REGENERON

Regeneron Reports Fourth Quarter and Full Year 2012 Financial and Operating Results

February 14, 2013

TARRYTOWN, N.Y., Feb. 14, 2013 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial and operating results for the fourth quarter and full year 2012 and provided an update on development programs.

The Company reported total revenues of $415 million in the fourth quarter and $1.4 billion for the year ended December 31, 2012. Total revenues included EYLEA U.S. net product sales of $276 million in the fourth quarter and $838 million for the full year 2012. Total revenues for the full year included a $50 million milestone payment from Sanofi and $25 million of milestone payments from Bayer HealthCare in connection with regulatory approvals of ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion and EYLEA (aflibercept) Injection for Intravitreal Injection, respectively, as described below.

The Company reported non-GAAP net income of $171 million, or $1.47 per diluted share, in the fourth quarter and $530 million, or $4.66 per diluted share, for the year ended December 31, 2012. Non-GAAP net income excludes non-cash share-based compensation expense, non-cash interest expense related to the Company's convertible senior notes, and a non-cash tax benefit of $336 million recorded during the fourth quarter primarily as a result of releasing substantially all of the valuation allowance associated with the Company's deferred tax assets as of December 31, 2012. The Company reported GAAP net income of $470 million, or $4.08 per diluted share, in the fourth quarter and $750 million, or $6.75 per diluted share, for the full year 2012.

"2012 was truly a transformative year for Regeneron as strong U.S. net sales of EYLEA drove our first full year of profitability on a GAAP and non-GAAP basis," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "With the recent U.S. approval of EYLEA for the treatment of macular edema following central retinal vein occlusion (CRVO), and receipt of a Medicare J-Code for EYLEA in January 2013, we expect continued strong U.S. growth for EYLEA and forecast U.S. net sales of $1.2 billion to $1.3 billion in 2013. Outside the U.S., our partner Bayer HealthCare has begun to launch EYLEA for the treatment of neovascular age-related macular degeneration (wet AMD) in Japan, Europe, Australia, and other regions, and we expect to see substantial sales growth through 2013 and beyond as pricing approvals are received."

"Clinical development of EYLEA in additional indications continued to progress in 2012, as the Phase 3 program in diabetic macular edema (DME) was fully enrolled and a Phase 3 trial in macular edema following branch retinal vein occlusion (BRVO) was initiated," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer, and President, Regeneron Laboratories. "Our pipeline also advanced significantly during 2012, with the roll-out of our broad Phase 3 ODYSSEY program for REGN727, an antibody targeting PCSK9 to reduce low-density lipoprotein (LDL) cholesterol, and the full enrollment of our first Phase 3 trial for sarilumab, our IL-6 receptor antibody in rheumatoid arthritis. We are also encouraged by the potential of our IL-4R inhibitor, REGN668. REGN668 demonstrated positive proof of concept in allergic asthma and atopic dermatitis, and data from these trials will be submitted to medical conferences for presentation later in the year. We look forward to starting later stage, Phase 2b trials with this antibody during 2013."

Business Highlights - Fourth Quarter 2012 and 2013 to Date

EYLEA® (aflibercept) Injection for Intravitreal Injection

- The Company and Bayer HealthCare collaborate on the global development and commercialization of EYLEA outside the United States, and share profits and losses from commercialization of EYLEA outside the United States except for Japan, where the Company receives a royalty on sales. Regeneron maintains exclusive rights to EYLEA in the United States and is entitled to all profits from any such sales.
- In November 2012, Bayer HealthCare received regulatory approval for EYLEA in the European Union for the treatment of patients with wet AMD. In November 2012, Bayer HealthCare received pricing approval for EYLEA in Japan for the treatment of patients with wet AMD.
- Net sales recorded by Bayer HealthCare for EYLEA outside of the United States were $19 million in the fourth quarter of 2012.
- Launches in additional countries are anticipated to continue throughout 2013 as regulatory and pricing approvals are achieved.
- Bayer HealthCare submitted applications for marketing authorization for EYLEA in Europe in December 2012 and in Japan in January 2013 for the treatment of macular edema following CRVO.

ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion

- The Company and Sanofi collaborate on the global development and commercialization of ZALTRAP, and share profits and losses from commercialization of ZALTRAP except for Japan, where the Company receives a royalty on sales. Sales of ZALTRAP in the United States commenced in August 2012, and net sales recorded by Sanofi were $23 million in the fourth quarter and $32 million for the full year of 2012.
- In February 2013, the European Commission (EC) granted marketing authorization in the European Union for ZALTRAP concentrate for solution for infusion in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.
- Marketing authorization applications for ZALTRAP are currently under review by other regulatory agencies worldwide.

Monoclonal Antibodies

- Regeneron has eleven fully human monoclonal antibodies based on the Company's *VelocImmune*® technology in clinical development, including six in collaboration with Sanofi.
- ODYSSEY, a large, global Phase 3 program with REGN727, an antibody targeting PCSK9 to reduce LDL cholesterol, was initiated in June 2012 and is currently enrolling patients. The Company expects to report initial results from a Phase 3 ODYSSEY trial in the second half of 2013.
- REGN668, an antibody targeting IL-4R, demonstrated positive proof of concept in allergic asthma and atopic dermatitis. Data in atopic dermatitis will be presented at the 71st Annual Meeting of the American Academy of Dermatology in March 2013. Data in allergic asthma will be submitted to medical conferences for presentation later in the year.
- REGN1500, an antibody against an undisclosed target that is being developed outside of the Sanofi collaboration, entered clinical

development.

Fourth Quarter and Full Year 2012 Financial Results

Total Revenues: Total revenues were $415 million in the fourth quarter and $1.4 billion for the full year 2012, compared to $123 million in the fourth quarter and $446 million for the full year 2011. Total revenues include collaboration revenues of $127 million in the fourth quarter and $494 million for the full year 2012, compared to $86 million in the fourth quarter and $370 million for the full year 2011. Included in collaboration revenues in 2012 were $15 million and $10 million substantive milestone payments from Bayer HealthCare which the Company earned in the third quarter and fourth quarter of 2012, respectively, in connection with receipt of marketing and pricing approvals in Japan for EYLEA for the treatment of wet AMD. In addition, the Company earned a $50 million substantive milestone payment from Sanofi in the third quarter of 2012 in connection with FDA approval of ZALTRAP for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen.

Product Revenues: Net product sales were $281 million in the fourth quarter and $858 million for the full year 2012, compared to $30 million in the fourth quarter and $45 million for the full year 2011. The increase was due to the approval and launch of EYLEA in November 2011. EYLEA net product sales were $276 million in the fourth quarter and $838 million for the full year 2012, compared to $25 million for both the fourth quarter and full year 2011. ARCALYST net product sales were $5 million in both the fourth quarters of 2012 and 2011, and $20 million for both the full years 2012 and 2011.

Research and Development (R&D) Expenses: In 2012, GAAP R&D expenses were $181 million in the fourth quarter and $626 million for the full year, compared to $129 million in the fourth quarter and $530 million for the full year 2011. The higher R&D expenses in 2012 were principally due to increased R&D headcount and activities, primarily related to the Company's antibody collaboration with Sanofi, and higher non-cash share-based compensation expense, partly offset by lower EYLEA development costs incurred by Bayer HealthCare. In 2012, R&D related non-cash share-based compensation expense was $18 million for the fourth quarter and $54 million for the full year, compared to $9 million in the fourth quarter and $33 million for the full year 2011.

Selling, General, and Administrative (SG&A) Expenses: In 2012, GAAP SG&A expenses were $58 million in the fourth quarter and $211 million for the full year, compared to $36 million in the fourth quarter and $117 million for the full year 2011. The increase was primarily due to higher selling expenses in connection with commercialization of EYLEA, higher SG&A headcount, and higher non-cash share-based compensation expense. In 2012, SG&A related non-cash share-based compensation expense was $12 million in the fourth quarter and $39 million for the full year, compared to $6 million in the fourth quarter and $23 million for the full year 2011.

Cost of Goods Sold (COGS): In 2012, GAAP COGS was $30 million in the fourth quarter and $84 million for the full year, compared to $3 million in the fourth quarter and $4 million for the full year 2011. The increase in 2012 was due to the launch of EYLEA in the fourth quarter of 2011.

Interest Expense: In 2012, GAAP interest expense was $11 million in the fourth quarter and $45 million for the full year, compared to $9 million in the fourth quarter and $21 million for the full year 2011. In connection with the Company's convertible senior notes, which were issued in October 2011, the Company incurred interest expense of $8 million in the fourth quarter of 2012, and $29 million for the full year 2012, which included $6 million and $22 million of non-cash interest expense, respectively. In both the fourth quarter and full year 2011, the Company incurred interest expense of $5 million related to the Company's convertible senior notes, which included $4 million of non-cash interest expense.

