYLEA in the U.S. decreased in the fourth quarter and full year 2023, compared to the same periods of 2022, primarily due to changing market dynamics, resulting in a lower net selling price and lower volumes. EYLEA volumes in the fourth quarter of 2023 were impacted by the August 2023 launch of EYLEA HD and subsequent transition of EYLEA patients to EYLEA HD.

Sanofi collaboration revenue increased in the fourth quarter and full year 2023, compared to the same periods of 2022, primarily due to the Company's

share of profits from commercialization of antibodies, which were $886 million and $619 million in the fourth quarter of 2023 and 2022, respectively, and $3.137 billion and $2.082 billion for the full year 2023 and 2022, respectively. The change in the Company's share of profits from commercialization of antibodies was driven by higher profits associated with an increase in Dupixent sales. In addition, during 2023 (third quarter) the Company earned the final $50 million sales-based milestone from Sanofi based upon aggregate annual sales of antibodies outside the U.S., compared to earning two $50 million sales-based milestones in 2022 (including one in the fourth quarter of 2022).

The Company recorded collaboration revenue during 2023 and 2022 in connection with payments from Roche attributable to global gross profits from sales of Ronapreve. The decrease in other collaboration revenue was due to lower sales of Ronapreve.

Refer to Table 4 for a summary of collaboration revenue.

Other revenue for the fourth quarter and full year 2023 included the recognition of $16 million and $50 million, respectively, of revenue in connection with the Company's agreement with BARDA to fund certain costs for a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection. The increase in other revenue in 2023 was also due to higher royalties earned in connection with sales of Novartis' Ilaris® (canakinumab).

Operating Expenses

	GAAP		% Change	Non-GAAP[(a)]		% Change
($ in millions)	Q4 2023	Q4 2022		Q4 2023	Q4 2022	
Research and development (R&D)	$ 1,177	$ 1,043	13%	$ 1,031	$ 911	13%
Acquired in-process research and development (IPR&D)	$ 30	$ 30	—%	*	*	n/a
Selling, general, and administrative (SG&A)	$ 738	$ 661	12%	$ 622	$ 579	7%
Cost of goods sold (COGS)	$ 307	$ 302	2%	$ 259	$ 126	106%
Cost of collaboration and contract manufacturing (COCM)	$ 210	$ 238	(12%)	*	*	n/a
Other operating (income) expense, net	$ (1)	$ (7)	(86%)	*	*	n/a

	GAAP		% Change	Non-GAAP[(a)]		% Change
	FY 2023	FY 2022		FY 2023	FY 2022	
Research and development	$ 4,439	$ 3,593	24%	$ 3,919	$ 3,169	24%
Acquired in-process research and development	$ 186	$ 255	(27%)	*	*	n/a
Selling, general, and administrative	$ 2,631	$ 2,116	24%	$ 2,232	$ 1,853	20%
Cost of goods sold	$ 932	$ 800	17%	$ 770	$ 507	52%
Cost of collaboration and contract manufacturing	$ 884	$ 760	16%	*	*	n/a
Other operating (income) expense, net	$ (2)	$ (90)	(98%)	*	*	n/a

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

- GAAP and non-GAAP R&D expenses increased in the fourth quarter and full year 2023, compared to the same periods in the prior year, driven by additional costs incurred in connection with higher headcount and headcount-related costs, the advancement of the Company's late-stage pipeline, and increased manufacturing activity associated with the Company's product candidates.
- Acquired IPR&D for the full year 2023 included a $100 million development milestone in connection with the Phase 1 ALN-APP program, which is in collaboration with Alnylam Pharmaceuticals, Inc. Acquired IPR&D for the full year 2022 included a $195 million charge related to the Company's acquisition of Checkmate Pharmaceuticals, Inc.
- GAAP and non-GAAP SG&A expenses increased in the fourth quarter of 2023, compared to the fourth quarter of 2022, primarily due to higher headcount and headcount-related costs and higher commercialization-related expenses for various products, including the Company's retinal franchise, partly offset by lower contributions to an independent not-for-profit patient assistance organization. GAAP and non-GAAP SG&A expenses increased for the full year 2023, compared to full year 2022, primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Libtayo, and, to a lesser extent, various other products, and higher contributions to an independent not-for-profit patient assistance organization.

