

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 9, 2016 (February 9, 2016)

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**REGENERON PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Charter)

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**New York**  
(State or other jurisdiction  
of Incorporation)

**000-19034**  
(Commission  
File No.)

**13-3444607**  
(IRS Employer  
Identification No.)

**777 Old Saw Mill River Road, Tarrytown, New York 10591-6707**

(Address of principal executive offices, including zip code)

**(914) 847-7000**

(Registrant's telephone number, including area code)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02 Results of Operations and Financial Condition.**

On February 9, 2016, Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") issued a press release announcing its financial and operating results for the quarter and year ended December 31, 2015. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information included or incorporated in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release, dated February 9, 2016, Reporting Fourth Quarter and Full Year 2015 Financial and Operating Results.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 9, 2016

REGENERON PHARMACEUTICALS, INC.

By:	<u>/s/ Joseph J. LaRosa</u>
Name:	Joseph J. LaRosa
Title:	Senior Vice President, General Counsel and Secretary

Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	Press Release, dated February 9, 2016, Reporting Fourth Quarter and Full Year 2015 Financial and Operating Results.

**REGENERON**

## Press Release

**Regeneron Reports Fourth Quarter and Full Year 2015 Financial and Operating Results**

- Fourth quarter 2015 EYLEA® (afibercept) Injection U.S. net sales increased 44% to \$746 million versus fourth quarter 2014 and full year 2015 EYLEA U.S. net sales increased 54% to \$2.68 billion versus full year 2014
- Fourth quarter 2015 EYLEA global net sales<sup>(1)</sup> increased 42% to \$1.16 billion versus fourth quarter 2014 and full year 2015 EYLEA global net sales<sup>(1)</sup> increased 47% to \$4.09 billion versus full year 2014
- Full year 2015 non-GAAP net income per diluted share<sup>(2)</sup> increased 21% to \$12.07 versus full year 2014. Full year 2015 non-GAAP net income<sup>(2)</sup> increased 19% to \$1.40 billion versus full year 2014. Fourth quarter 2015 non-GAAP net income per diluted share increased 1% to \$2.83 versus fourth quarter 2014. Fourth quarter non-GAAP net income of \$327 million was unchanged versus fourth quarter of 2014.
- Estimated full year 2016 EYLEA U.S. net sales growth of approximately 20% over 2015

**Tarrytown, New York (February 9, 2016)** -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2015 and provided an update on development programs.

**Financial Highlights**

(\$ in millions, except per share data)

	Three Months Ended December 31,			Year Ended December 31,		
	2015	2014*	% Change	2015	2014*	% Change
EYLEA U.S. net product sales	\$ 746	\$ 518	44%	\$ 2,676	\$ 1,736	54%
Total revenues	\$ 1,098	\$ 802	37%	\$ 4,104	\$ 2,820	46%
Non-GAAP net income <sup>(2)</sup>	\$ 327	\$ 328	—%	\$ 1,404	\$ 1,175	19%
Non-GAAP net income per share - diluted <sup>(2)</sup>	\$ 2.83	\$ 2.79	1%	\$ 12.07	\$ 10.00	21%
GAAP net income	\$ 155	\$ 90	72%	\$ 636	\$ 338	88%
GAAP net income per share - diluted	\$ 1.34	\$ 0.78	72%	\$ 5.52	\$ 2.98	85%

\* See note (4) below for an explanation of revisions made to certain amounts previously reported for the three months and year ended December 31, 2014.

"Regeneron had a successful 2015, with strong growth in EYLEA sales for retinal diseases, the approval of Praluent for hypercholesterolemia, and important advances across all stages of our pipeline," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In 2016, we look forward to driving increased physician education, patient access, and reimbursement for Praluent in the United States and to launching this important medicine in other countries around the world. We also anticipate significant pipeline progress including the U.S. FDA action on the sarilumab application for rheumatoid arthritis, the Phase 3 results and

potential U.S. regulatory submission for dupilumab in atopic dermatitis, and the continued progress of our development programs for retinal diseases, asthma, pain, infectious diseases, and cancer. Realizing these important product and pipeline opportunities will require significant investments, which are essential to support our long-term growth and success."

