

# REGENERON PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

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Address	777 OLD SAW MILL RIVER ROAD TARRYTOWN, NY 10591
Telephone	9143477000
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
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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, 2017 (February 9, 2017)

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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, 2017, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and year ended December 31, 2016. 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, 2017, Reporting Fourth Quarter and Full Year 2016 Financial and Operating Results.

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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, 2017

REGENERON PHARMACEUTICALS, INC.

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

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## Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	Press Release, dated February 9, 2017, Reporting Fourth Quarter and Full Year 2016 Financial and Operating Results.

**REGENERON**

## Press Release

**Regeneron Reports Fourth Quarter and Full Year 2016 Financial and Operating Results**

- Fourth quarter 2016 EYLEA<sup>®</sup> (afibercept) Injection U.S. net sales increased 15% to \$858 million versus fourth quarter 2015 and full year 2016 EYLEA U.S. net sales increased 24% to \$3.32 billion versus full year 2015
- Fourth quarter 2016 EYLEA global net sales<sup>(1)</sup> increased 17% to \$1.35 billion versus fourth quarter 2015 and full year 2016 EYLEA global net sales<sup>(1)</sup> increased 27% to \$5.20 billion versus full year 2015
- U.S. Court of Appeals for the Federal Circuit has granted stay of permanent injunction for Praluent<sup>®</sup> (alirocumab) during appeal process

**Tarrytown, New York (February 9, 2017)** -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2016 and provided a business update.

**Financial Highlights**

(\$ in millions, except per share data)

	Three Months Ended December 31,			Year Ended December 31,		
	2016	2015 <sup>*</sup>	% Change	2016	2015 <sup>*</sup>	% Change
EYLEA U.S. net product sales	\$ 858	\$ 746	15%	\$ 3,323	\$ 2,676	24%
Total revenues	\$ 1,227	\$ 1,098	12%	\$ 4,860	\$ 4,104	18%
GAAP net income	\$ 253	\$ 155	63%	\$ 896	\$ 636	41%
GAAP net income per share - diluted	\$ 2.19	\$ 1.34	63%	\$ 7.70	\$ 5.52	39%
Non-GAAP net income <sup>(2)</sup>	\$ 353	\$ 258	37%	\$ 1,319	\$ 944	40%
Non-GAAP net income per share - diluted <sup>(2)</sup>	\$ 3.04	\$ 2.23	36%	\$ 11.32	\$ 8.12	39%

<sup>\*</sup> See Table 3 of this press release for an explanation of revisions made to 2015 non-GAAP amounts previously reported.

"The hard work of our scientists over the last decades has brought Regeneron to the next phase of our evolution - this year we anticipate launching two additional important therapies, significantly expanding our impact for patients with serious diseases and our company's growth potential," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In March, we look forward to the potential U.S. approval of Dupixent, our innovative and breakthrough IL4/13 blocking antibody, in adults with atopic dermatitis. We believe Dupixent may have the potential to help additional patients with serious allergic diseases, with pivotal Phase 3 data in adult asthma patients expected later this year. We are also studying Dupixent in patients with nasal polyps and pediatric patients with asthma or atopic dermatitis."

## **Business Highlights**

### **Marketed Product Update**

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

- In the fourth quarter of 2016, net sales of EYLEA in the United States increased 15% to \$858 million from \$746 million in the fourth quarter of 2015. For the full year of 2016, net sales of EYLEA in the United States increased 24% to \$3.323 billion from \$2.676 billion for the full year 2015. Overall distributor inventory levels remained within the Company's one- to two-week targeted range.
- Bayer commercializes EYLEA outside the United States. In the fourth quarter of 2016, net sales of EYLEA outside of the United States <sup>(1)</sup> were \$496 million , compared to \$413 million in the fourth quarter of 2015. In the fourth quarter of 2016, Regeneron recognized \$165 million from its share of net profit from EYLEA sales outside the United States, compared to \$140 million in the fourth quarter of 2015. For the full year of 2016, net sales of EYLEA outside of the United States <sup>(1)</sup> were \$1.872 billion , compared to \$1.413 billion for the full year 2015. For the full year of 2016, Regeneron recognized \$649 million from its share of net profit from EYLEA sales outside the United States, compared to \$467 million for the full year 2015.

