Regeneron Reports Fourth Quarter and Full Year 2024 Financial and Operating Results; Initiates Quarterly Dividend and Increases Total Share Repurchase Capacity to ~$4.5 Billion

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- *Fourth quarter 2024 revenues increased 10% to $3.79 billion versus fourth quarter 2023*
- *Full year 2024 revenues increased 8% to $14.20 billion versus 2023; excluding Ronapreve[TM(a)(b)], revenues increased 10%*
- *Fourth quarter 2024 Dupixent® global net sales (recorded by Sanofi) increased 15% to $3.70 billion versus fourth quarter 2023; full year 2024 Dupixent global net sales increased 22% to $14.15 billion versus 2023*
- *Fourth quarter 2024 U.S. net sales for EYLEA HD® and EYLEA® increased 2% versus fourth quarter 2023 to $1.50 billion, including $305 million from EYLEA HD; full year 2024 U.S. net sales for EYLEA HD and EYLEA increased 1% versus 2023 to $5.97 billion versus 2023, including $1.20 billion from EYLEA HD*
- *Fourth quarter 2024 Libtayo® global net sales increased 50% to $367 million versus fourth quarter 2023; full year 2024 Libtayo global net sales increased 40% to $1.22 billion versus 2023*
- *Fourth quarter 2024 GAAP diluted EPS of $8.06 and non-GAAP diluted EPS[(a)] of $12.07; fourth quarter 2024 includes unfavorable $0.11 impact from acquired IPR&D charge*
- *Initiation of quarterly cash dividend program, $0.88 dividend declared; additional $3.0 billion share repurchase program authorized, bringing current repurchase capacity to ~$4.5 billion*
- *Regulatory applications submitted to FDA for EYLEA HD pre-filled syringe, Dupixent in bullous pemphigoid, odronextamab in follicular lymphoma, and linvoseltamab in multiple myeloma*
- *Positive Phase 3 results reported for EYLEA HD in retinal vein occlusion (RVO) and Libtayo in high-risk adjuvant cutaneous squamous cell carcinoma (CSCC)*

TARRYTOWN, N.Y., Feb. 04, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2024 and provided a business update.

"Regeneron's financial and commercial strength allows for continued investment in our industry-leading R&D pipeline, while simultaneously returning capital to our shareholders through our newly initiated dividend program and increased share repurchase capacity," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "In 2025, we will continue to focus on our four blockbuster medicines as we progress our approximately 40 investigational candidates covering dozens of disease states with expansive market potential."

Financial Highlights

($ in millions, except per share data)	Q4 2024	Q4 2023	% Change	FY 2024	FY 2023	% Change
Total revenues	$ 3,789	$ 3,434	10%	$ 14,202	$ 13,117	8%
GAAP net income	$ 918	$ 1,160	(21%)	$ 4,413	$ 3,954	12%
GAAP net income per share - diluted	$ 8.06	$ 10.19	(21%)	$ 38.34	$ 34.77	10%
Non-GAAP net income[(a)]	$ 1,390	$ 1,366	2%	$ 5,319	$ 5,045	5%
Non-GAAP net income per share - diluted[(a)]	$ 12.07	$ 11.86	2%	$ 45.62	$ 43.79	4%

"2024 was another year of top- and bottom-line growth for Regeneron. This strong financial performance, coupled with the strength of our balance sheet, allows us to initiate a quarterly cash dividend program as well as increase our current share repurchase capacity to approximately $4.5 billion," said Christopher Fenimore, Executive Vice President, Finance and Chief Financial Officer of Regeneron.

Business Highlights

Key Pipeline Progress
Regeneron has approximately 40 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

- The Company announced that the primary endpoint was met in the Phase 3 QUASAR trial investigating EYLEA HD for the

treatment of patients with macular edema following RVO, including those with central, branch, and hemiretinal vein occlusions. In the trial, patients treated with EYLEA HD every 8 weeks (after initial monthly doses) experienced non-inferior vision gains compared to those treated with the approved monthly dosing regimen of EYLEA, the current standard of care. The Company plans to submit a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) in the first quarter of 2025.
- A regulatory application for a pre-filled syringe was submitted to the FDA, with an FDA decision expected by mid-2025.