## **Business Highlights**

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

- In the fourth quarter of 2015, net sales of EYLEA in the United States increased 44% to \$746 million from \$518 million in the fourth quarter of 2014. For the full year of 2015, net sales of EYLEA in the United States increased 54% to \$2.676 billion from \$1.736 billion for the full year 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 fourth quarter of 2015, net sales of EYLEA outside of the United States<sup>(1)</sup> were \$413 million, compared to \$297 million in the fourth quarter of 2014. In the fourth quarter of 2015, Regeneron recognized \$140 million from its share of net profit from EYLEA sales outside the United States, compared to \$88 million in the fourth quarter of 2014. For the full year of 2015, net sales of EYLEA outside of the United States<sup>(1)</sup> were \$1.413 billion, compared to \$1.039 billion for the full year 2014. For the full year of 2015, Regeneron recognized \$467 million from its share of net profit from EYLEA sales outside the United States, compared to \$301 million for the full year 2014.
- In October 2015, the European Commission granted marketing authorization of EYLEA for the treatment of visual impairment due to myopic choroidal neovascularization.

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

- In the fourth quarter of 2015, net sales of Praluent were \$7 million. For the full year of 2015, net sales of Praluent were \$11 million. Product sales for Praluent are recorded by Sanofi, and the Company shares in any profits or losses from the commercialization of Praluent. Praluent was launched in the United States in the third quarter of 2015 and in certain countries in the European Union in the fourth quarter of 2015.
- The Phase 3 ODYSSEY OUTCOMES trial completed enrollment during the fourth quarter of 2015.

## **Pipeline Progress**

Regeneron has thirteen product candidates in clinical development. These consist of EYLEA and twelve fully human monoclonal antibodies generated using the Company's *VelocImmune*® technology, including four in collaboration with Sanofi. In addition to EYLEA and Praluent, highlights from the antibody pipeline include:

Sarilumab is the Company's antibody targeting IL-6R for rheumatoid arthritis. In December 2015, the U.S. Food and Drug Administration (FDA) accepted for review a Biologics License Application (BLA) for sarilumab, with a target action date of October 30, 2016. Sarilumab is currently being studied in the global Phase 3 SARIL-RA program

Dupilumab, the Company's antibody that blocks signaling of IL-4 and IL-13, is currently being studied in atopic dermatitis, asthma, nasal polyps, 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.
- A Phase 3 pivotal study of dupilumab in patients with uncontrolled persistent asthma continues to enroll patients.

Fasinumab is an antibody targeting Nerve Growth Factor (NGF). A sixteen-week Phase 2b/3 clinical trial for pain due to osteoarthritis has completed enrollment. The FDA has confirmed that the Company may proceed with studies of longer than sixteen-week duration.

REGN2222, an antibody targeting the respiratory syncytial virus (RSV), is in Phase 3 clinical development. In October 2015, the FDA granted Fast Track designation to REGN2222 for the prevention of serious lower respiratory tract disease caused by RSV.

### **Select Upcoming 2016 Milestones**

<b>Clinical Programs</b>	<b>Milestones</b>
EYLEA	• Initiate Phase 3 study for the treatment of diabetic retinopathy in patients without diabetic macular edema (DME)
REGN2176-3 (PDGFR-beta Antibody co-formulated with aflibercept)	• Report results from Phase 2 study
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	• Initiate Phase 2 study
Praluent	• Independent Data Monitoring Committee (IDMC) interim analyses of ODYSSEY OUTCOMES trial • Ongoing launch in the United States as well as in additional territories outside the United States
Sarilumab (IL-6R Antibody)	• Regulatory decision in the United States • File for regulatory approvals outside the United States • Report results from Phase 3 SARIL-RA-MONARCH trial evaluating sarilumab versus adalimumab in monotherapy
Dupilumab (IL-4R Antibody)	• Report results from Phase 3 atopic dermatitis pivotal trials • Complete rolling BLA submission for atopic dermatitis in the United States
Fasinumab (NGF Antibody)	• Report results from Phase 2b/3 study in osteoarthritis • Initiate longer duration (greater than 16 weeks) Phase 3 trial
Immuno-oncology (PD-1 Antibody and bi-specific antibody against CD20 and CD3)	• Report data from Phase 1 studies in patients with cancer

## ***Fourth Quarter and Full Year 2015 Financial Results***

**Product Revenues:** Net product sales were \$750 million in the fourth quarter and \$2.689 billion for the full year 2015, compared to \$522 million in the fourth quarter and \$1.751 billion for the full year 2014. EYLEA net product sales in the United States were \$746 million in the fourth quarter and \$2.676 billion for the full year 2015, compared to \$518 million in the fourth quarter and \$1.736 billion for the full year 2014.