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

- In the fourth quarter of 2016, global net sales of Praluent were \$41 million , compared to \$7 million in the fourth quarter of 2015. For the full year of 2016, global net sales of Praluent were \$116 million , compared to \$11 million for the full year 2015. 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 commencing in the fourth quarter of 2015.
- On January 5, 2017, the United States District Court for the District of Delaware issued a permanent injunction prohibiting the Company and Sanofi from marketing, selling, or manufacturing Praluent in the United States. On February 8, 2017, the United States Court of Appeals for the Federal Circuit stayed (suspended) the injunction pending appeal. This ruling means that Regeneron and Sanofi will continue marketing, selling, and manufacturing Praluent in the United States during the appeal process.
- In the fourth quarter of 2016, the European Commission approved a Praluent dosing regimen of 300mg every 4 weeks. In January 2017, the U.S. Food and Drug Administration (FDA) extended the review period for the supplemental Biologics License Application (sBLA) for a monthly dosing regimen of Praluent. The FDA determined that Regeneron's and Sanofi's responses to information requested by the FDA during its review of the sBLA was a major amendment, which results in a three month extension of the Prescription Drug User Fee Act (PDUFA) date to allow time for the FDA to review the additional information. The new target action date is April 24, 2017.
- The ODYSSEY OUTCOMES trial remains ongoing, and is assessing the potential of Praluent to demonstrate cardiovascular benefit. In November 2016, an independent Data Monitoring Committee (DMC) completed a second pre-specified interim analysis. Based on the results of this analysis, the DMC recommended the trial continue as planned. The DMC will continue to monitor the ongoing safety and efficacy of Praluent in the trial.

## **Pipeline Progress**

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

Sarilumab, the Company's antibody targeting IL-6R for rheumatoid arthritis.

- In January 2017, Health Canada approved Kevzara™ (sarilumab) for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have an inadequate response to or intolerance to one or more biologic or non-biologic Disease-Modifying Anti-Rheumatic Drugs (DMARDs). This is the first approval of Kevzara worldwide.
- In July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for sarilumab. In addition, in October 2016, an application for marketing approval for sarilumab was submitted in Japan.
- On October 28, 2016, the Company and Sanofi announced that the FDA issued a Complete Response Letter (CRL) regarding the BLA for sarilumab. The CRL refers to certain deficiencies identified during a routine good manufacturing practice inspection of the Sanofi fill-and-finish facility in Le Trait, France.
- In the first quarter of 2017, the Company expects to resubmit the sarilumab BLA, contingent upon successful completion of the pre-approval inspection for Dupixent, and anticipates a two-month review cycle for sarilumab with an action date in the second quarter of 2017. Refer to "Sanofi's Le Trait Facility Update" section below for further information.
- In November 2016, the Company and Sanofi presented additional results from the Phase 3 SARIL-RA-MONARCH study, which demonstrated the superiority of sarilumab monotherapy versus adalimumab (marketed by AbbVie Inc. as HUMIRA®) monotherapy in improving the clinical signs and symptoms in adults with active rheumatoid arthritis at the American College of Rheumatology (ACR) Annual Meeting.

Dupixent (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.

- The FDA previously designated Dupixent as a Breakthrough Therapy for the treatment of adult patients with inadequately controlled moderate-to-severe atopic dermatitis, and in September 2016, accepted the BLA for priority review with a target action date of March 29, 2017.
- In October 2016, the FDA granted Breakthrough Therapy designation for Dupixent for the treatment of moderate to severe (12 to less than 18 years of age) and severe (6 months to less than 12 years of age) atopic dermatitis in pediatric patients who are not adequately controlled with, or who are intolerant to, topical medication.
- In October 2016, additional data from LIBERTY AD SOLO 1 and SOLO 2 atopic dermatitis studies of Dupixent were presented at the European Academy of Dermatology and Venereology conference and simultaneously published in the *New England Journal of Medicine*.
- In December 2016, the EMA accepted for review the MAA for Dupixent for the treatment of adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

- The pivotal Phase 3 LIBERTY ASTHMA QUEST study of dupilumab for the treatment of asthma completed enrollment during the third quarter of 2016.
- A Phase 3 study of dupilumab for the treatment of nasal polyps was initiated in the fourth quarter of 2016.