Dupixent (dupilumab)

- In November 2024, the European Commission (EC) approved Dupixent to treat eosinophilic esophagitis (EoE) in children aged 1 to 11 years, making Dupixent the first and only medicine indicated to treat these young patients.
- The FDA accepted for review the resubmission of an sBLA for Dupixent to treat adults and adolescents aged 12 years and older with chronic spontaneous urticaria (CSU) whose disease is not adequately controlled with H1 antihistamine treatment, with a target action date of April 18, 2025.
- An sBLA for Dupixent in bullous pemphigoid was submitted to the FDA.
- A Phase 3 study in lichen simplex chronicus was initiated.

Libtayo (cemiplimab)

- The Company announced positive results from a Phase 3 trial of Libtayo, which demonstrated that adjuvant treatment with Libtayo was the first and only immunotherapy that led to a statistically significant and clinically meaningful improvement in the primary endpoint of disease-free survival (DFS) in patients with high-risk CSCC after surgery.
- A Phase 3 study of Libtayo administered intralesionally in patients with early-stage CSCC was initiated.

Hematology Programs

- In January 2025, the Company resubmitted to the FDA the BLA for linvoseltamab, a bispecific antibody targeting BCMA and CD3, in relapsed/refractory (R/R) multiple myeloma following resolution of third-party manufacturing issues.
- In January 2025, the Company resubmitted to the FDA the BLA for odronextamab, a bispecific antibody targeting CD20 and CD3, in R/R follicular lymphoma.
- The Company presented new and updated data for odronextamab spanning several B-cell non-Hodgkin lymphoma (B-NHL) subtypes across earlier lines of treatment at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition.
- The Company announced positive Phase 2 results for two antibodies targeting distinct domains of Factor XI. REGN7508 (catalytic domain) is designed to maximize anticoagulant activity while minimizing bleeding risk, and REGN9933 (A2 domain) is designed to provide an additional option for patients with the highest bleeding risk who would otherwise not be candidates for currently available anticoagulants. Per the Phase 2 results, there was a robust antithrombotic effect for each antibody, and no clinically relevant bleeding was observed.
- The Company announced positive updated data from a Phase 3 study of pozelimab (C5 antibody), in combination with cemdisiran (siRNA therapy), against ravulizumab, a standard-of-care C5 inhibitor, in patients with paroxysmal nocturnal hemoglobinuria (PNH). The study showed that the combination treatment helped patients achieve and maintain greater disease control, compared to ravulizumab. These results were presented at the 66th ASH Annual Meeting and Exposition.

Other Programs

- The EC approved Kevzara® (sarilumab) for the treatment of polymyalgia rheumatica (PMR) and polyarticular juvenile idiopathic arthritis (pJIA).
- A Phase 3 study for mibavademab, an agonist antibody to leptin receptor (LEPR), in generalized lipodystrophy was initiated.
- Enrollment was completed in a Phase 2 study in obesity for trevogrumab, an antibody to myostatin (GDF8), in combination with semaglutide with and without garetosmab, an antibody to Activin A.
- A Phase 2 study for itepekimab, an antibody to IL-33, in chronic rhinosinusitis without nasal polyposis (CRSsNP) was initiated.
- A Phase 2 study for REGN7544, an antagonist antibody to NPR1, in postural orthostatic tachycardia syndrome (POTS) was initiated.
- The Company shared initial data from the first patient in a Phase 1 study of linvoseltamab, in combination with Dupixent, in severe food allergy at the 43rd Annual J.P. Morgan Healthcare Conference.

