# Regeneron Reports Second Quarter 2015 Financial and Operating Results

August 4, 2015

TARRYTOWN, N.Y., Aug. 4, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2015 and provided an update on development programs.

***Financial Highlights***

| ($ in millions, except per share data) | Three Months Ended June 30, | | |
|---|---|---|---|
| | 2015 | 2014* | % Change |
| EYLEA U.S. net product sales | $ 655 | $ 415 | 58 % |
| Total revenues | $ 999 | $ 666 | 50 % |
| Non-GAAP net income (2) | $ 338 | $ 289 | 17 % |
| Non-GAAP net income per share - diluted (2) | $ 2.89 | $ 2.47 | 17 % |
| GAAP net income | $ 195 | $ 96 | 103 % |
| GAAP net income per share - diluted | $ 1.69 | $ 0.85 | 99 % |

** See note (4) below for an explanation of revisions made to certain amounts previously reported for the three months ended June 30, 2014.*

"With the recent approval of Praluent for hypercholesterolemia patients, a new collaboration with Sanofi in immuno-oncology, and increased U.S. demand for EYLEA, Regeneron has made critical, transformative advances in 2015," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We have discovered and developed four approved therapies for patients with serious diseases, and are actively advancing late-stage programs for patients with rheumatoid arthritis, asthma, atopic dermatitis, pain and respiratory syncytial virus. Our team is focused on delivering on all of these important near and mid-term opportunities, while continuing to advance the scientific innovation that will drive our long-term success."

***Business Highlights***

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

- In the second quarter of 2015, net sales of EYLEA in the United States increased 58% to $655 million from $415 million in the second quarter of 2014. Overall distributor inventory levels remained within the Company's one- to two-week targeted range.
- Bayer HealthCare commercializes EYLEA outside the United States. In the second quarter of 2015, net sales of EYLEA outside of the United States(1) were $338 million, compared to $247 million in the second quarter of 2014. In the second quarter of 2015, Regeneron recognized $107 million from its share of net profit from EYLEA sales outside the United States, compared to $67 million in the second quarter of 2014.
- In June 2015, the Ministry of Health, Labour and Welfare (MHLW) in Japan approved EYLEA for the treatment of patients with macular edema secondary to retinal vein occlusion (RVO), which includes macular edema secondary to branch retinal vein occlusion (BRVO) in addition to the previously-approved indication of macular edema secondary to central retinal vein occlusion (CRVO).

**Praluent® (alirocumab) Injection for the Treatment of High Low-Density Lipoprotein (LDL) Cholesterol**

- In July 2015, following the U.S. Food and Drug Administration (FDA) approval of Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol, the Company and Sanofi commenced their launch of Praluent.
- In July 2015, the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for the marketing authorization of Praluent, recommending its approval for use in certain adult patients with hypercholesterolemia.
- In July 2015, the Company and Sanofi reported that the Phase 3 ODYSSEY JAPAN trial met its primary endpoint. At week 24, Japanese patients treated with Praluent experienced an average 64% greater reduction from baseline in LDL-C when added to current standard of care including statins, compared to standard of care alone.
- The Phase 3 ODYSSEY program remains ongoing.

**Pipeline Progress**

Regeneron has fifteen fully human monoclonal antibodies generated using the Company's *VelocImmune*® technology in clinical development, including five in collaboration with Sanofi[5]. In addition to Praluent, highlights from the antibody pipeline include:

Sarilumab, the Company's antibody targeting IL-6R for rheumatoid arthritis, is currently being studied in the global Phase 3 SARIL-RA program. The Company and Sanofi plan to submit a Biologics License Application (BLA) in the United States by the end of 2015.

Dupilumab, the Company's antibody that blocks signaling of IL-4 and IL-13, is currently being studied in atopic dermatitis, asthma, nasal polyps in patients with chronic sinusitis, and eosinophilic esophagitis.

- Multiple Phase 3 studies of dupilumab in atopic dermatitis are currently underway. Phase 3 pivotal trials in atopic dermatitis are fully enrolled.
- The second pivotal study of dupilumab in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015.

Fasinumab, an antibody targeting Nerve Growth Factor (NGF), entered Phase 2b/3 clinical development (sixteen-week study) for pain due to osteoarthritis in the second quarter of 2015.

REGN2222, an antibody targeting the respiratory syncytial virus (RSV), recently entered Phase 3 clinical development[5].

REGN2176-3, a combination product comprised of an antibody to PDGFR-beta co-formulated with EYLEA, entered Phase 2 clinical development for the treatment of neovascular age-related macular degeneration (wet AMD) in the second quarter of 2015.