#### Sanofi's Le Trait Facility Update

- Sanofi's facility in Le Trait, France conducts fill-and-finish activities for certain products, including sarilumab and dupilumab .
- The FDA has reclassified the Le Trait fill-and-finish facility as "acceptable" based on review of responses to an FDA Form 483.
- A pre-approval inspection for Dupixent has been scheduled for the first quarter of 2017.

REGN2810, the Company's antibody to programmed cell death protein 1 (PD-1), is being studied in patients with cancer. A Phase 2 potentially pivotal study for the treatment of advanced cutaneous squamous cell carcinoma, as well as various Phase 1 studies, continue to enroll patients.

Fasinumab, the Company's antibody targeting Nerve Growth Factor (NGF), is being studied in patients with pain due to osteoarthritis and chronic low back pain.

- In October 2016, the FDA placed the Phase 2b study of fasinumab in chronic low back pain on clinical hold and requested an amendment of the study protocol; this was based on the FDA's recommendation that patients with advanced osteoarthritis at baseline not receive higher doses of fasinumab. Following this development, the Company completed an unplanned analysis which showed clear evidence of efficacy with improvement in pain scores in all fasinumab groups compared to placebo at the 8- and 12-week time points, and preliminary safety results are generally consistent with what has been previously reported with the class. The Company and Teva plan to design pivotal Phase 3 studies in chronic low back pain.
- In October 2016, the Company announced that at the 36-week analysis of the Phase 2/3 clinical study of fasinumab in patients with moderate-to-severe osteoarthritis pain of the hip or knee, the incidence of adjudicated arthropathies was found to be potentially dose-dependent, with a higher rate of patients experiencing arthropathies in the higher dose groups. In the ongoing fasinumab osteoarthritis pivotal Phase 3 program, the Company and Teva are planning to advance only the lower doses from the Phase 2/3 study, subject to discussion with the FDA and other health authorities.

Nesvacumab, an antibody to Ang2 co-formulated with aflibercept for intravitreal injection, is currently being studied in patients with neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME). The Phase 2 RUBY study of nesvacumab/aflibercept for the treatment of DME completed enrollment during the fourth quarter of 2016, and the Phase 2 ONYX study of nesvacumab/aflibercept for the treatment of wet AMD completed enrollment during the first quarter of 2017.

REGN3767, an antibody to Lymphocyte Activation Gene 3 (LAG-3) protein, entered Phase 1 clinical development for treatment of advanced malignancies in the fourth quarter of 2016.

REGN2477, an antibody to Activin A, received orphan drug designation from the FDA for the treatment of Fibrodysplasia Ossificans Progressiva (FOP) in the first quarter of 2017.

## Select Upcoming 2017 Milestones

Programs	Milestones
Praluent	<ul style="list-style-type: none"><li>• Complete ODYSSEY OUTCOMES study</li></ul>
Sarilumab (IL-6R Antibody)	<ul style="list-style-type: none"><li>• Re-submission of the BLA in the first quarter of 2017 contingent upon successful FDA re-inspection of Le Trait facility. FDA action would then be expected in the second quarter of 2017.</li><li>• Submission for additional regulatory approvals and regulatory agency decisions on applications outside of the United States</li></ul>
Dupilumab (IL-4R Antibody)	<ul style="list-style-type: none"><li>• FDA target action date of March 29, 2017 for atopic dermatitis</li><li>• Report results from Phase 3 asthma study</li><li>• Submit sBLA for asthma in adults</li><li>• Report results from Phase 2 study in eosinophilic esophagitis</li><li>• Initiate Phase 3 studies in pediatric patients in atopic dermatitis and asthma</li><li>• Initiate Phase 2 study in food allergies</li></ul>
REGN2222 (RSV-F Antibody)	<ul style="list-style-type: none"><li>• Report results from Phase 3 study</li></ul>
Fasinumab (NGF Antibody)	<ul style="list-style-type: none"><li>• Initiate additional Phase 3 study in patients with osteoarthritis pain</li><li>• Initiate Phase 3 study in chronic low back pain</li></ul>
REGN2810 (PD-1 Antibody)	<ul style="list-style-type: none"><li>• Initiate Phase 2 study in non-small cell lung cancer</li><li>• Initiate Phase 2 study in basal cell carcinoma</li></ul>
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	<ul style="list-style-type: none"><li>• Report data from Phase 2 studies in DME and wet AMD</li></ul>