Income Tax Benefit: In the fourth quarter of 2012, the Company recorded a GAAP income tax benefit of $336 million, primarily attributable to the release of substantially all of the valuation allowance associated with the Company's deferred tax assets. The decision to reverse the valuation allowance was made after the Company determined that it was more likely than not that these deferred tax assets would be realized. Due to the release of the valuation allowance in 2012, starting in 2013, the Company will record income taxes on GAAP income using an estimated effective tax rate (which is expected to approximate statutory tax rates). Non-GAAP net income excludes the release of the valuation allowance described above, as well as non-cash income tax expense. The Company does not currently pay, or expect to pay in the near future, significant cash income taxes. When the Company begins paying significant cash income taxes, it expects to no longer exclude non-cash income tax expense from non-GAAP net income.

Non-GAAP and GAAP Net Income (Loss): The Company reported non-GAAP net income of $171 million, or $1.79 per basic share and $1.47 per diluted share, in the fourth quarter of 2012, compared to a non-GAAP net loss of $34 million, or $0.37 per share (basic and diluted), in the fourth quarter of 2011. The Company reported non-GAAP net income of $530 million, or $5.60 per basic share and $4.66 per diluted share, for the full year 2012, compared to a non-GAAP net loss of $162 million, or $1.79 per share (basic and diluted), for the full year 2011. Non-GAAP net income (loss) excludes non-cash share-based compensation expense, non-cash interest expense related to the convertible senior notes, and non-cash income tax expense or benefit.

The Company reported GAAP net income of $470 million, or $4.92 per basic share and $4.08 per diluted share, in the fourth quarter of 2012, compared to a GAAP net loss of $53 million, or $0.58 per share (basic and diluted), in the fourth quarter of 2011. The Company reported GAAP net income of $750 million, or $7.92 per basic share and $6.75 per diluted share, for the full year 2012, compared to a GAAP net loss of $222 million, or $2.45 per share (basic and diluted), for the full year 2011.

Cash Position: At December 31, 2012, cash and marketable securities totaled $588 million (including $8 million of restricted cash and marketable securities), compared to $811 million (including $8 million of restricted cash and marketable securities) at December 31, 2011. In addition, accounts receivable related to sales of EYLEA totaled $592 million at December 31, 2012, compared to $26 million at December 31, 2011.

Use of Non-GAAP Financial Measures: The Company believes that the presentation of non-GAAP measures is useful to investors because it excludes (i) non-cash share-based compensation expense which fluctuates 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, (ii) non-cash interest expense related to the Company's convertible senior notes since this is not deemed useful in evaluating the Company's operating performance, (iii) non-cash income tax expense, since the Company does not currently pay, or expect to pay in the near future, significant cash income taxes due primarily to the utilization of net operating loss and tax credit carry-forwards; therefore, non-cash income tax expense is not deemed useful in evaluating the Company's operating performance, and (iv) a non-cash tax benefit as a result of releasing substantially all of the valuation allowance associated with the Company's deferred tax assets. Furthermore, 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. However, there are limitations in the use of these 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. The non-GAAP financial measures should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2012 financial and operating results on Thursday, February 14, 2013, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International). A link to the webcast may be accessed from the 'Events and Presentations' page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for 30 days.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

Regeneron Forward-Looking Statement

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept); unforeseen safety issues resulting from the administration of products and product candidates in patients; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; 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 product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any further product success; and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2011 and its Form 10-Q for the quarter ended September 30, 2012. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise, unless required by law.

This news release and/or the financial results attached to this news release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of these measures.