***Second Quarter 2015 Financial Results***

**Product Revenues:** Net product sales were $658 million in the second quarter of 2015, compared to $418 million in the second quarter of 2014. EYLEA net product sales in the United States were $655 million in the second quarter of 2015, compared to $415 million in the second quarter of 2014.

**Total Revenues:** Total revenues, which include product revenues described above, increased by 50% to $999 million in the second quarter of 2015, compared to $666 million in the second quarter of 2014. Total revenues also include collaboration revenues of $329 million in the second quarter of 2015, compared to $240 million in the second quarter of 2014. Collaboration revenues in the second quarter of 2015 increased primarily due to higher reimbursement of the Company's research and development expenses under its antibody collaboration with Sanofi and an increase in the Company's net profit from commercialization of EYLEA outside the United States. Refer to Table 4 for a summary of collaboration revenue.

**Research and Development (R&D) Expenses:** GAAP R&D expenses were $390 million in the second quarter of 2015, compared to $295 million in the second quarter of 2014. The higher R&D expenses in the second quarter of 2015 were principally due to higher development costs related to dupilumab and higher headcount to support the Company's increased R&D activities. In addition, in the second quarter of 2015, R&D-related non-cash share-based compensation expense was $60 million, compared to $44 million in the second quarter of 2014.

**Selling, General, and Administrative (SG&A) Expenses:** GAAP SG&A expenses were $175 million in the second quarter of 2015, compared to $97 million in the second quarter of 2014. The increase was primarily due to higher headcount and headcount-related costs, higher commercialization expenses related to Praluent, sarilumab, and EYLEA, and higher costs associated with the Branded Prescription Drug Fee. In addition, in the second quarter of 2015, SG&A-related non-cash share-based compensation expense was $32 million, compared to $20 million in the second quarter of 2014.

**Cost of Goods Sold (COGS):** GAAP COGS was $61 million in the second quarter of 2015, compared to $30 million in the second quarter of 2014. COGS, which primarily consists of royalties as well as costs in connection with producing EYLEA commercial supplies, increased principally due to the increase in U.S. EYLEA net product sales.

**Income Tax Expense:** GAAP income tax expense was $133 million in the second quarter of 2015, compared to $112 million in the second quarter of 2014. The effective tax rate was 40.7% for the second quarter of 2015, compared to 53.9% for the second quarter of 2014.

**Non-GAAP and GAAP Net Income:** The Company reported non-GAAP net income of $338 million, or $3.29 per basic share and $2.89 per diluted share, in the second quarter of 2015, compared to non-GAAP net income of $289 million, or $2.88 per basic share and $2.47 per diluted share, in the second quarter of 2014.

The Company reported GAAP net income of $195 million, or $1.89 per basic share and $1.69 per diluted share, in the second quarter of 2015, compared to GAAP net income of $96 million, or $0.96 per basic share and $0.85 per diluted share, in the second quarter of 2014.

A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

***2015 Financial Guidance[3]***

The Company's updated full year 2015 financial guidance consists of the following components:

| | |
|---|---|
| EYLEA U.S. net product sales | 45% - 50% growth over 2014<br>*(previously 30% - 35% growth over 2014)* |
| Non-GAAP unreimbursed R&D [2] | $510 million - $550 million<br>*(previously $525 million - $575 million)* |
| Non-GAAP SG&A [2] | $610 million - $650 million<br>*(previously $650 million - $725 million)* |
| Cash tax as a % of non-GAAP pre-tax income [2] | 15% - 22%<br>*(previously 10% - 20%)* |

| | |
|---|---|
| Capital expenditures | $675 million - $750 million<br>*(previously $650 million - $750 million)* |

(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 Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer HealthCare. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within "Bayer HealthCare collaboration revenue" in its Statements of Operations.

(2) This press release uses non-GAAP net income, non-GAAP net income per share, non-GAAP unreimbursed R&D, non-GAAP SG&A, and cash tax as a percentage of non-GAAP pre-tax income, 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, as applicable: (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) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control; and (iv) income tax expense for 2014, which was principally a non-cash expense due primarily to utilization of net operating loss and tax credit carry-forwards, and deductions related to employee stock option exercises. In 2015, income tax expense adjustments consider the tax effect of reconciling items and an adjustment from GAAP tax expense to the amount of taxes that are paid or payable in cash in respect of the current period. As there is a significant difference between the Company's effective tax rate and actual cash income taxes paid or payable, GAAP income tax expense is not deemed useful in evaluating the Company's operating performance. Non-GAAP unreimbursed R&D represents non-GAAP R&D expenses reduced by R&D expense reimbursements from the Company's collaboration partners. 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 historical GAAP to non-GAAP results is included in Table 3 of this press release.

