

REGENERON

Regeneron Reports Second Quarter 2012 Financial and Operating Results

July 25, 2012

TARRYTOWN, N.Y., July 25, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial and operating results for the second quarter of 2012 and provided an update on development programs.

The Company reported total revenues of \$304 million in the second quarter and \$536 million in the first half of 2012. Total revenues included EYLEA net product sales of \$194 million in the second quarter and \$318 million in the first half of 2012. The Company reported non-GAAP net income of \$102 million, or \$0.90 per diluted share, in the second quarter and \$142 million, or \$1.28 per diluted share, in the first half 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 \$77 million, or \$0.70 per diluted share, in the second quarter and \$88 million, or \$0.81 per diluted share, in the first half of 2012.

"The EYLEA launch continues to progress extremely well and is driving strong sales and earnings growth," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Based on the results to date, we now forecast 2012 U.S. EYLEA net product sales of \$700 to \$750 million and expect to be profitable for the full year. We look forward to marketing approvals and launch of EYLEA outside the U.S. by our collaborator, Bayer HealthCare, during the second half of the year. We also await the September 23, 2012 PDUFA date for an FDA decision on our application to market EYLEA in the U.S. for the treatment of central retinal vein occlusion (CRVO), which would be in addition to our already approved EYLEA indication in the U.S. for neovascular age-related macular degeneration (wet AMD)."

Second Quarter 2012 Clinical Program Highlights

EYLEA® (afibercept) Injection

- In May 2012, Bayer HealthCare's Japanese subsidiary, Bayer Yakuin, Ltd., and Santen Pharmaceutical Co, Ltd. entered into an agreement to co-promote EYLEA in Japan should marketing approval be achieved. In conjunction with this agreement, Bayer HealthCare and Regeneron amended their existing global license and collaboration agreement for EYLEA to convert the 50/50 profit share for Japan into a royalty arrangement that approximates the economics of the profit split.
- In June 2012, Bayer HealthCare received marketing approval for EYLEA in Colombia for the treatment of patients with wet AMD. Regulatory applications were previously submitted in the European Union, Japan, and other countries for this indication and marketing approval has also been received in Australia.
- Enrollment in the international Phase 3 study in diabetic macular edema (DME) was completed in the second quarter. Enrollment in the U.S. Phase 3 study was completed in the fourth quarter of 2011.
- Regeneron's application to market EYLEA for CRVO in the United States has a PDUFA date of September 23, 2012.

ZALTRAP® (afibercept)

- In June 2012, data from a Phase 3 trial with ZALTRAP were presented at an oral session at the American Society of Clinical Oncology (ASCO) meeting in Chicago.
- The application to market ZALTRAP in the United States for patients previously treated for metastatic colorectal cancer has a PDUFA date of August 4, 2012.

ARCALYST® (rilonacept)

- Regeneron's sBLA for marketing approval of ARCALYST in the United States for the prevention of gout flares in patients initiating uric acid-lowering therapy has a PDUFA date of July 30, 2012. In May 2012, an FDA Arthritis Advisory Committee voted to recommend against approval of ARCALYST for this indication.

Monoclonal Antibodies

- Ten fully human monoclonal antibodies based on our *VelocImmune*® technology continued in clinical development, including seven in collaboration with Sanofi.
- Following discussions with U.S. and E.U. regulatory authorities, ODYSSEY, a large, global Phase 3 program with REGN727 was initiated in June 2012. This is the first Phase 3 program of an investigational drug targeting PCSK9 to reduce low-density lipoprotein (LDL) cholesterol. 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.
- In May 2012, data from an additional Phase 2 trial with REGN727 were published online in *The Lancet* and also presented at an oral session at the 80th European Atherosclerosis Society (EAS) Congress in Milan, Italy.
- In June 2012, data from a Phase 2b trial with sarilumab in rheumatoid arthritis were presented at an oral session at the Annual European Congress of Rheumatology of the European League Against Rheumatism (EULAR). The Phase 3 MOBILITY trial continues to enroll patients.

Second Quarter 2012 Financial Results

Total Revenues: Total revenues were \$304 million in the second quarter of 2012, compared to \$108 million in the second quarter of 2011. Total revenues include collaboration revenues of \$98 million in the second quarter of 2012, and \$96 million in the second quarter of 2011.

Product Revenues: Net product sales were \$200 million in the second quarter of 2012, compared to \$5 million in the second quarter of 2011. The increase was due to the approval and launch of EYLEA in November 2011. EYLEA net product sales were \$194 million in the second quarter of 2012. ARCALYST net product sales were \$6 million in the second quarter of 2012, compared to \$5 million in the second quarter of 2011.

Research and Development (R&D) Expenses: GAAP R&D expenses were \$147 million in the second quarter of 2012, compared to \$143 million in the second quarter of 2011. The increase in 2012 was primarily due to higher R&D headcount and activities (partly related to the Company's antibody collaboration with Sanofi and partly related to the Company's own internal R&D efforts) and higher non-cash share-based compensation expense, partly offset by lower wet AMD development costs incurred by Bayer HealthCare. In the second quarter of 2012, R&D related non-cash share-based compensation expense was \$11 million, compared to \$8 million in the second quarter of 2011.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$48 million in the second quarter of 2012, compared to \$25 million in the second 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 second quarter of 2012, SG&A related non-cash share-based compensation expense was \$8 million, compared to \$5 million in the second quarter of 2011.

