



## Regeneron Reports Third Quarter 2013 Financial and Operating Results

November 5, 2013

TARRYTOWN, N.Y., Nov. 5, 2013 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial and operating results for the third quarter of 2013 and provided an update on development programs.

The Company reported total revenues of \$597 million in the third quarter and \$1.494 billion in the first nine months of 2013, compared to \$428 million in the third quarter and \$964 million in the first nine months of 2012. EYLEA U.S. net product sales grew 49% to \$363 million in the third quarter of 2013 from \$244 million in the third quarter of 2012. EYLEA U.S. net product sales grew 79% to \$1.007 billion in the first nine months of 2013 from \$562 million in the first nine months of 2012. The Company's total revenues in both the third quarter and first nine months of 2013 included \$45 million of milestone payments from Bayer HealthCare in connection with the companies' EYLEA collaboration outside the United States. These were comprised of a \$15 million development milestone and two \$15 million sales milestones. Total revenues in both the third quarter and first nine months of 2012 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.

The Company reported non-GAAP net income of \$277 million, or \$2.40 per diluted share, in the third quarter and \$676 million, or \$5.92 per diluted share, in the first nine months of 2013, compared to \$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. The Company reported GAAP net income of \$141 million, or \$1.25 per diluted share, in the third quarter and \$328 million, or \$2.95 per diluted share, in the first nine months of 2013, compared to \$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 decrease in third quarter 2013 GAAP net income resulted primarily from higher operating expenses and because the Company began recording an income tax provision in 2013.

"We are pleased with our quarterly financial performance, which continues to be driven by both the U.S. and ex-U.S. growth of EYLEA. Moreover, our late stage clinical pipeline continues to have strong momentum. Importantly, today we announced that we recently submitted to the FDA a supplemental BLA in the diabetic macular edema (DME) indication, and are encouraged that we were able to accomplish this approximately one-year ahead of our original plan. In the third quarter, we previously reported positive Phase 3 data for EYLEA in DME. We also announced two additional positive Phase 3 trials last month - the VIBRANT trial for EYLEA in macular edema following branch retinal vein occlusion (BRVO) and the ODYSSEY MONO trial for alicumab in patients with elevated cholesterol," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Finally, we expect to report results from the Phase 3 MOBILITY trial for sarilumab in patients with rheumatoid arthritis before the end of the year."

### ***Business Highlights***

#### **EYLEA® (aflibercept) Injection for Intravitreal Injection**

- EYLEA is currently approved in the United States for the treatment of neovascular age-related macular degeneration (wet AMD) and macular edema following central retinal vein occlusion (CRVO). In the third quarter of 2013, net sales of EYLEA in the United States were \$363 million, compared to \$244 million in the third quarter of 2012.
- Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the European Union, Japan, Australia, and other countries. In the third quarter of 2013, net sales of EYLEA outside of the United States<sup>(1)</sup> were \$125 million, compared to \$102 million in the second quarter of 2013. Regeneron's share of the profits on these EYLEA net sales (including royalties on sales in Japan) was \$46 million in the third quarter of 2013, and after repaying \$14 million in development expenses, the Company recognized \$32 million in net profit from EYLEA sales outside the United States in the quarter.
- The European Commission approved EYLEA for the treatment of visual impairment due to macular edema secondary to CRVO in the third quarter of 2013.
- EYLEA is approved for the treatment of wet AMD in approximately 50 countries. Additional approvals and launches are anticipated to continue through 2014.
- In August 2013, the Company and Bayer HealthCare reported positive, top line, one-year results from the Phase 3 VISTA-DME and VIVID-DME trials in DME. Data from these studies were presented at the Retina Society and EURETINA medical conferences in September 2013. Additionally, we have recently submitted a supplemental BLA for U.S. regulatory approval of EYLEA in DME, and applications for regulatory approval in the European Union are expected to be submitted for this indication by the end of 2013.
- In October 2013, the Company reported positive, top line results from the Phase 3 VIBRANT trial for the treatment of macular edema following branch retinal vein occlusion (BRVO).