## Fourth Quarter and Full Year 2016 Financial Results

**Product Revenues:** Net product sales were \$863 million in the fourth quarter and \$3.338 billion for the full year 2016, compared to \$750 million in the fourth quarter and \$2.689 billion for the full year 2015. EYLEA net product sales in the United States were \$858 million in the fourth quarter and \$3.323 billion for the full year 2016, compared to \$746 million in the fourth quarter and \$2.676 billion for the full year 2015.

**Total Revenues:** Total revenues, which include product revenues described above, increased by 12% to \$1.227 billion in the fourth quarter of 2016, compared to \$1.098 billion in the fourth quarter of 2015. Total revenues also include Sanofi and Bayer collaboration revenues of \$313 million in the fourth quarter of 2016, compared to \$330 million in the fourth quarter of 2015. Full year 2016 total revenues increased by 18% to \$4.860 billion, compared to \$4.104 billion for the full year 2015, and included collaboration revenues of \$1.403 billion for the full year 2016, compared to \$1.339 billion for the full year 2015. Refer to Table 4 for a summary of collaboration revenue.

**Research and Development (R&D) Expenses:** In 2016, GAAP R&D expenses were \$479 million in the fourth quarter and \$2.052 billion for the full year, compared to \$461 million in the fourth quarter and \$1.621 billion for the full year 2015. The higher R&D expenses for the full

year 2016 compared to the full year 2015 were principally due to the \$75 million up-front payment made in connection with the April 2016 license and collaboration with Intellia, the \$25 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet, higher development costs, including manufacturing drug supplies, primarily related to fasinumab and REGN2810, and higher headcount to support the Company's increased R&D activities, partly offset by lower development costs primarily related to Praluent. In addition, in 2016, R&D-related non-cash share-based compensation expense was \$75 million for the fourth quarter and \$313 million for the full year, compared to \$73 million in the fourth quarter and \$256 million for the full year 2015.

**Selling, General, and Administrative (SG&A) Expenses:** In 2016, GAAP SG&A expenses were \$326 million in the fourth quarter and \$1.178 billion for the full year, compared to \$295 million in the fourth quarter and \$839 million for the full year 2015. The higher SG&A expenses for the full year 2016 compared to the full year 2015 were primarily due to higher commercialization-related expenses in connection with EYLEA and Praluent, higher commercialization-related expenses in connection with preparing to launch sarilumab and dupilumab, and higher headcount. In addition, in 2016, SG&A-related non-cash share-based compensation expense was \$74 million for the fourth quarter and \$231 million for the full year, compared to \$82 million in the fourth quarter and \$193 million for the full year 2015.

**Cost of Goods Sold (COGS):** In 2016, GAAP COGS was \$45 million in the fourth quarter and \$195 million for the full year, compared to \$71 million in the fourth quarter and \$242 million for the full year 2015. COGS decreased principally due to a decrease in royalties since the Company's obligation to pay Genentech based on U.S. sales of EYLEA ended in May 2016, partly offset by an increase in various start-up costs in connection with the Company's Limerick, Ireland commercial manufacturing facility and an increase in U.S. EYLEA net sales.