  Non-GAAP SG&A expenses excluded certain charges related to acquisition and integration-related activities primarily incurred in connection with the July 2022 acquisition of Libtayo worldwide rights.

- GAAP and non-GAAP COGS for the fourth quarter and full year 2023, when compared to the same periods in the prior year, included higher start-up costs for the Company's Rensselaer, New York fill/finish facility and an increase in period costs at the Company's manufacturing facilities (resulting from lower production volumes). GAAP COGS for the fourth

quarter and full year 2023, when compared to the same periods in the prior year, included lower inventory write-offs and reserves (which were primarily related to REGEN-COV® in 2022).

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 2022, respectively.

- COCM decreased in the fourth quarter of 2023, compared to the fourth quarter of 2022, primarily due to lower Dupixent manufacturing costs as a result of the transition to a higher-yielding manufacturing process. COCM increased for the full year 2023, compared to full year 2022, primarily due to the recognition of costs in connection with manufacturing commercial supplies for Sanofi related to Praluent outside the United States and for Bayer related to EYLEA outside the United States.
- Other operating (income) expense, net for the full year 2022 included the recognition of amounts previously deferred in connection with up-front and development milestone payments received in connection with the Company's previous Sanofi Immuno-Oncology, Teva, and Mitsubishi Tanabe Pharma Corporation collaborative arrangements.

Other Financial Information

GAAP other income (expense) included the recognition of net unrealized losses on equity securities of $238 million for full year 2023, compared to $40 million for full year 2022. GAAP and Non-GAAP other income (expense) also included interest income of $496 million and $160 million for the full year 2023 and 2022, respectively.

In the fourth quarter and full year 2023, the Company's GAAP effective tax rate (ETR) was (1.0%) and 5.9%, respectively, compared to 9.6% and 10.7% in the fourth quarter and full year 2022, respectively. The GAAP ETR in the fourth quarter and full year 2023, compared to the same periods in the prior year, included a higher benefit from stock-based compensation, federal tax credits for research activities, and the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate. In the fourth quarter and full year 2023, the non-GAAP ETR was 2.4% and 9.1%, respectively, compared to 11.3% and 12.1% in the fourth quarter and full year 2022, respectively.

GAAP net income per diluted share was $10.19 in the fourth quarter of 2023, compared to $10.50 in the fourth quarter of 2022. GAAP net income per diluted share was $34.77 for the full year 2023, compared to $38.22 for full year 2022. Non-GAAP net income per diluted share was $11.86 in the fourth quarter of 2023, compared to $12.56 in the fourth quarter of 2022. Non-GAAP net income per diluted share was $43.79 for the full year 2023, compared to $44.98 for full year 2022. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

During the fourth quarter and full year 2023, the Company repurchased shares of its common stock and recorded the cost of the shares, or $295 million and $2.215 billion, respectively, as Treasury Stock. As of December 31, 2023, $1.5 billion remained available for share repurchases under the Company's share repurchase program.

2024 Financial Guidance[(c)]

The Company's full year 2024 financial guidance consists of the following components:

	2024 Guidance
GAAP R&D	$4.820–$5.070 billion
Non-GAAP R&D[(a)]	$4.300–$4.500 billion
GAAP SG&A	$2.890–$3.090 billion
Non-GAAP SG&A[(a)]	$2.500–$2.650 billion
GAAP gross margin on net product sales[(d)]	86%–88%
Non-GAAP gross margin on net product sales[(a)(d)]	89%–91%
COCM[(e)]*	$850–$910 million
Capital expenditures*	$825–$950 million
GAAP effective tax rate	8%–10%
Non-GAAP effective tax rate[(a)]	10%–12%

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

A reconciliation of full year 2024 GAAP to non-GAAP financial guidance is included below:

	Projected Range	
($ in millions)	**Low**	**High**
GAAP R&D	$ 4,820	$ 5,070
Stock-based compensation expense	510	540
Acquisition and integration costs	10	30
Non-GAAP R&D	$ 4,300	$ 4,500
GAAP SG&A	$ 2,890	$ 3,090
Stock-based compensation expense	350	380
Acquisition and integration costs	40	60

Non-GAAP SG&A	$ 2,500	$ 2,650
GAAP gross margin on net product sales	86%	88%
Stock-based compensation expense	1%	1%
Intangible asset amortization expense	1%	1%
Acquisition and integration costs	<1%	<1%
Non-GAAP gross margin on net product sales	89%	91%
GAAP ETR	8%	10%
Income tax effect of GAAP to non-GAAP reconciling items	2%	2%
Non-GAAP ETR	10%	12%

(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 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 acquisition and integration 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 the Company 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. Roche records net product sales of Ronapreve outside the United States.

(c) The Company's 2024 financial guidance does not assume the completion of any 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) Represents Libtayo global net sales, inclusive of sales outside the United States which were recorded by Sanofi prior to July 1, 2022.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2023 financial and operating results on Friday, February 2, 2024, 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 over 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, 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 LinkedIn.

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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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® HD (aflibercept) Injection 8 mg, EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab), Veopoz ™ (pozelimab), odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, NTLA-2001, 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; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; 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), 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

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:

Ryan Crowe
Investor Relations
914-847-8790
ryan.crowe@regeneron.com

Christina Chan
Corporate Affairs
914-847-8827
christina.chan@regeneron.com

TABLE 1

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

	December 31,	
	2023	2022
Assets:		
Cash and marketable securities	$ 16,241.3	$ 14,334.1
Accounts receivable, net	5,667.3	5,328.7
Inventories	2,580.5	2,401.9
Property, plant, and equipment, net	4,146.4	3,763.0
Intangible assets, net	1,038.6	915.5
Deferred tax assets	2,575.4	1,723.7
Other assets	830.7	747.6
Total assets	$ 33,080.2	$ 29,214.5
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 3,818.6	$ 3,301.4
Finance lease liabilities	720.0	720.0
Deferred revenue	585.6	547.7
Long-term debt	1,982.9	1,981.4
Stockholders' equity	25,973.1	22,664.0
Total liabilities and stockholders' equity	$ 33,080.2	$ 29,214.5

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,	
	2023	2022	2023	2022
Revenues:				
Net product sales	$ 1,851.8	$ 1,699.3	$ 7,078.0	$ 6,893.7
Collaboration revenue	1,370.0	1,587.4	5,503.1	4,914.1
Other revenue	212.5	127.7	536.1	365.1
	3,434.3	3,414.4	13,117.2	12,172.9
Expenses:				
Research and development	1,177.2	1,043.1	4,439.0	3,592.5
Acquired in-process research and development	30.0	30.0	186.1	255.1
Selling, general, and administrative	737.7	660.5	2,631.3	2,115.9
Cost of goods sold	306.8	302.2	932.1	800.0
Cost of collaboration and contract manufacturing	210.2	238.4	883.7	760.4
Other operating (income) expense, net	(0.5)	(6.6)	(2.1)	(89.9)
	2,461.4	2,267.6	9,070.1	7,434.0
Income from operations	972.9	1,146.8	4,047.1	4,738.9
Other income (expense):				
Other income (expense), net	193.0	195.3	225.2	179.3
Interest expense	(18.3)	(17.4)	(73.0)	(59.4)
	174.7	177.9	152.2	119.9
Income before income taxes	1,147.6	1,324.7	4,199.3	4,858.8
Income tax (benefit) expense	(12.0)	127.6	245.7	520.4
Net income	$ 1,159.6	$ 1,197.1	$ 3,953.6	$ 4,338.4
Net income per share - basic	$ 10.88	$ 11.19	$ 37.05	$ 40.51
Net income per share - diluted	$ 10.19	$ 10.50	$ 34.77	$ 38.22
Weighted average shares outstanding - basic	106.6	107.0	106.7	107.1
Weighted average shares outstanding - diluted	113.8	114.0	113.7	113.5