#### **ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion**

- ZALTRAP is currently approved in over 30 countries, including the United States and the European Union. Marketing authorization applications for ZALTRAP are currently under review by additional regulatory agencies worldwide.
- ZALTRAP net product sales commenced in the United States in August 2012 and in Europe in the first quarter of 2013. In the third quarter of 2013, Sanofi's worldwide net sales of ZALTRAP were \$18 million, compared to \$8 million in the third quarter of 2012.

### **Monoclonal Antibodies**

- Regeneron has thirteen fully human monoclonal antibodies based on the Company's *VelocImmune*<sup>®</sup> technology in clinical development, including seven in collaboration with Sanofi.
- ODYSSEY, a large, global Phase 3 program with alirocumab, an antibody targeting PCSK9 to reduce LDL cholesterol, was initiated in June 2012. The ODYSSEY program includes eleven clinical trials evaluating the effect of alirocumab dosed every two weeks. All of these trials are fully enrolled with the exception of the 18,000 patient ODYSSEY OUTCOMES study. In addition, a trial of alirocumab dosed every four weeks (ODYSSEY CHOICE) is expected to begin enrollment by the end of 2013. In October, positive top-line results were reported from the Phase 3 ODYSSEY MONO trial. These were the first Phase 3 data to be reported from the PCSK9 inhibitor class of investigational drugs. Alirocumab is being developed in collaboration with Sanofi.
- In the second quarter of 2013, Phase 2b trials of dupilumab in asthma and atopic dermatitis were initiated and are currently enrolling patients. Additionally, in the third quarter of 2013, a Phase 2 trial of dupilumab in nasal polyposis was initiated. Dupilumab is being developed in collaboration with Sanofi.
- The Phase 3 program with sarilumab in rheumatoid arthritis includes multiple trials. SARIL-RA-MOBILITY has completed enrollment and data are expected by the end of 2013. SARIL-RA-TARGET continues to enroll patients. SARIL-RA-COMPARE and SARIL-RA-ASCERTAIN were initiated during the second quarter of 2013. Additionally, a Phase 2 study, SARIL-NIU-SATURN, in non-infectious uveitis is expected to commence in the fourth quarter of 2013. Sarilumab is being developed in collaboration with Sanofi.
- REGN1908-1909, an antibody combination against an undisclosed target, entered clinical development during the third quarter of 2013.

### ***Third Quarter 2013 Financial Results***

**Product Revenues:** Net product sales were \$367 million in the third quarter of 2013, compared to \$249 million in the third quarter of 2012. EYLEA net product sales in the United States were \$363 million in the third quarter of 2013, compared to \$244 million in the third quarter of 2012. ARCALYST net product sales were \$4 million in the third quarter of 2013, compared to \$5 million in the third quarter of 2012.

**Total Revenues:** Total revenues increased by 40% to \$597 million in the third quarter of 2013, compared to \$428 million in the third quarter of 2012. Total revenues include collaboration revenues of \$223 million in the third quarter of 2013, compared to \$172 million in the third quarter of 2012. Collaboration revenue in the third quarter of 2013 included \$45 million of milestone payments earned from Bayer HealthCare. Collaboration revenue in the third quarter 2012 included a \$50 million milestone payment from Sanofi and a \$15 million milestone payment from Bayer HealthCare.

**Research and Development (R&D) Expenses:** GAAP R&D expenses were \$224 million in the third quarter of 2013, compared to \$158 million in the third quarter of 2012. The increase was principally due to increased R&D activities, primarily related to the Company's antibody collaboration with Sanofi, higher R&D headcount, and higher non-cash share-based compensation expense. In the third quarter of 2013, R&D related non-cash share-based compensation expense was \$28 million, compared to \$13 million in the third quarter of 2012.

**Selling, General, and Administrative (SG&A) Expenses:** GAAP SG&A expenses were \$98 million in the third quarter of 2013, compared to \$47 million in the third quarter of 2012. The increase was primarily due to higher expenses in connection with commercialization of EYLEA and higher non-cash share-based compensation expense. In the third quarter of 2013, SG&A related non-cash share-based compensation expense was \$17 million, compared to \$7 million in the third quarter of 2012.

**Cost of Goods Sold (COGS):** GAAP COGS was \$28 million in the third quarter of 2013, compared to \$20 million in the third quarter of 2012. The increase was due to higher EYLEA sales in 2013.