**Cost of Collaboration and Contract Manufacturing (COCM):** In 2016, GAAP COCM was \$30 million in the fourth quarter and \$105 million for the full year, compared to \$40 million in the fourth quarter and \$151 million for the full year 2015. COCM decreased primarily due to lower royalties since the Company's obligation to pay Genentech based on sales of EYLEA outside the United States also ended in May 2016.

**Income Tax Expense:** In the fourth quarter of 2016, GAAP income tax expense was \$88 million and the effective tax rate was 25.9% , compared to \$72 million and 31.8% in the fourth quarter of 2015. In 2016, GAAP income tax expense was \$434 million and the effective tax rate was 32.7% for the full year, compared to \$589 million and 48.1% for the full year 2015. The effective tax rates for the both the fourth quarter and full year of 2016 were positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with stock-based compensation, partly offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the federal statutory rate. As described in Table 3 of this press release, the Company adopted Accounting Standards Update 2016-09 (ASU 2016-09), *Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting* , during the second quarter of 2016. ASU 2016-09 requires companies to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital on the balance sheet).

**GAAP and Non-GAAP Net Income:** The Company reported GAAP net income of \$253 million , or \$2.41 per basic share and \$2.19 per diluted share, in the fourth quarter of 2016, compared to GAAP net income of \$155 million , or \$1.49 per basic share and \$1.34 per diluted share, in the fourth quarter of 2015. The Company reported GAAP net income of \$896 million , or \$8.55 per basic share and \$7.70 per diluted share, for the full year 2016, compared to GAAP net income of \$636 million , or \$6.17 per basic share and \$5.52 per diluted share, for the full year 2015.

The Company reported non-GAAP net income of \$353 million , or \$3.35 per basic share and \$3.04 per diluted share, in the fourth quarter of 2016, compared to non-GAAP net income of \$258 million , or \$2.48 per basic share and \$2.23 per diluted share, in the fourth quarter of 2015. The Company reported non-GAAP net income of \$1.319 billion , or \$12.60 per basic share and \$11.32 per diluted share, for the full year 2016, compared to non-GAAP net income of \$944 million , or \$9.16 per basic share and \$8.12 per diluted share, for the full year 2015.

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

**Tarrytown, New York Facilities Update:** On December 30, 2016, the Company entered into a Purchase Agreement with BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC (collectively, BMR), pursuant to which the Company has agreed to purchase from BMR its Tarrytown, New York facilities (the Facility), which includes laboratory and office space the Company's currently leases, for a purchase price of \$720 million. The closing of the Purchase Agreement is anticipated in the first quarter of 2017.

The Company intends to fund the acquisition contemplated by the Purchase Agreement with a new financing; accordingly, the Company has entered into an engagement letter with Banc of America Leasing & Capital, LLC (BAL) to arrange a \$720 million lease financing in connection with this acquisition. Immediately thereafter, the Company intends to lease the Facility from an affiliate of BAL for a term of five years. At the end of the lease term, the Company expects to have an option to extend the term of the lease, purchase the Facility at a predetermined amount, or sell the Facility to a third party on behalf of BAL.

### **2017 Financial Guidance <sup>(3)</sup>**

The Company's full year 2017 financial guidance consists of the following components:

EYLEA U.S. net product sales	Single digit percentage growth over 2016
Sanofi reimbursement of Regeneron commercialization-related expenses	\$400 million - \$450 million
Non-GAAP unreimbursed R&D <sup>(2) (4)</sup>	\$950 million - \$1.025 billion
Non-GAAP SG&A <sup>(2) (4)</sup>	\$1.175 billion - \$1.250 billion
Effective tax rate	32% - 38%
Capital expenditures	\$375 million - \$450 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 in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within "Bayer 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, and non-GAAP SG&A, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). These non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. Non-GAAP adjustments also include the income tax effect of reconciling items.

The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate 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. 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. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. 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 2017 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release and assumes that Praluent will remain on the market throughout 2017.