**Total Revenues:** Total revenues, which include product revenues described above, increased by 37% to \$1.098 billion in the fourth quarter of 2015, compared to \$802 million in the fourth quarter of 2014. Total revenues also include collaboration revenues of \$330 million in the fourth quarter of 2015, compared to \$272 million in the fourth quarter of 2014. Full year 2015 total revenues increased by 46% to \$4.104 billion, compared to \$2.820 billion for the full year 2014, and included collaboration revenues of \$1.339 billion for the full year 2015, compared to \$1.037 billion for the full year 2014. Collaboration revenues in the fourth quarter and full year 2015 increased primarily due to higher reimbursement of the Company's research and development expenses under its antibody collaboration with Sanofi, an increase in the Company's net profit from commercialization of EYLEA outside the United States, and reimbursement of the Company's research and development expenses and amortization of up-front payments received in connection with the Company's July 2015 immuno-oncology collaboration with Sanofi, partly offset by the Company's share of higher collaboration losses primarily in connection with commercialization of Praluent. Collaboration revenue for the full year 2015 and 2014 also included \$15 million and \$105 million, respectively, of sales milestone payments from Bayer HealthCare.

Refer to Table 4 for a summary of collaboration revenue.

**Research and Development (R&D) Expenses:** In 2015, GAAP R&D expenses were \$461 million in the fourth quarter and \$1.621 billion for the full year, compared to \$352 million in the fourth quarter and \$1.271 billion for full year 2014. The higher 2015 R&D expenses in the fourth quarter and full year were principally due to higher development costs primarily related to dupilumab and higher headcount to support the Company's increased R&D activities. In 2014, GAAP R&D expenses also included the Company's 50% share, or \$34 million, of the cost of purchasing a FDA priority review voucher. In addition, in 2015, R&D-related non-cash share-based compensation expense was \$73 million for the fourth quarter and \$256 million for the full year, compared to \$51 million in the fourth quarter and \$184 million for the full year 2014.

**Selling, General, and Administrative (SG&A) Expenses:** In 2015, GAAP SG&A expenses were \$295 million in the fourth quarter and \$839 million for the full year, compared to \$175 million in the fourth quarter and \$519 million for full year 2014. The increases were primarily due to higher headcount and higher commercialization expenses related to EYLEA and Praluent. These increases were partly offset by a 2014 incremental charge related to the Branded Prescription Drug Fee, based on final regulations issued by the Internal Revenue Service (IRS) in July 2014. In 2015, SG&A-related non-cash share-based compensation expense was \$82 million for the fourth quarter and \$193 million for the full year, compared to \$61 million in the fourth quarter and \$135 million for the full year 2014.

**Cost of Goods Sold (COGS):** In 2015, GAAP COGS was \$71 million in the fourth quarter and \$242 million for the full year, compared to \$38 million in the fourth quarter and \$129 million for



the full year 2014. COGS primarily consists of royalties as well as costs in connection with producing U.S. EYLEA commercial supplies, and various start-up costs in connection with the Company's Limerick, Ireland commercial manufacturing facility. COGS increased principally due to the increase in U.S. EYLEA net product sales, as well as an increase in Limerick start-up costs.

**Cost of Collaboration and Contract Manufacturing (COCM):** In 2015, GAAP COCM was \$40 million in the fourth quarter and \$151 million for the full year, compared to \$22 million in the fourth quarter and \$76 million for the full year 2014. COCM includes costs the Company incurs in connection with producing commercial drug supplies for Sanofi and Bayer HealthCare. COCM increased primarily due to royalties payable to Genentech in connection with sales of EYLEA outside the United States, as well as the recognition of costs associated with commercial supplies of EYLEA manufactured for Bayer HealthCare.

**Other Income (Expense):** In 2015 and 2014, GAAP other expense includes losses on extinguishment of debt related to conversions of a portion of the Company's 1.875% convertible senior notes. In addition, GAAP other expense includes interest expense on the Company's convertible senior notes, which decreased due to conversions of a substantial portion of these notes in 2014 and 2015.

**Income Tax Expense:** In the fourth quarter of 2015, GAAP income tax expense was \$72 million and the effective tax rate was 31.8%, compared to \$100 million and 52.5% in the fourth quarter of 2014. In 2015, GAAP income tax expense was \$589 million and the effective tax rate was 48.1% for the full year, compared to \$423 million and 55.6% for the full year 2014. The effective tax rates for the full year of both 2015 and 2014 were negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the federal statutory rate and the non-tax deductible Branded Prescription Drug Fee, partly offset by the federal tax credit for increased research activities and, in 2015, a higher domestic manufacturing deduction. In the fourth quarter of 2015, the 2015 federal tax credit for increased research activities was enacted retroactive to the beginning of the year.