**Cost of Collaboration Manufacturing:** GAAP cost of collaboration manufacturing, which was \$10 million in the third quarter of 2013, primarily consisted of third-party royalties, as well as costs in connection with producing commercial supplies of EYLEA for Bayer HealthCare and ZALTRAP for Sanofi.

**Interest Expense:** GAAP interest expense was \$12 million in the third quarter of 2013, compared to \$11 million in the third quarter of 2012. 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 third quarter of 2013 and \$7 million in the third quarter of 2012. Non-cash interest expense related to the convertible senior notes was \$6 million in the third quarter of 2013 and \$5 million in the third quarter of 2012.

**Income Tax Expense:** GAAP income tax expense was \$84 million in the third quarter of 2013. The effective tax rate was 37.4% for the quarter.

In the third quarter of 2012, the Company did not recognize any income tax provision because it continued to recognize a full valuation allowance against its net operating loss carry-forward and other deferred tax assets. In the fourth quarter of 2012, the Company recorded an income tax benefit attributable to the release of substantially all of the valuation allowance against the Company's deferred tax assets. Starting in 2013, the Company has recorded income taxes on GAAP income using an estimated effective tax rate. Non-GAAP net income excludes non-cash income tax expense. The Company does not currently pay, or expect to pay in the near future, significant cash income taxes.

**Non-GAAP and GAAP Net Income:** The Company reported non-GAAP net income of \$277 million, or \$2.82 per basic share and \$2.40 per diluted share, in the third quarter of 2013, compared to 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.

The Company reported GAAP net income of \$141 million, or \$1.44 per basic share and \$1.25 per diluted share, in the third quarter of 2013, compared to GAAP net income of \$191 million, or \$2.02 per basic share and \$1.72 per diluted share, in the third quarter of 2012. The decrease in third quarter 2013 GAAP net income resulted primarily from higher operating expenses and because the Company began recording an income tax provision in 2013.

**Cash Position:** At September 30, 2013, cash, cash equivalents, and marketable securities totaled \$775 million, compared to \$588 million (including \$8 million of restricted cash and marketable securities) at December 31, 2012. In addition, accounts receivable related to sales of EYLEA totaled \$854 million at September 30, 2013, compared to \$592 million at December 31, 2012.

(1) Regeneron records net product sales of EYLEA in the United States. Outside the United States, EYLEA net product sales comprise sales by Bayer HealthCare in countries other than Japan and sales by Santen Pharmaceuticals in Japan under a co-promotion agreement with a Japanese subsidiary of Bayer HealthCare. The Company recognizes its share of the profits (including royalties on sales in Japan) from EYLEA sales outside the United States within "Bayer HealthCare collaboration revenue" in its Statement of Operations.

(2) This press release uses non-GAAP net income and non-GAAP net income per share, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The Company believes that the presentation of these non-GAAP measures is useful to investors because they exclude (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, and (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. In addition, 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 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 Regeneron 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 2013 financial and operating results on Tuesday, November 5, 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](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 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, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com).

## Forward-Looking Statement

This press 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. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations in 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 EYLEA®, ZALTRAP®, and ARCALYST®, and Regeneron's product candidates, potential new indications for marketed products, and research and clinical programs now underway or planned; 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 and new indications for marketed products; ongoing regulatory obligations and oversight impacting Regeneron's research and clinical programs and business; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA, ZALTRAP, and ARCALYST and other product candidates and possible new indications for marketed products; Regeneron's ability to manufacture and manage supply chains for multiple products and product candidates; competing drugs and product candidates that may be superior to EYLEA, ZALTRAP, and ARCALYST and other product candidates and possible new indications for marketed products; uncertainty of market acceptance of Regeneron's products and product candidates; 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, including serious complications or side effects in connection with the use of Regeneron product candidates in clinical trials; 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 LLC, to be canceled or terminated without any further product success; and risks associated with intellectual property of other parties 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, 2012 and its Form 10-Q for the quarterly period ended September 30, 2013. These statements are made by Regeneron based on management's current beliefs and judgment, and 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.