(4) A reconciliation of full year 2017 non-GAAP to GAAP financial guidance is included below:

<i>(In millions)</i>	Projected Range	
	Low	High
GAAP unreimbursed R&D <sup>(5)</sup>	\$ 1,250	\$ 1,345
R&D: Non-cash share-based compensation expense	(300)	(320)
Non-GAAP unreimbursed R&D	\$ 950	\$ 1,025
GAAP SG&A	\$ 1,380	\$ 1,485
SG&A: Non-cash share-based compensation expense	(205)	(235)
Non-GAAP SG&A	\$ 1,175	\$ 1,250

(5) Unreimbursed R&D represents R&D expenses reduced by R&D expense reimbursements from the Company's collaborators and/or customers.

## Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2016 financial and operating results on Thursday, February 9, 2017, at 8:30 AM. To access this call, dial (888) 771-4371 (U.S.) or (847) 585-4405 (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 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 rheumatoid arthritis, atopic dermatitis, asthma, pain, cancer, 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; risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation relating to Praluent, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; the likelihood and timing of achieving any of the anticipated milestones described in this news 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 EYLEA<sup>®</sup> (afibercept) Injection, Praluent<sup>®</sup> (alirocumab) Injection, sarilumab, Dupixent<sup>®</sup> (dupilumab), REGN2810, fasinumab, nesvacumab, REGN3767, and REGN2477; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA 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, as well as actions by Regeneron's collaborators or third-party manufacturers, or other parties performing steps in the supply chain, impacting the foregoing; 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, Sanofi reimbursement of Regeneron commercialization-related expenses, non-GAAP unreimbursed R&D, non-GAAP SG&A, effective tax rate, and capital expenditures; and the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success. 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. 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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TABLE 1

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

	December 31,	
	2016	2015
<b>Assets:</b>		
Cash and marketable securities	\$ 1,902,944	\$ 1,677,385
Accounts receivable - trade, net	1,343,368	1,152,489
Accounts receivable from Sanofi and Bayer	268,252	315,304
Inventories	399,356	238,578
Deferred tax assets	825,303	461,945
Property, plant, and equipment, net	2,083,421	1,594,120
Other assets	150,822	169,311
Total assets	<u>\$ 6,973,466</u>	<u>\$ 5,609,132</u>
<b>Liabilities and stockholders' equity:</b>		
Accounts payable, accrued expenses, and other liabilities	\$ 980,659	\$ 760,619
Deferred revenue	1,062,436	818,166
Capital and facility lease obligations	481,126	364,708
Convertible senior notes	—	10,802
Stockholders' equity	4,449,245	3,654,837
Total liabilities and stockholders' equity	<u>\$ 6,973,466</u>	<u>\$ 5,609,132</u>

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,	
	2016	2015	2016	2015
<b>Revenues:</b>				
Net product sales	\$ 862,521	\$ 749,524	\$ 3,338,390	\$ 2,689,478
Sanofi collaboration revenue	131,165	165,672	658,665	758,873
Bayer collaboration revenue	181,484	164,809	744,270	580,488
Other revenue	51,657	18,072	119,102	74,889
	<u>1,226,827</u>	<u>1,098,077</u>	<u>4,860,427</u>	<u>4,103,728</u>
<b>Expenses:</b>				
Research and development	479,206	461,210	2,052,295	1,620,577
Selling, general, and administrative	325,937	294,954	1,177,697	838,526
Cost of goods sold	44,534	71,078	194,624	241,702
Cost of collaboration and contract manufacturing	30,147	39,753	105,070	151,007
	<u>879,824</u>	<u>866,995</u>	<u>3,529,686</u>	<u>2,851,812</u>
Income from operations	<u>347,003</u>	<u>231,082</u>	<u>1,330,741</u>	<u>1,251,916</u>
Other income (expense), net	(5,476)	(3,793)	(926)	(26,819)
Income before income taxes	341,527	227,289	1,329,815	1,225,097
Income tax expense	(88,412)	(72,295)	(434,293)	(589,041)
Net income	<u>\$ 253,115</u>	<u>\$ 154,994</u>	<u>\$ 895,522</u>	<u>\$ 636,056</u>
Net income per share - basic	\$ 2.41	\$ 1.49	\$ 8.55	\$ 6.17
Net income per share - diluted	\$ 2.19	\$ 1.34	\$ 7.70	\$ 5.52
Weighted average shares outstanding - basic	105,113	103,765	104,719	103,061
Weighted average shares outstanding - diluted	115,788	115,496	116,367	115,230