**Non-GAAP and GAAP Net Income:** The Company reported non-GAAP net income of \$327 million, or \$3.15 per basic share and \$2.83 per diluted share, in the fourth quarter of 2015, compared to non-GAAP net income of \$328 million, or \$3.23 per basic share and \$2.79 per diluted share, in the fourth quarter of 2014. The Company reported non-GAAP net income of \$1.404 billion, or \$13.62 per basic share and \$12.07 per diluted share, for the full year 2015, compared to non-GAAP net income of \$1.175 billion, or \$11.68 per basic share and \$10.00 per diluted share, for the full year 2014.

The Company reported GAAP net income of \$155 million, or \$1.49 per basic share and \$1.34 per diluted share, in the fourth quarter of 2015, compared to GAAP net income of \$90 million, or \$0.89 per basic share and \$0.78 per diluted share, in the fourth quarter of 2014. The Company reported GAAP net income of \$636 million, or \$6.17 per basic share and \$5.52 per diluted share, for the full year 2015, compared to GAAP net income of \$338 million, or \$3.36 per basic share and \$2.98 per diluted share, for the full year 2014.

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

## 2016 Financial Guidance<sup>(3)</sup>

The Company's full year 2016 financial guidance consists of the following components:

EYLEA U.S. net product sales	Approximately 20% growth over 2015
Non-GAAP unreimbursed R&D <sup>(2)</sup>	\$875 million - \$950 million
Non-GAAP SG&A <sup>(2)</sup>	\$925 million - \$1,000 million
Cash tax as a % of non-GAAP pre-tax income <sup>(2)</sup>	35% - 45%*
Capital expenditures	\$580 million - \$680 million

\* - Includes a non-recurring tax payment of approximately \$222 million related to the immuno-oncology upfront payment from Sanofi that the Company received in 2015.

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- (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) the incremental charge recorded in the third quarter of 2014 related to the issuance of the final IRS regulations that provide guidance on the annual fee imposed by the Patient Protection and Affordable Care Act (the final IRS regulations differed from the temporary regulations issued in 2011 which resulted in the recognition of a catch-up adjustment); (iii) 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; (iv) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control; and (v) income tax expense for 2014, which was principally a non-cash expense due primarily to utilization of net operating loss and tax credit carryforwards, 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 2016 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 originally reported for the three months and year ended December 31, 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-K for the year ended December 31, 2015 (Notes 1 and 14 of the Notes to Consolidated Financial Statements) for further details.
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## Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2015 financial and operating results on Tuesday, February 9, 2016, 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, 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 high LDL-cholesterol, eye diseases, 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](http://www.regeneron.com) or follow @Regeneron on Twitter.

## 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" or the "Company"), 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; the likelihood and timing of achieving any of the anticipated milestones described in this new release; 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 and REGN2222; 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 September 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.

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#### **Contact Information:**

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TABLE 1

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

	December 31,	
	2015	2014*
<b>Assets:</b>		
Cash and marketable securities	\$ 1,677,385	\$ 1,360,634
Accounts receivable - trade, net	1,152,489	739,379
Accounts receivable from Sanofi and Bayer HealthCare	315,304	236,993
Inventories	238,578	128,861
Deferred tax assets	461,945	315,416
Property, plant, and equipment, net	1,594,120	974,309
Other assets	169,311	82,080
<b>Total assets</b>	<b>\$ 5,609,132</b>	<b>\$ 3,837,672</b>
<b>Liabilities and stockholders' equity:</b>		
Accounts payable, accrued expenses, and other liabilities	\$ 760,619	\$ 619,083
Deferred revenue	818,166	209,274
Facility lease obligations	364,708	312,291
Convertible senior notes	10,802	146,773
Stockholders' equity	3,654,837	2,550,251
<b>Total liabilities and stockholders' equity</b>	<b>\$ 5,609,132</b>	<b>\$ 3,837,672</b>

