



Regeneron Reports Third Quarter 2012 Financial and Operating Results

October 24, 2012

TARRYTOWN, N.Y., Oct. 24, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) today announced financial and operating results for the third quarter of 2012 and provided an update on development programs.

The Company reported total revenues of \$428 million in the third quarter and \$964 million in the first nine months of 2012. Total revenues included EYLEA net product sales of \$244 million in the third quarter and \$562 million in the first nine months of 2012. Total revenues also included a \$50 million milestone payment from Sanofi and a \$15 million milestone payment from Bayer HealthCare in connection with regulatory approvals of ZALTRAP and EYLEA, respectively, as described below. The Company reported non-GAAP net income of \$217 million, or \$1.89 per diluted share, in the third quarter and \$359 million, or \$3.19 per diluted share, in the first nine months of 2012. Non-GAAP net income excludes non-cash share-based compensation expense and non-cash interest expense related to the Company's convertible senior notes. The Company reported GAAP net income of \$191 million, or \$1.72 per diluted share, in the third quarter and \$280 million, or \$2.55 per diluted share, in the first nine months of 2012.

"The EYLEA launch continues to progress well and is driving strong sales and earnings growth. We now forecast 2012 U.S. EYLEA net product sales of \$790 to \$815 million," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "With the recent approval of EYLEA in the United States for the treatment of macular edema following central retinal vein occlusion (CRVO), and the anticipated launch beginning by the end of this year in Japan, Australia, and Europe, we expect EYLEA to continue to drive growth through 2013 and beyond. In addition, we and Sanofi have announced the roll-out of our broad Phase 3 ODYSSEY program for REGN727, our cholesterol-lowering PCSK9 antibody, and the Phase 3 program for sarilumab, our IL-6 receptor antibody, in rheumatoid arthritis."

Third Quarter and October 2012 Business Highlights

EYLEA® (afibercept) Injection for Intravitreal Injection

- The Company and Bayer HealthCare collaborate on the global development and commercialization of EYLEA outside the United States. In September 2012, Bayer HealthCare received approval for EYLEA in Japan for the treatment of patients with neovascular age-related macular degeneration (wet AMD). In addition, in October 2012, Bayer HealthCare received approval for EYLEA in Brazil for the treatment of patients with wet AMD. Marketing approval was also received in Australia and Colombia earlier in the year.
- In September 2012, the European Committee for Medicinal Products for Human Use (CHMP) recommended approval of EYLEA to the European Medicines Agency (EMA) for wet AMD and final approval is anticipated by the end of the year.
- Launches in all of these countries are anticipated beginning later this year and continuing into 2013.
- In September 2012, EYLEA was also approved in the United States 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. Following a Priority Review, in August 2012, the U.S. Food and Drug Administration (FDA) approved ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), for patients with metastatic colorectal cancer (mCRC) who are resistant or have progressed following an oxaliplatin-containing regimen. Sales of ZALTRAP in the United States commenced in August 2012, and net sales recorded by Sanofi were \$8 million in the third quarter of 2012.
- Marketing authorization applications for ZALTRAP are currently under review by the EMA and other regulatory agencies worldwide.
- A Phase 1 study was initiated in September 2012, combining ZALTRAP with the Company's angiopoietin-2 inhibitor (REGN910) in patients with advanced malignancies.

ARCALYST® (rilonacept)

- In July 2012, the FDA issued a Complete Response Letter for the supplemental biologics license application (sBLA) for ARCALYST Injection for Subcutaneous Use for the prevention of gout flares in patients initiating uric acid-lowering therapy. The Company has discontinued development of ARCALYST for gout.

Monoclonal Antibodies

- Regeneron has ten fully human monoclonal antibodies based on the Company's *VelocImmune*® technology in clinical development, including six in collaboration with Sanofi.
- Following discussions with U.S. and E.U. regulatory authorities, ODYSSEY, a large, global Phase 3 program with REGN727, an investigational drug targeting PCSK9 to reduce low-density lipoprotein (LDL) cholesterol, was initiated in

June 2012. The ODYSSEY program will include over ten clinical trials and will test the safety and efficacy of REGN727 in multiple treatment strategies and patient types. The ODYSSEY OUTCOMES trial, assessing reduction in serious cardiovascular events, and several other trials in the ODYSSEY program, are currently enrolling patients.