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,	
	2023	**2022**	**2023**	**2022**
GAAP R&D	$ 1,177.2	$ 1,043.1	$ 4,439.0	$ 3,592.5
Stock-based compensation expense	132.7	131.0	488.7	406.8
Acquisition and integration costs	13.6	1.4	31.3	17.0
Non-GAAP R&D	$ 1,030.9	$ 910.7	$ 3,919.0	$ 3,168.7
GAAP SG&A	$ 737.7	$ 660.5	$ 2,631.3	$ 2,115.9
Stock-based compensation expense	82.6	78.4	307.1	256.4
Acquisition and integration costs	33.3	3.5	91.8	6.6
Non-GAAP SG&A	$ 621.8	$ 578.6	$ 2,232.4	$ 1,852.9
GAAP COGS	$ 306.8	$ 302.2	$ 932.1	$ 800.0
Stock-based compensation expense	25.1	22.6	89.2	61.8
Acquisition and integration costs	0.9	—	2.3	—
Intangible asset amortization expense	21.9	19.7	80.9	34.8
Charges related to REGEN-COV	—	133.7	(10.0)	196.6
Non-GAAP COGS	$ 258.9	$ 126.2	$ 769.7	$ 506.8
GAAP other income (expense), net	$ 174.7	$ 177.9	$ 152.2	$ 119.9
(Gains) losses on investments, net	(58.1)	(80.5)	266.4	36.8
Non-GAAP other income (expense), net	$ 116.6	$ 97.4	$ 418.6	$ 156.7
GAAP net income	$ 1,159.6	$ 1,197.1	$ 3,953.6	$ 4,338.4
Total of GAAP to non-GAAP reconciling items above	252.0	309.8	1,347.7	1,016.8
Income tax effect of GAAP to non-GAAP reconciling items	(45.3)	(57.9)	(256.8)	(191.3)
Non-GAAP net income	$ 1,366.3	$ 1,449.0	$ 5,044.5	$ 5,163.9
Non-GAAP net income per share - basic	$ 12.82	$ 13.54	$ 47.28	$ 48.22
Non-GAAP net income per share - diluted	$ 11.86	$ 12.56	$ 43.79	$ 44.98
Shares used in calculating:				
Non-GAAP net income per share - basic	106.6	107.0	106.7	107.1
Non-GAAP net income per share - diluted	115.2	115.4	115.2	114.8

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue reconciliation:				
Total revenues	$ 3,434.3	$ 3,414.4	$ 13,117.2	$ 12,172.9
Global gross profit payment from Roche in connection with sales of Ronapreve	2.1	396.4	224.3	627.3
Other	(3.8)	—	(13.3)	—
Total revenues excluding Ronapreve	$ 3,436.0	$ 3,018.0	$ 12,906.2	$ 11,545.6
Effective tax rate reconciliation:				
GAAP ETR	(1.0%)	9.6%	5.9%	10.7%
Income tax effect of GAAP to non-GAAP reconciling items	3.4%	1.7%	3.2%	1.4%
Non-GAAP ETR	2.4%	11.3%	9.1%	12.1%

	Year Ended December 31,	
	2023	2022
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 4,594.0	$ 5,014.9
Capital expenditures	(718.6)	(590.1)
Free cash flow	$ 3,875.4	$ 4,424.8