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

TABLE 2

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

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014*	2015	2014*
<b>Revenues:</b>				
Net product sales	\$ 749,524	\$ 521,518	\$ 2,689,478	\$ 1,750,762
Sanofi collaboration revenue	165,672	135,271	758,873	541,299
Bayer HealthCare collaboration revenue	164,809	137,095	580,488	495,555
Other revenue	18,072	8,445	74,889	31,941
	<u>1,098,077</u>	<u>802,329</u>	<u>4,103,728</u>	<u>2,819,557</u>
<b>Expenses:</b>				
Research and development	461,210	351,745	1,620,577	1,271,353
Selling, general, and administrative	294,954	175,307	838,526	519,267
Cost of goods sold	71,078	37,957	241,702	129,030
Cost of collaboration and contract manufacturing	39,753	21,517	151,007	75,988
	<u>866,995</u>	<u>586,526</u>	<u>2,851,812</u>	<u>1,995,638</u>
Income from operations	<u>231,082</u>	<u>215,803</u>	<u>1,251,916</u>	<u>823,919</u>
<b>Other income (expense):</b>				
Investment and other income (expense)	1,750	2,952	6,283	8,157
Interest expense	(3,609)	(6,350)	(14,241)	(37,372)
Loss on extinguishment of debt	(1,934)	(22,682)	(18,861)	(33,469)
	<u>(3,793)</u>	<u>(26,080)</u>	<u>(26,819)</u>	<u>(62,684)</u>
Income before income taxes	227,289	189,723	1,225,097	761,235
Income tax expense	<u>(72,295)</u>	<u>(99,628)</u>	<u>(589,041)</u>	<u>(423,109)</u>
Net income	<u>\$ 154,994</u>	<u>\$ 90,095</u>	<u>\$ 636,056</u>	<u>\$ 338,126</u>
Net income per share - basic	\$ 1.49	\$ 0.89	\$ 6.17	\$ 3.36
Net income per share - diluted	\$ 1.34	\$ 0.78	\$ 5.52	\$ 2.98
Weighted average shares outstanding - basic	103,765	101,467	103,061	100,612
Weighted average shares outstanding - diluted	115,496	114,246	115,230	113,413

\* Certain revisions have been made to the amounts originally reported for the three months and year ended December 31, 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 December 31,		Year Ended December 31,	
	2015	2014*	2015	2014*
GAAP net income	\$ 154,994	\$ 90,095	\$ 636,056	\$ 338,126
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	72,570	51,180	255,708	184,347
SG&A: Non-cash share-based compensation expense	82,212	61,095	193,026	134,715
SG&A: Branded Prescription Drug Fee incremental charge	—	—	—	40,600
COGS and COCM: Non-cash share-based compensation expense	3,609	744	10,315	2,688
Interest expense: Non-cash interest related to convertible senior notes	41	2,375	2,818	17,821
Other expense: Loss on extinguishment of debt	1,934	22,682	18,861	33,469
Non-cash income taxes	11,433	99,628	287,110	423,109
Non-GAAP net income	<u>\$ 326,793</u>	<u>\$ 327,799</u>	<u>\$ 1,403,894</u>	<u>\$ 1,174,875</u>
Non-GAAP net income per share - basic	\$ 3.15	\$ 3.23	\$ 13.62	\$ 11.68
Non-GAAP net income per share - diluted <sup>(a)</sup>	\$ 2.83	\$ 2.79	\$ 12.07	\$ 10.00
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	103,765	101,467	103,061	100,612
Non-GAAP net income per share - diluted <sup>(b)</sup>	115,639	117,825	116,355	117,966

\* Certain revisions have been made to the amounts originally reported for the three months and year ended December 31, 2014. See note (4) above.

- (a) For diluted non-GAAP net income per share calculation, excludes \$5.0 million of interest expense for the year ended December 31, 2014 related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive. Such amounts were not material for the three months ended December 31, 2015 and 2014, and for the year ended December 31, 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 December 31,		Year Ended December 31,	
	2015	2014	2015	2014
<i>Sanofi collaboration revenue:</i>				
Regeneron's share of losses in connection with commercialization of antibodies	\$ (96,459)	\$ (24,253)	\$ (240,042)	\$ (41,378)
Reimbursement of Regeneron research and development expenses	171,366	143,664	776,086	552,567
Reimbursement of Regeneron commercialization-related expenses	68,205	12,417	157,350	19,480
Other	22,560	3,443	65,479	10,630
Total Sanofi collaboration revenue	165,672	135,271	758,873	541,299
<i>Bayer HealthCare collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	140,100	88,011	466,667	301,302
Sales milestones	—	30,000	15,000	105,000
Cost-sharing of Regeneron development expenses	3,326	(1,661)	18,962	26,231
Other	21,383	20,745	79,859	63,022
Total Bayer HealthCare collaboration revenue	164,809	137,095	580,488	495,555
Total collaboration revenue	\$ 330,481	\$ 272,366	\$ 1,339,361	\$ 1,036,854