

# REGENERON

## Regeneron Reports First Quarter 2012 Financial and Operating Results

April 26, 2012

TARRYTOWN, N.Y., April 26, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial and operating results for the first quarter of 2012 and provided an update on development programs.

The Company reported total revenues of \$232 million in the first quarter of 2012, which include EYLEA net product sales of \$124 million. The Company reported non-GAAP net income of \$40 million, or \$0.37 per diluted share, in the first quarter 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 \$12 million, or \$0.11 per diluted share, in the first quarter of 2012.

"The first quarter was a true milestone for Regeneron as it was the first time in our history that we achieved profitability as a result of product sales," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "This success was driven by the strong EYLEA launch and based on results to date, we now forecast 2012 U.S. EYLEA net product sales of \$500 to \$550 million and expect to be profitable on a non-GAAP basis for the full year."

"The first four months of 2012 have seen substantial progress on our pipeline," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer and President, Regeneron Research Laboratories. "The ZALTRAP® (aflibercept) Biologics License Applications (BLA) for the treatment of patients with previously treated metastatic colorectal cancer was accepted for Priority Review by the U.S. Food and Drug Administration (FDA). We also published and presented positive results from our Phase 1 and Phase 2 studies of REGN727, which is being developed for lowering LDL cholesterol, and announced plans to initiate a Phase 3 program shortly. In addition, an FDA Advisory Committee recommended that companies developing antibodies targeting Nerve Growth Factor (NGF) for the treatment of pain be permitted to move forward cautiously, and we are discussing with the FDA our plans for additional trials with our NGF antibody."

### First Quarter 2012 Clinical Program Highlights

#### EYLEA® (aflibercept) Injection

- In February 2012, Bayer HealthCare, our collaborator outside the United States, received marketing approval for EYLEA in Australia. Regulatory applications were previously submitted in the European Union, Japan, and other countries.
- The FDA granted a Prescription Drug User Fee Act (PDUFA) date of September 23, 2012 as the target date for a regulatory decision on the sBLA in central retinal vein occlusion (CRVO).
- A Phase 3 study in branch retinal vein occlusion (BRVO) was initiated.
- Enrollment in the U.S. Phase 3 study in diabetic macular edema (DME) was completed.

#### ZALTRAP® (aflibercept)

- Regulatory applications for marketing approval of ZALTRAP in patients with metastatic colorectal cancer previously treated with an oxaliplatin-based regimen were submitted to the European Medicines Agency in the fourth quarter of 2011 and FDA in February 2012. The U.S. BLA was granted Priority Review status with a PDUFA date of August 4, 2012.
- The Phase 3 VENICE trial evaluating the addition of ZALTRAP to a regimen of docetaxel and prednisone for the first-line treatment of metastatic androgen-independent prostate cancer did not meet the pre-specified criterion of improvement in overall survival. The safety profile was generally consistent with previous studies of ZALTRAP in combination with docetaxel.

#### ARCALYST® (rilonacept)

- The FDA granted a PDUFA date of July 30, 2012 for the sBLA for ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy and will hold an advisory committee meeting on May 8, 2012.

#### Monoclonal Antibodies

- Ten fully human monoclonal antibodies based on our *VelocImmune*® technology continued in clinical development, including seven in collaboration with Sanofi.
- Data from two Phase 2 trials with REGN727, an antibody to PCSK9, a novel target for LDL cholesterol reduction, were presented at the American College of Cardiology Annual Meeting. Data from a third Phase 2 trial will be presented at the European Atherosclerosis Society Congress in May 2012. Initiation of Phase 3 studies is planned for the second quarter of 2012.
- An FDA Arthritis Advisory Committee voted unanimously in favor of a role for the ongoing development of anti-NGF agents in osteoarthritis. The Arthritis Advisory Committee also voted twenty to one in favor of a role for development of anti-NGF

agents to manage the pain associated with conditions for which there are no agents with demonstrated analgesic efficacy. The Committee's recommendation will be considered by the FDA, but is not binding on the FDA. Discussions with the FDA are underway regarding plans for additional trials with the REGN475 NGF antibody.

- Sanofi elected not to continue co-development of REGN475, and Regeneron now has sole global rights to REGN475. Sanofi remains obligated to fund agreed-upon REGN475 development costs through the end of 2012, and is entitled to receive a mid-single digit royalty on any future sales of REGN475.

### First Quarter 2012 Financial Results

**Total Revenues:** Total revenues were \$232 million in the first quarter of 2012, compared to \$112 million in the first quarter of 2011. Total revenues include total collaboration revenues of \$97 million in the first quarter of 2012, compared to \$98 million in the first quarter of 2011.

**Product Revenues:** Net product sales were \$128 million in the first quarter of 2012, compared to \$4 million in the first quarter of 2011. The increase was due to the approval and launch of EYLEA in November 2011. EYLEA net product sales in the first quarter of 2012 were \$124 million. ARCALYST net product sales were \$4 million in both the first quarter of 2012 and the first quarter of 2011.

**Research and Development (R&D) Expenses:** GAAP R&D expenses were \$139 million in the first quarter of 2012, compared to \$129 million in the first quarter of 2011. The higher R&D expenses in 2012 were primarily related 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. In the first quarter of 2012, R&D related non-cash share-based compensation expense was \$11 million, compared to \$8 million in the first quarter of 2011.