Corporate and Business Development Updates

- In February 2025, the Company's board of directors approved the initiation of a quarterly cash dividend program and declared a cash dividend of $0.88 per share on the Company's common stock and Class A stock, payable on March 20, 2025 to shareholders of record as of February 20, 2025. The Company intends to pay a cash dividend on a quarterly basis going forward, subject to market conditions and approval by the Company's board of directors in its sole discretion.
- In February 2025, the Company's board of directors also authorized an additional $3.0 billion share repurchase program, bringing the total current capacity to approximately $4.5 billion. 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.

- In January 2025, the Company entered into an agreement with Truveta Inc. pursuant to which the Company will sequence exomes and conduct genotyping and imputation of up to ten million de-identified consented volunteers using biospecimens provided by Truveta health system members across the United States.
- The Company announced its inclusion on the Dow Jones Sustainability World Index (DJSI World) for the sixth consecutive year, as well as its fifth consecutive inclusion on the Dow Jones Sustainability North America Index (DJSI North America).

Select Upcoming 2025 Milestones

Programs	Milestones
EYLEA HD	- Submit sBLA in RVO (first quarter 2025) and FDA decision on sBLA (second half 2025) - FDA decision for pre-filled syringe (mid-2025) - FDA decision on sBLA with two-year data for wet age-related macular degeneration (wAMD) and diabetic macular edema (DME) (target action date of April 20, 2025) - Submit sBLA for every 4-week dosing regimen (first quarter 2025) and FDA decision on sBLA (second half 2025)
Immunology & Inflammation	- Report results from Phase 3 study for itepekimab (IL-33 antibody) in chronic obstructive pulmonary disease (COPD) (second half 2025) and submit BLA (second half 2025) - FDA decision on sBLA for Dupixent in CSU (target action date of April 18, 2025) - sBLA acceptance for Dupixent in bullous pemphigoid (first half 2025) and FDA decision on sBLA (second half 2025); regulatory submission in European Union (EU) (first half 2025) - Initiate additional Phase 3 studies for itepekimab (IL-33 antibody) (first half 2025) - Report additional data from Phase 1 study for linvoseltamab (BCMA and CD3 bispecific antibody) in combination with Dupixent in severe food allergies
Solid Organ Oncology	- Submit sBLA for Libtayo in adjuvant CSCC (first half 2025) - Report results from Phase 3 study of fianlimab (LAG-3 antibody), in combination with Libtayo, versus pembrolizumab in first-line metastatic melanoma (second half 2025) and submit BLA (second half 2025) - Report initial Phase 2 data for fianlimab (LAG-3 antibody) in combination with Libtayo in first-line advanced non-small cell lung cancer (NSCLC) (first half 2025) - Report additional data for ubamatamab (MUC16 and CD3 bispecific antibody) in ovarian cancer - Report additional data from solid tumor costimulatory bispecific antibody programs
Hematology	- FDA decision on BLA for odronextamab (CD20 and CD3 bispecific antibody) in R/R follicular lymphoma (second half 2025) - FDA decision on BLA for linvoseltamab (BCMA and CD3 bispecific antibody) in R/R multiple myeloma (mid-2025) - Initiate Phase 3 program for Factor XI antibodies (REGN9933 and REGN7508)
Genetic Medicines	- Report additional data from Phase 1/2 study for DB-OTO (AAV-based gene therapy) in patients with hearing deficit due to variants of the otoferlin gene (mid-2025) - Report results from Phase 3 study for pozelimab (C5 antibody) in combination with cemdisiran in myasthenia gravis (second half 2025)
Internal Medicine	- Report results from Phase 2 study for semaglutide in combination with trevogrumab (myostatin antibody) with and without garetosmab (Activin A antibody) in obesity (second half 2025) - Report results from Phase 2 study for mibavademab (LEPR agonist antibody) in combination with tirzepatide in obesity (second half 2025) - Report results from Phase 3 study for garetosmab (Activin A antibody) in fibrodysplasia ossificans progressiva (FOP) (second half 2025)