TABLE 4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Sanofi collaboration revenue:				
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 885.9	$ 619.0	$ 3,136.5	$ 2,082.0
Sales-based milestones earned	—	50.0	50.0	100.0
Reimbursement for manufacturing of commercial supplies	107.0	166.9	613.0	633.7
Other	—	—	—	28.7
Immuno-oncology	—	—	—	11.3
Total Sanofi collaboration revenue	992.9	835.9	3,799.5	2,855.7
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	345.4	324.0	1,376.4	1,317.4
Reimbursement for manufacturing of ex-U.S. commercial supplies	31.4	31.1	111.1	91.4
One-time payment in connection with change in Japan arrangement	—	—	—	21.9
Total Bayer collaboration revenue	376.8	355.1	1,487.5	1,430.7
Other collaboration revenue:				
Global gross profit payment from Roche in connection with sales of Ronapreve	2.1	396.4	224.3	627.3
Other	(1.8)	—	(8.2)	0.4
Total collaboration revenue	$ 1,370.0	$ 1,587.4	$ 5,503.1	$ 4,914.1

TABLE 5

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

	Three Months Ended December 31,						
	2023			2022			% Change
	U.S.	ROW[g]	Total	U.S.	ROW	Total	(Total Sales)
EYLEA HD[a]	$ 123.1	$ —	$ 123.1	$ —	$ —	$ —	*
EYLEA[a]	$ 1,337.5	$ 889.6	$ 2,227.1	$ 1,496.4	$ 838.6	$ 2,335.0	(5%)
Total EYLEA HD and EYLEA	$ 1,460.6	$ 889.6	$ 2,350.2	$ 1,496.4	$ 838.6	$ 2,335.0	1%
Dupixent[b]	$ 2,486.0	$ 730.1	$ 3,216.1	$ 1,936.3	$ 512.6	$ 2,448.9	31%
Libtayo[c]	$ 154.8	$ 89.0	$ 243.8	$ 110.0	$ 58.8	$ 168.8	44%
Praluent[d]	$ 61.3	$ 125.9	$ 187.2	$ 35.5	$ 97.9	$ 133.4	40%
REGEN-COV[e]	$ —	$ 5.6	$ 5.6	$ —	$ 1,088.4	$ 1,088.4	(99%)

Kevzara[b]	$ 66.2	$ 46.0	$ 112.2	$ 46.6	$ 34.6	$ 81.2	38%
Other products[f]	$ 86.5	$ 18.5	$ 105.0	$ 16.6	$ 15.0	$ 31.6	232%

	Year Ended December 31,						
	2023			2022			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA HD[a]	$ 165.8	$ —	$ 165.8	$ —	$ —	$ —	*
EYLEA[a]	$ 5,719.6	$ 3,495.2	$ 9,214.8	$ 6,264.6	$ 3,382.8	$ 9,647.4	(4%)
Total EYLEA HD and EYLEA	$ 5,885.4	$ 3,495.2	$ 9,380.6	$ 6,264.6	$ 3,382.8	$ 9,647.4	(3%)
Dupixent[b]	$ 8,855.6	$ 2,732.5	$ 11,588.1	$ 6,668.0	$ 2,013.2	$ 8,681.2	33%
Libtayo[c]	$ 538.8	$ 330.0	$ 868.8	$ 374.5	$ 203.5	$ 578.0	50%
Praluent[d]	$ 182.4	$ 456.5	$ 638.9	$ 130.0	$ 337.4	$ 467.4	37%
REGEN-COV[e]	$ —	$ 618.8	$ 618.8	$ —	$ 1,769.6	$ 1,769.6	(65%)
Kevzara[b]	$ 214.7	$ 171.2	$ 385.9	$ 199.7	$ 158.3	$ 358.0	8%
Other products[f]	$ 150.5	$ 67.4	$ 217.9	$ 56.1	$ 69.1	$ 125.2	74%

* Percentage not meaningful

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

[b] Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits 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 for the years ended December 31, 2023 and 2022 is approximately $6 million and $34 million, respectively, and for the fourth quarter of 2022 approximately $17 million, of net product sales recorded by Sanofi in connection with sales in certain markets outside the United States (Sanofi recorded net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 had been 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] Roche records net product sales outside the United States; the parties share gross profits from sales 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 2023 Financial Results" section above for a complete listing of net product sales recorded by the Company.

[g] Rest of world (ROW)

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Source: Regeneron Pharmaceuticals, Inc.