**Selling, General, and Administrative (SG&A) Expenses:** GAAP SG&A expenses were \$58 million in the first quarter of 2012, compared to \$23 million in the first quarter of 2011. The increase was primarily related to higher selling expenses in connection with commercialization of EYLEA, higher SG&A headcount, and higher non-cash share-based compensation expense. In the first quarter of 2012, SG&A related non-cash share-based compensation expense was \$13 million, compared to \$7 million in the first quarter of 2011.

**Cost of Goods Sold (COGS):** GAAP COGS was \$12 million in the first quarter of 2012, compared to approximately \$400,000 in the first quarter of 2011. The increase in COGS 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 first quarter of 2012, compared to \$4 million in the first quarter of 2011. In the first 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 \$40 million, or \$0.43 per basic share and \$0.37 per diluted share, in the first quarter of 2012, compared to a non-GAAP net loss of \$29 million, or \$0.32 per share (basic and diluted), in the first 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 \$12 million, or \$0.12 per basic share and \$0.11 per diluted share, in the first quarter of 2012, compared to a GAAP net loss of \$43 million, or \$0.49 per share (basic and diluted), in the first quarter of 2011.

**Cash Position:** At March 31, 2012, cash and marketable securities totaled \$695 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.

**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 first quarter 2012 financial and operating results on Thursday, April 26, 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](http://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, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA® (afibercept) Injection, and has filed regulatory applications with the U.S. Food and Drug Administration (FDA) for second indications for each of these products. A regulatory application has also been submitted to the FDA for the product candidate ZALTRAP® (afibercept) Concentrate for Intravenous Infusion. Phase 3 studies are in progress with EYLEA® in a third indication, and with product candidate sarilumab.

Earlier-stage clinical programs are underway with nine additional monoclonal antibodies. 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](http://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; 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; 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.*

### Contacts Information:

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TABLE 1

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

	March 31, 2012	December 31, 2011
<b>ASSETS</b>		
Cash, restricted cash, and marketable securities	\$ 695,190	\$ 810,550
Accounts receivable - trade, net	159,462	28,254
Accounts receivable from Sanofi	78,885	74,781
Property, plant, and equipment, net	369,959	367,955
Other assets	46,663	42,043
Total assets	<u>\$ 1,350,159</u>	<u>\$ 1,323,583</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable, accrued expenses, and other liabilities	\$ 114,178	\$ 102,068
Deferred revenue	291,124	300,250
Facility lease obligations	160,627	160,514
Convertible senior notes	280,206	275,019
Stockholders' equity	504,024	485,732
Total liabilities and stockholders' equity	<u>\$ 1,350,159</u>	<u>\$ 1,323,583</u>

TABLE 2

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

	For the three months ended March 31,	
	2012	2011
	<u>          </u>	<u>          </u>

Revenues:		
Net product sales	\$ 127,931	\$ 4,427
Sanofi collaboration revenue	85,005	85,329
Bayer HealthCare collaboration revenue	12,483	12,481
Technology licensing	5,893	7,845
Contract research and other	477	2,122
	<u>231,789</u>	<u>112,204</u>
Expenses:		
Research and development	138,862	129,392
Selling, general, and administrative	58,428	23,411
Cost of goods sold	12,298	382
	<u>209,588</u>	<u>153,185</u>
Income (loss) from operations	<u>22,201</u>	<u>(40,981)</u>
Other income (expense):		
Investment income	610	1,037
Interest expense	(11,160)	(3,719)
	<u>(10,550)</u>	<u>(2,682)</u>
Net income (loss) before income tax benefit	11,651	(43,663)
Income tax benefit		216
Net income (loss)	<u>\$ 11,651</u>	<u>\$ (43,447)</u>
Net income (loss) per share - basic	\$ 0.12	\$ (0.49)
Net income (loss) per share - diluted	\$ 0.11	\$ (0.49)
Weighted average shares outstanding - basic	93,446	89,162
Weighted average shares outstanding - diluted	107,734	89,162

TABLE 3

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

	For the three months ended March 31,	
	2012	2011
GAAP net income (loss)	\$ 11,651	\$ (43,447)
<i>Adjustments:</i>		
R&D: Non-cash share-based compensation expense <sup>(1)</sup>	10,556	7,791
SG&A: Non-cash share-based compensation expense <sup>(1)</sup>	12,578	7,011
COGS: Non-cash share-based compensation expense <sup>(1)</sup>	111	
Interest expense: Non-cash interest related to convertible senior notes <sup>(2)</sup>	5,218	
Non-GAAP net income (loss)	<u>\$ 40,114</u>	<u>\$ (28,645)</u>
Non-GAAP net income (loss) per share - basic	\$ 0.43	\$ (0.32)
Non-GAAP net income (loss) per share - diluted	\$ 0.37 <sup>(3)</sup>	\$ (0.32)
Shares used in calculating:		
Non-GAAP net income (loss) per share - basic	93,446	89,162
Non-GAAP net income (loss) per share - diluted <sup>(4)</sup>	112,495	89,162

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

<sup>(2)</sup> 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

<sup>(3)</sup> For diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

<sup>(4)</sup> 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

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