(3) The Company's 2015 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(4) Applicable amounts previously reported for the three months ended June 30, 2014 and as of December 31, 2014 have been revised to reflect certain revisions, including a correction to the Company's accounting for certain stock option awards. These revisions consisted entirely of non-cash adjustments and had no impact on the Company's previously reported non-GAAP financial measures, including non-GAAP net income and non-GAAP net income per share. Refer to the Company's Form 10-Q for the quarterly period ended June 30, 2015 (Notes 1 and 4 of the Notes to Condensed Consolidated Financial Statements) for further details.

(5) In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015.

**Conference Call Information**

Regeneron will host a conference call and simultaneous webcast to discuss its second quarter 2015 financial and operating results on Tuesday, August 4, 2015, 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 commercializes medicines for eye diseases, high LDL-cholesterol, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the Company, please visit www.regeneron.com.

**Forward-Looking Statements and Use of Digital Media**

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("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 of 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned; 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's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including without limitation Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, REGN2222, and REGN2176-3; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA® (aflibercept) Injection and Praluent), research and clinical programs, and business, including those relating to patient privacy; 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 and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or

others and whether mandated or voluntary), on the commercial success 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, including without limitation those relating to EYLEA U.S. net product sales, non-GAAP unreimbursed R&D, non-GAAP SG&A, cash tax as a percentage of non-GAAP pre-tax income, and capital expenditures; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled 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 U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2014 and its Form 10-Q for the quarterly period ended June 30, 2015. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

**Non-GAAP Financial Measures**

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 historical non-GAAP financial measures.

**Contact Information:**


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TABLE 1

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

| | June 30, 2015 | December 31, 2014* |
|---|---|---|
| Assets: | | |
| Cash and marketable securities | $ 1,193,843 | $ 1,360,634 |
| Accounts receivable - trade, net | 1,071,665 | 739,379 |
| Accounts receivable from Sanofi and Bayer HealthCare | 323,460 | 236,993 |
| Inventories | 171,266 | 128,861 |
| Deferred tax assets | 393,387 | 315,416 |
| Property, plant, and equipment, net | 1,326,112 | 974,309 |
| Other assets | 47,237 | 82,080 |
| Total assets | $ 4,526,970 | $ 3,837,672 |
| Liabilities and stockholders' equity: | | |
| Accounts payable, accrued expenses, and other liabilities | $ 606,313 | $ 619,083 |
| Deferred revenue | 192,589 | 209,274 |
| Facility lease obligations | 359,250 | 312,291 |
| Convertible senior notes | 30,360 | 146,773 |
| Stockholders' equity | 3,338,458 | 2,550,251 |
| Total liabilities and stockholders' equity | $ 4,526,970 | $ 3,837,672 |

** Certain revisions have been made to the previously reported December 31, 2014 amounts. See note (4) above.*

TABLE 2

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014* | 2015 | 2014* |
| Revenues: | | | | |
| Net product sales | $ 657,819 | $ 418,022 | $ 1,202,392 | $ 780,400 |
| Sanofi collaboration revenue | 195,110 | 142,595 | 368,466 | 273,103 |
| Bayer HealthCare collaboration revenue | 134,237 | 97,295 | 258,083 | 222,607 |
| Technology licensing and other revenue | 11,451 | 7,788 | 39,288 | 15,330 |
| | 998,617 | 665,700 | 1,868,229 | 1,291,440 |
| Expenses: | | | | |
| Research and development | 390,330 | 294,501 | 733,443 | 581,880 |
| Selling, general, and administrative | 174,588 | 96,730 | 333,579 | 199,957 |
| Cost of goods sold | 60,855 | 29,945 | 103,425 | 57,418 |
| Cost of collaboration and contract manufacturing (COCM) | 27,985 | 16,434 | 69,370 | 32,533 |
| | 653,758 | 437,610 | 1,239,817 | 871,788 |
| Income from operations | 344,859 | 228,090 | 628,412 | 419,652 |
| Other income (expense): | | | | |
| Investment and other income | 1,849 | 1,677 | 1,930 | 2,614 |
| Interest expense | (2,748) | (10,177) | (8,917) | (21,790) |
| Loss on extinguishment of debt | (15,964) | (10,787) | (16,906) | (10,787) |
| | (16,863) | (19,287) | (23,893) | (29,963) |
| Income before income taxes | 327,996 | 208,803 | 604,519 | 389,689 |
| Income tax expense | (133,353) | (112,452) | (333,855) | (225,033) |
| Net income | $ 194,643 | $ 96,351 | $ 270,664 | $ 164,656 |
| Net income per share - basic | $ 1.89 | $ 0.96 | $ 2.64 | $ 1.65 |
| Net income per share - diluted | $ 1.69 | $ 0.85 | $ 2.35 | $ 1.46 |
| Weighted average shares outstanding - basic | 102,886 | 100,391 | 102,558 | 100,085 |
| Weighted average shares outstanding - diluted | 115,259 | 113,032 | 114,962 | 113,121 |