Fourth Quarter and Full Year 2024 Financial Results

Revenues

($ in millions)	Q4 2024	Q4 2023	% Change	FY 2024	FY 2023	% Change
Net product sales:						
EYLEA HD - U.S.	$ 305	$ 123	148%	$ 1,201	$ 166	*
EYLEA - U.S.	1,190	1,338	(11%)	4,767	5,720	(17%)
Total EYLEA HD and EYLEA - U.S.	1,495	1,461	2%	5,968	5,886	1%
Libtayo - Global	367	244	50%	1,217	863	41%
Praluent®- U.S.	63	61	3%	242	182	33%
Evkeeza®- U.S.	38	24	58%	126	77	64%
Inmazeb®- U.S.	40	62	(35%)	76	70	9%

Total net product sales	2,003	1,852	8%	7,629	7,078	8%
Collaboration revenue:						
Sanofi	1,213	993	22%	4,531	3,800	19%
Bayer	377	377	—%	1,499	1,487	1%
Other	17	—	*	28	216	(87%)
Other revenue	179	212	(16%)	515	536	(4%)
Total revenues	$ 3,789	$ 3,434	10%	$ 14,202	$ 13,117	8%
Total revenues excluding Ronapreve[a]	$ 3,789	$ 3,436	10%	$ 14,201	$ 12,906	10%

* Percentage not meaningful

EYLEA HD was approved by the FDA in August 2023 and net product sales in 2024 were driven by the transition of patients from other anti-VEGF products, including EYLEA, as well as new patients naïve to anti-VEGF therapy. Net product sales of EYLEA HD and EYLEA in the fourth quarter and full year 2024 were adversely impacted by a lower net selling price compared to the same periods of 2023. In addition, fourth quarter 2024 total EYLEA HD and EYLEA net product sales were favorably impacted by approximately $85 million as a result of higher wholesaler inventory levels for EYLEA, partially offset by lower wholesaler inventory levels for EYLEA HD, at the end of the fourth quarter 2024 compared to the end of the third quarter 2024.

Sanofi collaboration revenue increased in the fourth quarter and full year 2024, compared to the same periods of 2023, due to an increase in the Company's share of profits from the commercialization of antibodies, which were $1.043 billion and $886 million in the fourth quarter of 2024 and 2023, respectively, and $3.924 billion and $3.137 billion for full year 2024 and 2023, 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. Sanofi collaboration revenue in 2023 was positively impacted by the recognition of a $50 million sales-based milestone.

Collaboration revenue for full year 2023 included $224 million in connection with the Company's share of global gross profits from sales of Ronapreve by Roche.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

	GAAP		%	Non-GAAP[a]		%
($ in millions)	**Q4 2024**	**Q4 2023**	**Change**	**Q4 2024**	**Q4 2023**	**Change**
Research and development (R&D)	$ 1,412	$ 1,177	20%	$ 1,224	$ 1,031	19%
Acquired in-process research and development (IPR&D)	$ 14	$ 30	(53%)	*	*	n/a
Selling, general, and administrative (SG&A)	$ 792	$ 738	7%	$ 681	$ 622	9%
Cost of goods sold (COGS)	$ 327	$ 307	7%	$ 271	$ 259	5%
Cost of collaboration and contract manufacturing (COCM)	$ 239	$ 210	14%	*	*	n/a
Other operating expense (income), net	$ 16	$ (1)	**	$ —	*	**

	GAAP		%	Non-GAAP[a]		%
	FY 2024	**FY 2023**	**Change**	**FY 2024**	**FY 2023**	**Change**
Research and development	$ 5,132	$ 4,439	16%	$ 4,563	$ 3,919	16%
Acquired in-process research and development	$ 101	$ 186	(46%)	*	*	n/a
Selling, general, and administrative	$ 2,954	$ 2,631	12%	$ 2,544	$ 2,232	14%
Cost of goods sold	$ 1,087	$ 932	17%	$ 898	$ 770	17%
Cost of collaboration and contract manufacturing	$ 883	$ 884	—%	*	*	n/a
Other operating expense (income), net	$ 53	$ (2)	**	$ —	*	**