Cost of Goods Sold (COGS): GAAP COGS was \$22 million in the second quarter of 2012, compared to approximately \$400,000 in the second 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 second quarter of 2012, compared to \$4 million in the second quarter of 2011. In the second 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 \$102 million, or \$1.07 per basic share and \$0.90 per diluted share, in the second quarter of 2012, compared to a non-GAAP net loss of \$50 million, or \$0.55 per share (basic and diluted), in the second 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 \$77 million, or \$0.81 per basic share and \$0.70 per diluted share, in the second quarter of 2012, compared to a GAAP net loss of \$63 million, or \$0.69 per share (basic and diluted), in the second quarter of 2011.

Cash Position: At June 30, 2012, cash and marketable securities totaled \$597 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 \$348 million at June 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 second quarter 2012 financial and operating results on Wednesday, July 25, 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 two products in the United States, EYLEA[®] (afibercept) Injection and ARCALYST[®] (riloncept) Injection For Subcutaneous Use. Regeneron has filed regulatory applications with the U.S. Food and Drug Administration (FDA) for second indications for EYLEA and ARCALYST and for the product candidate ZALTRAP[®] (afibercept) Concentrate for Intravenous Infusion. 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 EYLEA and ARCALYST and Regeneron's product candidates, potential new indications for marketed products, and research and clinical programs now underway or planned; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA and other product and drug candidates and possible new indications for marketed products; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; competing drugs that may be superior to EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products; uncertainty of market acceptance of EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unforeseen safety issues resulting from the administration of products and product candidates in patients; 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 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)

	<u>June 30, 2012</u>	<u>December 31, 2011</u>
ASSETS		
Cash, restricted cash, and marketable securities	\$ 597,484	\$ 810,550
Accounts receivable - trade, net	349,645	28,254
Accounts receivable from Sanofi	85,735	74,781
Property, plant, and equipment, net	372,278	367,955
Other assets	<u>52,358</u>	<u>42,043</u>
Total assets	<u>\$ 1,457,500</u>	<u>\$ 1,323,583</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	\$ 134,030	\$ 102,068
Deferred revenue	282,581	300,250
Facility lease obligations	160,741	160,514
Convertible senior notes	285,491	275,019
Stockholders' equity	<u>594,657</u>	<u>485,732</u>
Total liabilities and stockholders' equity	<u>\$ 1,457,500</u>	<u>\$ 1,323,583</u>

TABLE 2

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

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
Revenues:				
Net product sales	\$ 199,519	\$ 5,039	\$ 327,450	\$ 9,466
Sanofi collaboration revenue	88,988	84,446	173,993	169,775
Bayer HealthCare collaboration revenue	9,124	11,123	21,607	23,604
Technology licensing	5,893	5,228	11,786	13,073
Contract research and other	875	1,974	1,352	4,096
	<u>304,399</u>	<u>107,810</u>	<u>536,188</u>	<u>220,014</u>
Expenses:				
Research and development	147,373	143,149	286,235	272,541
Selling, general, and administrative	47,705	24,585	106,133	47,996
Cost of goods sold	21,843	395	34,141	777
	<u>216,921</u>	<u>168,129</u>	<u>426,509</u>	<u>321,314</u>
Income (loss) from operations	<u>87,478</u>	<u>(60,319)</u>	<u>109,679</u>	<u>(101,300)</u>
Other income (expense):				
Investment income	501	998	1,111	2,035
Interest expense	(11,236)	(4,047)	(22,396)	(7,766)
	<u>(10,735)</u>	<u>(3,049)</u>	<u>(21,285)</u>	<u>(5,731)</u>
Net income (loss) before income tax benefit	76,743	(63,368)	88,394	(107,031)
Income tax benefit		<u>863</u>		<u>1,079</u>

Net income (loss)	<u>\$ 76,743</u>	<u>\$ (62,505)</u>	<u>\$ 88,394</u>	<u>\$ (105,952)</u>
Net income (loss) per share - basic	\$ 0.81	\$ (0.69)	\$ 0.94	\$ (1.18)
Net income (loss) per share - diluted	\$ 0.70	\$ (0.69)	\$ 0.81	\$ (1.18)
Weighted average shares outstanding - basic	94,589	90,436	94,017	89,799
Weighted average shares outstanding - diluted	110,167	90,436	108,998	89,799

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 June 30,		Six months ended June 30,	
	2012	2011	2012	2011
GAAP net income (loss)	\$ 76,743	\$ (62,505)	\$ 88,394	\$ (105,952)
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense ⁽¹⁾	11,442	7,754	21,998	15,545
SG&A: Non-cash share-based compensation expense ⁽¹⁾	7,790	4,641	20,368	11,652
COGS: Non-cash share-based compensation expense ⁽¹⁾	391		502	
Interest expense: Non-cash interest related to convertible senior notes ⁽²⁾	<u>5,316</u>		<u>10,534</u>	
Non-GAAP net income (loss)	\$ 101,682	\$ (50,110)	\$ 141,796	\$ (78,755)
Non-GAAP net income (loss) per share - basic	\$ 1.07	\$ (0.55)	\$ 1.51	\$ (0.88)
Non-GAAP net income (loss) per share - diluted	\$ 0.90 ⁽³⁾	\$ (0.55)	\$ 1.28 ⁽³⁾	\$ (0.88)
Shares used in calculating:				
Non-GAAP net income (loss) per share - basic	94,589	90,436	94,017	89,799
Non-GAAP net income (loss) per share - diluted ⁽⁴⁾	114,928	90,436	113,760	89,799

(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 June 30, 2012 and \$3.8 million of interest expense for the six months ended June 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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