Contacts Information:

Michael Aberman, M.D.	Peter Dworkin
Investor Relations	Corporate Communications
914.847.7799	914.847.7640
michael.aberman@regeneron.com	peter.dworkin@regeneron.com

TABLE 1

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

	December 31, 2012	December 31, 2011
ASSETS		
Cash, restricted cash, and marketable securities	$ 587,511	$ 810,550
Accounts receivable - trade, net	593,207	28,254
Accounts receivable from Sanofi	99,913	74,781
Deferred tax assets	340,156	
Property, plant, and equipment, net	379,940	367,955
Other assets	79,763	42,043
Total assets	$ 2,080,490	$ 1,323,583
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$ 118,604	$ 102,068
Deferred revenue	259,173	300,250
Facility lease obligations	160,810	160,514
Convertible senior notes	296,518	275,019
Stockholders' equity	1,245,385	485,732
Total liabilities and stockholders' equity	$ 2,080,490	$ 1,323,583

TABLE 2

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended December 31,		Year ended December 31,	
	2012	2011	2012	2011
Revenues:				

Net product sales	$ 281,471	$ 29,752	$ 858,093	$ 44,686
Sanofi collaboration revenue	104,779	77,032	423,814	326,609
Bayer HealthCare collaboration revenue	21,791	9,374	70,099	43,072
Technology licensing	5,892	5,892	23,571	24,858
Contract research and other	669	927	2,900	6,599
	414,602	122,977	1,378,477	445,824
Expenses:				
Research and development	181,024	129,041	625,554	529,506
Selling, general, and administrative	57,739	36,349	210,755	117,261
Cost of goods sold	30,169	2,989	84,455	4,216
	268,932	168,379	920,764	650,983
Income (loss) from operations	145,670	(45,402)	457,713	(205,159)
Other income (expense):				
Investment income	384	799	2,012	3,549
Interest expense	(11,495)	(9,455)	(45,304)	(21,282)
	(11,111)	(8,656)	(43,292)	(17,733)
Income (loss) before income taxes	134,559	(54,058)	414,421	(222,892)
Income tax benefit	335,848	615	335,848	1,132
Net income (loss)	$ 470,407	$ (53,443)	$ 750,269	$ (221,760)
Net income (loss) per share - basic	$ 4.92	$ (0.58)	$ 7.92	$ (2.45)
Net income (loss) per share - diluted	$ 4.08	$ (0.58)	$ 6.75	$ (2.45)
Weighted average shares outstanding - basic	95,691	91,797	94,685	90,610
Weighted average shares outstanding - diluted	117,237	91,797	115,382	90,610

TABLE 3

REGENERON PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP NET INCOME (LOSS) TO NON-GAAP NET INCOME (LOSS) (Unaudited)
(In thousands, except per share data)

	Three months ended December 31,		Year ended December 31,	
	2012	**2011**	**2012**	**2011**
GAAP net income (loss)	$ 470,407	$ (53,443)	$ 750,269	$ (221,760)
Adjustments:				
R&D: Non-cash share-based compensation expense (1)	18,498	9,198	53,833	32,757
SG&A: Non-cash share-based compensation expense (1)	11,851	6,314	39,249	23,315
COGS: Non-cash share-based compensation expense (1)	422		1,075	
Interest expense: Non-cash interest related to convertible senior notes (2)	5,591	3,944	21,623	3,944
Income taxes: Non-cash income tax expense (3)	4,308		4,308	
Income taxes: Release of valuation allowance (4)	(340,156)		(340,156)	
Non-GAAP net income (loss)	$ 170,921	$ (33,987)	$ 530,201	$ (161,744)
Non-GAAP net income (loss) per share - basic	$ 1.79	$ (0.37)	$ 5.60	$ (1.79)
Non-GAAP net income (loss) per share - diluted	$ 1.47 (5)	$ (0.37)	$ 4.66 (5)	$ (1.79)
Shares used in calculating:				
Non-GAAP net income (loss) per share - basic	95,691	91,797	94,685	90,610
Non-GAAP net income (loss) per share - diluted (6)	117,237	91,797	115,382	90,610

(1) To exclude non-cash compensation expense related to employee stock option and restricted stock awards

(2) To exclude non-cash interest expense related to the amortization of the debt discount and debt issuance costs on the Company's 1.875% convertible senior notes

(3) To exclude GAAP income tax expense as this amount is not payable in cash

(4) To exclude non-cash tax benefit related to releasing substantially all of the valuation allowance associated with the Company's deferred tax assets

(5) For diluted non-GAAP per share calculations, excludes $1.9 million of interest expense for the three months ended December 31, 2012 and $7.5 million of interest expense for the year ended December 31, 2012, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

(6) For periods with non-GAAP net income, weighted average shares outstanding includes the dilutive effect, if any, of employee stock options, restricted stock awards, convertible senior notes, and warrants

SOURCE Regeneron Pharmaceuticals, Inc.