* GAAP and non-GAAP amounts are equivalent as no non-GAAP adjustments have been recorded.
** Percentage not meaningful

- GAAP and non-GAAP R&D expenses increased in the fourth quarter and full year 2024, compared to the same periods in the prior year, driven by the advancement of the Company's mid- and late-stage clinical pipeline and higher headcount-related costs.
- Acquired IPR&D expense for full year 2024 included a $45 million development milestone in connection with the Company's collaboration agreement with Sonoma Biotherapeutics, Inc. Acquired IPR&D expense for full year 2023 included a $100 million development milestone in connection with the Company's collaboration with Alnylam Pharmaceuticals, Inc.
- GAAP and non-GAAP SG&A expenses increased for full year 2024, compared to full year 2023, due to higher commercialization-related expenses to support the Company's launch of EYLEA HD and higher headcount and headcount-related costs partly related to the Company's international commercial expansion.
- GAAP and non-GAAP COGS increased for full year 2024, compared to full year 2023, primarily due to higher start-up costs for the Company's Rensselaer, New York fill/finish facility.
- GAAP other operating expense (income), net, for the fourth quarter and full year 2024 reflects charges related to the increase in the estimated fair value of the contingent consideration liability recognized in connection with the Company's 2023 acquisition of Decibel Therapeutics, Inc.

Other Financial Information

GAAP other income (expense), net included the recognition of net unrealized losses on equity securities of $213 million in the fourth quarter of 2024, compared to $58 million of net unrealized gains in the fourth quarter of 2023. GAAP other income (expense), net included the recognition of net unrealized gains on equity securities of $118 million for full year 2024, compared to net unrealized losses of $238 million for full year 2023. GAAP and non-GAAP other income (expense), net also included interest income of $711 million for full year 2024, compared to $496 million for full year 2023.

In the fourth quarter and full year 2024, the Company's GAAP effective tax rate (ETR) was 4.2% and 7.7%, respectively, compared to (1.0%) and 5.9% in the fourth quarter and full year 2023, respectively. The GAAP ETR increased in the fourth quarter of 2024, compared to the same period in the prior year, due to a lower benefit from stock-based compensation. In the fourth quarter and full year 2024, the non-GAAP ETR was 9.9% and 9.6%, respectively, compared to 2.4% and 9.1% in the fourth quarter and full year 2023, respectively.

GAAP net income per diluted share was $8.06 in the fourth quarter of 2024, compared to $10.19 in the fourth quarter of 2023. GAAP net income per diluted share was $38.34 for the full year 2024, compared to $34.77 for the full year 2023. Non-GAAP net income per diluted share was $12.07 in the fourth quarter of 2024, compared to $11.86 in the fourth quarter of 2023. Non-GAAP net income per diluted share was $45.62 for the full year 2024, compared to $43.79 for the full year 2023. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

The Company repurchased $976 million and $2.6 billion of shares of its common stock during the fourth quarter and full year 2024, respectively, and recorded the cost of the shares as Treasury Stock.

2025 Financial Guidance[(c)]

The Company's full year 2025 financial guidance consists of the following components:

	2025 Guidance
GAAP R&D	$5.560–$5.795 billion
Non-GAAP R&D[(a)]	$5.000–$5.200 billion
GAAP SG&A	$2.910–$3.095 billion
Non-GAAP SG&A[(a)]	$2.550–$2.700 billion
GAAP gross margin on net product sales[(d)]	84%–85%
Non-GAAP gross margin on net product sales[(a)(d)]	87%–88%
COCM[(e)*]	$1.000–$1.150 billion
Capital expenditures*	$850–$975 million
GAAP effective tax rate	9%–11%
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 2025 GAAP to non-GAAP financial guidance is included below:

($ in millions)	Projected Range Low	High
GAAP R&D	$ 5,560	$ 5,795
Stock-based compensation expense	560	590
Acquisition and integration costs	—	5
Non-GAAP R&D	$ 5,000	$ 5,200
GAAP SG&A	$ 2,910	$ 3,095
Stock-based compensation expense	360	390
Acquisition and integration costs	—	5
Non-GAAP SG&A	$ 2,550	$ 2,700
GAAP gross margin on net product sales	84%	85%
Intangible asset amortization expense	2%	2%
Stock-based compensation expense	1%	1%
Non-GAAP gross margin on net product sales	87%	88%
GAAP ETR	9%	11%
Income tax effect of GAAP to non-GAAP reconciling items	2%	2%
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 operating (income) expense, net, 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 flow, the Company believes that this non-GAAP measure provides a further measure of the Company's ability to generate cash flows from its operations. Additionally, the non-GAAP measures presented are intended to 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 2025 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.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2024 financial and

operating results on Tuesday, February 4, 2025, 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 by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using its proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. Regeneron is shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling Regeneron to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook, or X.

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), Ordspono ™ (odronextamab), itepekimab, fianlimab, garetosmab, linvoseltamab, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), REGN5713-5715, nexiguran ziclumeran (nex-z, NTLA-2001), REGN1908-1909, mibavademab, 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 (including biosimilar versions of Regeneron's Products); 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; changes in laws, regulations, and policies affecting the healthcare industry; 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 on Regeneron's business; and risks

associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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.

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TABLE 1

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

	December 31,	
	2024	**2023**
Assets:		
Cash and marketable securities	$ 17,912.6	$ 16,241.3
Accounts receivable, net	6,211.9	5,667.3
Inventories	3,087.3	2,580.5
Property, plant, and equipment, net	4,599.7	4,146.4
Intangible assets, net	1,148.6	1,038.6
Deferred tax assets	3,314.1	2,575.4
Other assets	1,485.2	830.7
Total assets	$ 37,759.4	$ 33,080.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 4,888.0	$ 3,818.6
Finance lease liabilities	720.0	720.0
Deferred revenue	813.4	585.6
Long-term debt	1,984.4	1,982.9
Stockholders' equity	29,353.6	25,973.1
Total liabilities and stockholders' equity	$ 37,759.4	$ 33,080.2

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,	
	2024	2023	2024	2023
Revenues:				
Net product sales	$ 2,002.9	$ 1,851.8	$ 7,629.2	$ 7,078.0
Collaboration revenue	1,606.9	1,370.0	6,057.8	5,503.1
Other revenue	179.4	212.5	515.0	536.1
	3,789.2	3,434.3	14,202.0	13,117.2
Expenses:				
Research and development	1,412.1	1,177.2	5,132.0	4,439.0
Acquired in-process research and development	13.8	30.0	101.0	186.1
Selling, general, and administrative	792.2	737.7	2,954.4	2,631.3
Cost of goods sold	326.8	306.8	1,087.3	932.1
Cost of collaboration and contract manufacturing	238.6	210.2	883.2	883.7
Other operating expense (income), net	15.5	(0.5)	53.4	(2.1)
	2,799.0	2,461.4	10,211.3	9,070.1
Income from operations	990.2	972.9	3,990.7	4,047.1
Other income (expense):				
Other income (expense), net	(21.6)	193.0	844.4	225.2
Interest expense	(10.5)	(18.3)	(55.2)	(73.0)
	(32.1)	174.7	789.2	152.2
Income before income taxes	958.1	1,147.6	4,779.9	4,199.3
Income tax expense (benefit)	40.4	(12.0)	367.3	245.7
Net income	$ 917.7	$ 1,159.6	$ 4,412.6	$ 3,953.6
Net income per share - basic	$ 8.53	$ 10.88	$ 40.90	$ 37.05
Net income per share - diluted	$ 8.06	$ 10.19	$ 38.34	$ 34.77
Weighted average shares outstanding - basic	107.6	106.6	107.9	106.7
Weighted average shares outstanding - diluted	113.8	113.8	115.1	113.7