*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 these measures.*

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TABLE 1

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

	<b>September 30,</b>	<b>December 31,</b>
	<b>2013</b>	<b>2012</b>
	<hr/>	<hr/>
Assets:		
Cash, restricted cash, and marketable securities	\$ 775,186	\$ 587,511
Accounts receivable - trade, net	855,844	593,207
Accounts receivable from Sanofi	136,980	99,913
Deferred tax assets	257,266	340,156
Property, plant, and equipment, net	453,891	379,940
Other assets	161,248	79,763
	<hr/>	<hr/>
Total assets	<b>\$ 2,640,415</b>	<b>\$ 2,080,490</b>
	<hr/>	<hr/>
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 229,711	\$ 118,604
Deferred revenue	238,358	259,173
Facility lease obligations	168,013	160,810
Convertible senior notes	314,162	296,518
Stockholders' equity	1,690,171	1,245,385
	<hr/>	<hr/>
Total liabilities and stockholders' equity	<b>\$ 2,640,415</b>	<b>\$ 2,080,490</b>
	<hr/>	<hr/>

TABLE 2

## REGENERON PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

*(In thousands, except per share data)*

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Revenue:				
Net product sales	\$ 367,118	\$ 249,172	\$ 1,019,751	\$ 576,622
Sanofi collaboration revenue	134,359	145,042	319,161	319,035
Bayer HealthCare collaboration revenue	88,583	26,701	134,594	48,308
Technology licensing	5,893	5,893	17,679	17,679
Other revenue	1,074	879	3,148	2,231
	<u>597,027</u>	<u>427,687</u>	<u>1,494,333</u>	<u>963,875</u>
Expenses:				
Research and development	224,045	158,295	591,807	444,530
Selling, general, and administrative	97,607	46,883	247,330	153,016
Cost of goods sold	28,253	20,145	83,557	54,286
Cost of collaboration manufacturing	10,320		23,684	
	<u>360,225</u>	<u>225,323</u>	<u>946,378</u>	<u>651,832</u>
Income from operations	<u>236,802</u>	<u>202,364</u>	<u>547,955</u>	<u>312,043</u>
Other income (expenses):				
Investment income	618	517	2,028	1,628
Interest expense	(11,736)	(11,413)	(34,776)	(33,809)
	<u>(11,118)</u>	<u>(10,896)</u>	<u>(32,748)</u>	<u>(32,181)</u>
Income before income taxes	225,684	191,468	515,207	279,862
Income tax expense	<u>(84,378)</u>		<u>(187,651)</u>	
Net income	<u>\$ 141,306</u>	<u>\$ 191,468</u>	<u>\$ 327,556</u>	<u>\$ 279,862</u>
Net income per share - basic	\$ 1.44	\$ 2.02	\$ 3.36	\$ 2.97
Net income per share - diluted	\$ 1.25	\$ 1.72	\$ 2.95	\$ 2.55
Weighted average shares outstanding - basic	98,226	95,012	97,602	94,349
Weighted average shares outstanding - diluted	116,713	115,830	115,554	109,780

TABLE 3

## REGENERON PHARMACEUTICALS, INC.

## RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME (Unaudited)

*(In thousands, except per share data)*

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
GAAP net income	\$ 141,306	\$ 191,468	\$ 327,556	\$ 279,862
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	28,258	13,337	82,741	35,335
SG&A: Non-cash share-based compensation expense	17,114	7,030	59,244	27,398
COGS: Non-cash share-based compensation expense	373	150	1,232	652
Interest expense: Non-cash interest related to convertible senior notes	5,823	5,499	17,139	16,033
Income taxes: Non-cash income tax expense	84,378		187,651	
Non-GAAP net income	<u>\$ 277,252</u>	<u>\$ 217,484</u>	<u>\$ 675,563</u>	<u>\$ 359,280</u>
Non-GAAP net income per share - basic	\$ 2.82	\$ 2.29	\$ 6.92	\$ 3.81
Non-GAAP net income per share - diluted <sup>(1)</sup>	\$ 2.40	\$ 1.89	\$ 5.92	\$ 3.19
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	98,226	95,012	97,601	94,349
Non-GAAP net income per share - diluted <sup>(2)</sup>	116,068	115,830	114,970	114,541

(1) For diluted non-GAAP per share calculations, excludes \$1.8 million and \$1.9 million, respectively, of interest expense for the three month periods ended September 30, 2013 and 2012, and \$5.5 million and \$5.6 million, respectively, of interest expense for the nine month periods ended September 30, 2013 and 2012, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

(2) 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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