- An additional Phase 3 trial, SARIL-RA-TARGET, was initiated in the global SARIL-RA Phase 3 program of sarilumab for the treatment of moderate-to-severe rheumatoid arthritis. The first Phase 3 trial in this program, SARIL-RA-MOBILITY, reached full enrollment during the quarter.
- REGN1400, an antibody against ErbB3 that is being developed outside of the Sanofi collaboration, entered clinical development for oncology.

Third Quarter 2012 Financial Results

Total Revenues: Total revenues were \$428 million in the third quarter of 2012, compared to \$103 million in the third quarter of 2011. Total revenues include collaboration revenues of \$172 million in the third quarter of 2012, and \$90 million in the third quarter of 2011. Included in collaboration revenues in the third quarter of 2012 was a \$50 million substantive milestone payment from Sanofi which the Company earned in connection with FDA approval of ZALTRAP for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, and a \$15 million substantive milestone payment from Bayer HealthCare which the Company earned in connection with receipt of marketing approval in Japan for EYLEA for the treatment of wet AMD.

Product Revenues: Net product sales were \$249 million in the third quarter of 2012, compared to \$5 million in the third quarter of 2011. The increase was due to the approval and launch of EYLEA in November 2011. EYLEA net product sales were \$244 million in the third quarter of 2012. ARCALYST net product sales were \$5 million in both the third quarter of 2012 and 2011.

Research and Development (R&D) Expenses: GAAP R&D expenses were \$158 million in the third quarter of 2012, compared to \$128 million in the third quarter of 2011. The increase in 2012 was primarily 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 the third quarter of 2012, R&D related non-cash share-based compensation expense was \$13 million, compared to \$8 million in the third quarter of 2011.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$47 million in the third quarter of 2012, compared to \$33 million in the third quarter of 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 the third quarter of 2012, SG&A related non-cash share-based compensation expense was \$7 million, compared to \$5 million in the third quarter of 2011.

Cost of Goods Sold (COGS): GAAP COGS was \$20 million in the third quarter of 2012, compared to approximately \$500,000 in the third quarter of 2011. The increase in 2012 was due to the launch of EYLEA in the fourth quarter of 2011.

Interest Expense: GAAP interest expense was \$11 million in the third quarter of 2012, compared to \$4 million in the third quarter of 2011. In the third quarter of 2012, interest expense included \$2 million of cash interest expense and \$5 million of non-cash interest expense related to the Company's convertible senior notes, which were issued in October 2011.

Non-GAAP and GAAP Net Income (Loss): The Company reported non-GAAP net income of \$217 million, or \$2.29 per basic share and \$1.89 per diluted share, in the third quarter of 2012, compared to a non-GAAP net loss of \$49 million, or \$0.54 per share (basic and diluted), in the third quarter of 2011. Non-GAAP net income (loss) excludes non-cash share-based compensation expense and non-cash interest expense related to the convertible senior notes.

The Company reported GAAP net income of \$191 million, or \$2.02 per basic share and \$1.72 per diluted share, in the third quarter of 2012, compared to a GAAP net loss of \$62 million, or \$0.68 per share (basic and diluted), in the third quarter of 2011.

Cash Position: At September 30, 2012, cash and marketable securities totaled \$583 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 \$505 million at September 30, 2012.

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 and (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. 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 third quarter 2012 financial and operating results on Wednesday, October 24, 2012, 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

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the

treatment of serious medical conditions. Regeneron markets three products in the United States, EYLEA[®] (afibercept) Injection, ZALTRAP[®] (ziv-afibercept) Injection for Intravenous Infusion, and ARCALYST[®] (rilonacept) Injection For Subcutaneous Use; ZALTRAP is co-commercialized with Sanofi. Phase 3 studies are in progress with EYLEA in two additional indications and with product candidates sarilumab and REGN727. Regeneron has active research and development programs in many disease areas, including ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information and recent news releases are available on the Regeneron web site at 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[®] (afibercept); 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 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 the reversal of tax valuation allowances; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any 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. 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.