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,	
	2024	2023	2024	2023
GAAP R&D	$ 1,412.1	$ 1,177.2	$ 5,132.0	$ 4,439.0
Stock-based compensation expense	174.7	132.7	543.8	488.7
Acquisition and integration costs	13.8	13.6	24.9	31.3
Non-GAAP R&D	$ 1,223.6	$ 1,030.9	$ 4,563.3	$ 3,919.0
GAAP SG&A	$ 792.2	$ 737.7	$ 2,954.4	$ 2,631.3
Stock-based compensation expense	103.1	82.6	355.0	307.1
Acquisition, integration, and other costs	8.5	33.3	55.2	91.8
Non-GAAP SG&A	$ 680.6	$ 621.8	$ 2,544.2	$ 2,232.4
GAAP COGS	$ 326.8	$ 306.8	$ 1,087.3	$ 932.1

Stock-based compensation expense	26.6	25.1	84.0	89.2
Acquisition and integration costs	0.3	0.9	2.0	2.3
Intangible asset amortization expense	29.1	21.9	103.5	80.9
Charges related to REGEN-COV	—	—	—	(10.0)
Non-GAAP COGS	$ 270.8	$ 258.9	$ 897.8	$ 769.7
GAAP other operating expense (income), net	$ 15.5	$ (0.5)	$ 53.4	$ (2.1)
Change in fair value of contingent consideration	15.5	—	53.4	—
Non-GAAP other operating expense (income), net	$ —	$ (0.5)	$ —	$ (2.1)
GAAP other income (expense), net	$ (32.1)	$ 174.7	$ 789.2	$ 152.2
Losses (gains) on investments, net	212.9	(58.1)	(118.3)	266.4
Non-GAAP other income (expense), net	$ 180.8	$ 116.6	$ 670.9	$ 418.6
GAAP net income	$ 917.7	$ 1,159.6	$ 4,412.6	$ 3,953.6
Total of GAAP to non-GAAP reconciling items above	584.5	252.0	1,103.5	1,347.7
Income tax effect of GAAP to non-GAAP reconciling items	(112.5)	(45.3)	(196.9)	(256.8)
Non-GAAP net income	$ 1,389.7	$ 1,366.3	$ 5,319.2	$ 5,044.5
Non-GAAP net income per share - basic	$ 12.92	$ 12.82	$ 49.30	$ 47.28
Non-GAAP net income per share - diluted	$ 12.07	$ 11.86	$ 45.62	$ 43.79
Shares used in calculating:				
Non-GAAP net income per share - basic	107.6	106.6	107.9	106.7
Non-GAAP net income per share - diluted	115.1	115.2	116.6	115.2

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Revenue reconciliation:				
Total revenues	$ 3,789.2	$ 3,434.3	$ 14,202.0	$ 13,117.2
Regeneron's share of profits in connection with Roche sales of Ronapreve	—	2.1	1.4	224.3
Other - Ronapreve	—	(3.8)	—	(13.3)
Total revenues excluding Ronapreve	$ 3,789.2	$ 3,436.0	$ 14,200.6	$ 12,906.2
Effective tax rate reconciliation:				
GAAP ETR	4.2%	(1.0%)	7.7%	5.9%
Income tax effect of GAAP to non-GAAP reconciling items	5.7%	3.4%	1.9%	3.2%
Non-GAAP ETR	9.9%	2.4%	9.6%	9.1%