** Certain revisions have been made to the previously reported amounts for the three and six months ended June 30, 2014. See note (4) above.*

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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014* | 2015 | 2014* |
| GAAP net income | $ 194,643 | $ 96,351 | $ 270,664 | $ 164,656 |
| *Adjustments:* | | | | |
| R&D: Non-cash share-based compensation expense | 60,045 | 43,814 | 119,547 | 87,118 |
| SG&A: Non-cash share-based compensation expense | 32,159 | 20,483 | 74,334 | 52,447 |
| COGS and COCM: Non-cash share-based compensation expense | 2,053 | 531 | 4,135 | 1,048 |
| Interest expense: Non-cash interest related to convertible senior notes | 335 | 4,947 | 2,583 | 10,871 |
| Other expense: Loss on extinguishment of debt | 15,964 | 10,787 | 16,906 | 10,787 |
| Non-cash income taxes | 32,925 | 112,452 | 185,891 | 225,033 |
| Non-GAAP net income | $ 338,124 | $ 289,365 | $ 674,060 | $ 551,960 |
| Non-GAAP net income per share - basic | $ 3.29 | $ 2.88 | $ 6.57 | $ 5.51 |
| Non-GAAP net income per share - diluted [(a)] | $ 2.89 | $ 2.47 | $ 5.78 | $ 4.70 |
| *Shares used in calculating:* | | | | |
| Non-GAAP net income per share - basic | 102,886 | 100,391 | 102,558 | 100,085 |
| Non-GAAP net income per share - diluted [(b)] | 116,977 | 117,805 | 116,778 | 118,027 |

** Certain revisions have been made to the amounts previously reported for the three and six months ended June 30, 2014. See note (4) above.*

(a) For diluted non-GAAP net income per share calculations, excludes $1.4 million of interest expense for the three months ended June 30, 2014, and $0.4 million and $3.2 million, respectively, of interest expense for the six-month periods ended June 30, 2015 and 2014, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive. Such amount was not material for the three months ended June 30, 2015.

(b) Weighted average shares outstanding includes the dilutive effect, if any, of employee stock options, restricted stock awards, convertible senior notes, and warrants.

TABLE 4

**REGENERON PHARMACEUTICALS, INC.**
**COLLABORATION REVENUE (Unaudited)**
***(In thousands)***

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2015** | **2014** | **2015** | **2014** |
| *Sanofi collaboration revenue:* | | | | |
| Regeneron's share of losses in connection with commercialization of antibodies | $ (46,313) | $ (4,295) | $ (68,718) | $ (4,295) |
| Regeneron's share of losses in connection with commercialization of ZALTRAP® | — | (692) | — | (3,904) |
| Reimbursement of Regeneron research and development expenses | 211,516 | 139,231 | 381,022 | 267,145 |
| Reimbursement of Regeneron commercialization-related expenses | 27,346 | 4,307 | 35,804 | 5,375 |
| Other | 2,561 | 4,044 | 20,358 | 8,782 |
| Total Sanofi collaboration revenue | 195,110 | 142,595 | 368,466 | 273,103 |
| *Bayer HealthCare collaboration revenue:* | | | | |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | 106,631 | 66,781 | 196,057 | 127,940 |
| Sales milestones | — | 15,000 | 15,000 | 45,000 |
| Cost-sharing of Regeneron development expenses | 8,390 | 2,120 | 12,301 | 22,980 |
| Other | 19,216 | 13,394 | 34,725 | 26,687 |
| Total Bayer HealthCare collaboration revenue | 134,237 | 97,295 | 258,083 | 222,607 |
| Total collaboration revenue | $ 329,347 | $ 239,890 | $ 626,549 | $ 495,710 |

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/regeneron-reports-second-quarter-2015-financial-and-operating-results-300122911.html

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