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TABLE 1

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

	September 30, 2012	December 31, 2011
ASSETS		
Cash, restricted cash, and marketable securities	\$ 583,325	\$ 810,550
Accounts receivable - trade, net	506,682	28,254
Accounts receivable from Sanofi	94,589	74,781
Property, plant, and equipment, net	372,917	367,955
Other assets	103,102	42,043
Total assets	<u>\$ 1,660,615</u>	<u>\$ 1,323,583</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	\$ 131,211	\$ 102,068
Deferred revenue	271,645	300,250
Facility lease obligations	160,776	160,514
Convertible senior notes	290,959	275,019
Stockholders' equity	806,024	485,732
Total liabilities and stockholders' equity	<u>\$ 1,660,615</u>	<u>\$ 1,323,583</u>

TABLE 2

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

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Revenues:				
Net product sales	\$ 249,172	\$ 5,468	\$ 576,622	\$ 14,934
Sanofi collaboration revenue	145,042	79,802	319,035	249,577
Bayer HealthCare collaboration revenue	26,701	10,094	48,308	33,698
Technology licensing	5,893	5,893	17,679	18,966
Contract research and other	879	1,576	2,231	5,672
	<u>427,687</u>	<u>102,833</u>	<u>963,875</u>	<u>322,847</u>
Expenses:				
Research and development	158,295	127,924	444,530	400,465
Selling, general, and administrative	46,883	32,916	153,016	80,912
Cost of goods sold	20,145	450	54,286	1,227
	<u>225,323</u>	<u>161,290</u>	<u>651,832</u>	<u>482,604</u>
Income (loss) from operations	<u>202,364</u>	<u>(58,457)</u>	<u>312,043</u>	<u>(159,757)</u>
Other income (expense):				
Investment income	517	715	1,628	2,750
Interest expense	(11,413)	(4,061)	(33,809)	(11,827)
	<u>(10,896)</u>	<u>(3,346)</u>	<u>(32,181)</u>	<u>(9,077)</u>
Income (loss) before income taxes	191,468	(61,803)	279,862	(168,834)
Income tax (expense) benefit		(562)		517
Net income (loss)	<u>\$ 191,468</u>	<u>\$ (62,365)</u>	<u>\$ 279,862</u>	<u>\$ (168,317)</u>
Net income (loss) per share - basic	\$ 2.02	\$ (0.68)	\$ 2.97	\$ (1.87)
Net income (loss) per share - diluted	\$ 1.72	\$ (0.68)	\$ 2.55	\$ (1.87)
Weighted average shares outstanding - basic	95,012	91,046	94,349	90,215
Weighted average shares outstanding - diluted	115,830	91,046	109,781	90,215

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 September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
GAAP net income (loss)	\$ 191,468	\$ (62,365)	\$ 279,862	\$ (168,317)
Adjustments:				
R&D: Non-cash share-based compensation expense ⁽¹⁾	13,337	8,015	35,335	23,560
SG&A: Non-cash share-based compensation expense ⁽¹⁾	7,030	5,349	27,398	17,001
COGS: Non-cash share-based compensation expense ⁽¹⁾	150		652	
Interest expense: Non-cash interest related to convertible senior notes ⁽²⁾	5,499		16,033	
Non-GAAP net income (loss)	<u>\$ 217,484</u>	<u>\$ (49,001)</u>	<u>\$ 359,280</u>	<u>\$ (127,756)</u>
Non-GAAP net income (loss) per share - basic	\$ 2.29	\$ (0.54)	\$ 3.81	\$ (1.42)
Non-GAAP net income (loss) per share - diluted	\$ 1.89 ⁽³⁾	\$ (0.54)	\$ 3.19 ⁽³⁾	\$ (1.42)
Shares used in calculating:				
Non-GAAP net income (loss) per share - basic	95,012	91,046	94,349	90,215
Non-GAAP net income (loss) per share - diluted ⁽⁴⁾	115,830	91,046	114,541	90,215

⁽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) For diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense for the three months ended September 30, 2012 and \$5.6 million of interest expense for the nine months ended September 30, 2012, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

(4) 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.

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