	Year Ended December 31,	
	2024	**2023**
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 4,420.5	$ 4,594.0
Capital expenditures	(755.9)	(718.6)
Free cash flow	$ 3,664.6	$ 3,875.4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Sanofi collaboration revenue:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 1,042.9	$ 885.9	$ 3,923.5	$ 3,136.5
Sales-based milestones earned	—	—	—	50.0
Reimbursement for manufacturing of commercial supplies	169.7	107.0	607.9	613.0
Total Sanofi collaboration revenue	1,212.6	992.9	4,531.4	3,799.5
Bayer collaboration revenue:				
Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States	348.8	345.4	1,403.3	1,376.4
Reimbursement for manufacturing of ex-U.S. commercial supplies	28.3	31.4	95.7	111.1
Total Bayer collaboration revenue	377.1	376.8	1,499.0	1,487.5
Other collaboration revenue:				
Regeneron's share of profits in connection with Roche sales of Ronapreve	—	2.1	1.4	224.3
Other	17.2	(1.8)	26.0	(8.2)
Total collaboration revenue	$ 1,606.9	$ 1,370.0	$ 6,057.8	$ 5,503.1

TABLE 5

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

	Three Months Ended December 31,						
	2024			**2023**			**% Change**
	U.S.	**ROW[g]**	**Total**	**U.S.**	**ROW**	**Total**	**(Total Sales)**
EYLEA HD and EYLEA[a]	$ 1,495.0	$ 887.9	$ 2,382.9	$ 1,460.6	$ 889.6	$ 2,350.2	1%
Dupixent[b]	$ 2,745.8	$ 951.8	$ 3,697.6	$ 2,486.0	$ 730.1	$ 3,216.1	15%
Libtayo[c]	$ 251.2	$ 115.7	$ 366.9	$ 154.8	$ 89.0	$ 243.8	50%
Praluent[d]	$ 62.7	$ 117.7	$ 180.4	$ 61.3	$ 125.9	$ 187.2	(4%)
Kevzara[b]	$ 82.4	$ 52.4	$ 134.8	$ 66.2	$ 46.0	$ 112.2	20%
REGEN-COV[e]	$ —	$ —	$ —	$ —	$ 5.6	$ 5.6	(100%)
Other products[f]	$ 78.5	$ 24.8	$ 103.3	$ 86.5	$ 18.5	$ 105.0	(2%)

	Year Ended December 31,						
	2024			**2023**			**% Change**
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**	**(Total Sales)**
EYLEA HD and EYLEA[a]	$ 5,968.2	$ 3,576.8	$ 9,545.0	$ 5,885.4	$ 3,495.2	$ 9,380.6	2%
Dupixent[b]	$ 10,398.7	$ 3,749.3	$ 14,148.0	$ 8,855.6	$ 2,732.5	$ 11,588.1	22%
Libtayo[c]	$ 787.3	$ 429.5	$ 1,216.8	$ 538.8	$ 330.0	$ 868.8	40%
Praluent[d]	$ 241.7	$ 523.3	$ 765.0	$ 182.4	$ 456.5	$ 638.9	20%

Kevzara[b]	$	270.2	$	188.5	$	458.7	$	214.7	$	171.2	$	385.9	19%
REGEN-COV[e]	$	—	$	3.5	$	3.5	$	—	$	618.8	$	618.8	(99%)
Other products[f]	$	202.9	$	86.5	$	289.4	$	150.5	$	67.4	$	217.9	33%

Note: The table above includes net product sales of Regeneron-discovered products. Such net product sales are recorded by the Company or others, as further described in the footnotes below.

[a] The Company 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 within Collaboration revenue.

[b] Sanofi records global net product sales of Dupixent and Kevzara, and the Company records its share of profits in connection with global sales of such products within Collaboration revenue.

[c] The Company records global net product sales of Libtayo and pays Sanofi a royalty on such sales. Prior to July 1, 2022, Sanofi recorded net product sales of Libtayo outside the United States. Included in this line item for the year ended December 31, 2023 is approximately $6 million of first quarter 2023 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).

[d] The Company 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, which is recorded within Other revenue.

[e] Roche records net product sales outside the United States and the Company records its share of gross profits from sales, which is recorded within Collaboration revenue.

[f] Included in this line item are products which are sold by the Company and others. Refer to "Fourth Quarter and Full Year 2024 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®, which are recorded by Kiniksa.

[g] Rest of world (ROW)

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Source: Regeneron Pharmaceuticals, Inc.