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,	
	2016	2015	2016	2015
GAAP net income	\$ 253,115	\$ 154,994	\$ 895,522	\$ 636,056
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	75,057	72,570	313,048	255,708
R&D: Upfront payment related to license and collaboration agreements	—	—	100,000	—
SG&A: Non-cash share-based compensation expense	74,002	82,212	231,183	193,026
COGS and COCM: Non-cash share-based compensation expense	5,499	3,609	15,647	10,315
Other expense: Non-cash interest and loss on extinguishment related to convertible senior notes	1	1,975	616	21,679
Income tax effect of reconciling items above <sup>(c)</sup>	(55,132)	(57,608)	(236,717)	(172,719)
Non-GAAP net income <sup>(c)</sup>	<u>\$ 352,542</u>	<u>\$ 257,752</u>	<u>\$ 1,319,299</u>	<u>\$ 944,065</u>
Non-GAAP net income per share - basic	\$ 3.35	\$ 2.48	\$ 12.60	\$ 9.16
Non-GAAP net income per share - diluted <sup>(a)</sup>	\$ 3.04	\$ 2.23	\$ 11.32	\$ 8.12

*Shares used in calculating:*

Non-GAAP net income per share - basic	105,113	103,765	104,719	103,061
Non-GAAP net income per share - diluted <sup>(b)</sup>	115,887	115,639	116,548	116,355

(a) For diluted non-GAAP net income per share calculations, interest expense related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes was excluded when these securities were dilutive. Such interest expense was not material for all periods presented.

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

(c) Prior to the quarter ended June 30, 2016, non-GAAP measures presented by the Company also included an income tax expense adjustment from GAAP tax expense to the amount of taxes that were paid or payable in cash in respect of the relevant period. Historically, there had been a significant difference between the Company's GAAP effective tax rate and actual cash income taxes paid or payable primarily due to the utilization of excess tax benefits in connection with employee exercises of stock options (which were recorded to additional paid-in capital for GAAP reporting purposes). In connection with the adoption of ASU 2016-09, *Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting*, during the second quarter of 2016, the Company chose to discontinue such non-GAAP adjustment as ASU 2016-09 requires entities to recognize excess tax benefits in connection with employee exercises of stock options in the income statement. The Company adopted this aspect of ASU 2016-09 prospectively. A reconciliation to the previously reported non-GAAP adjustment is presented below:

	<b>Three Months Ended December 31, 2015</b>	<b>Year Ended December 31, 2015</b>
Non-GAAP net income - as revised (see above)	\$ 257,752	\$ 944,065
Income tax effect of reconciling items (see above)	57,608	172,719
Non-cash income taxes (as previously reported)	11,433	287,110
Non-GAAP net income - as previously reported	<u>\$ 326,793</u>	<u>\$ 1,403,894</u>

*Note: As a result of the above revisions to non-GAAP net income, non-GAAP net income per share (basic and diluted) has also been revised accordingly.*

TABLE 4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
<i>Sanofi collaboration revenue:</i>				
Reimbursement of Regeneron research and development expenses	\$ 136,323	\$ 171,366	\$ 703,397	\$ 776,086
Reimbursement of Regeneron commercialization-related expenses	97,287	68,205	322,149	157,350
Regeneron's share of losses in connection with commercialization of antibodies	(125,528)	(96,459)	(459,058)	(240,042)
Other	23,083	22,560	92,177	65,479
Total Sanofi collaboration revenue	<u>131,165</u>	<u>165,672</u>	<u>658,665</u>	<u>758,873</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	165,051	140,100	649,232	466,667
Sales milestones	—	—	—	15,000
Cost-sharing of Regeneron development expenses	5,986	3,326	27,337	18,962
Other	10,447	21,383	67,701	79,859
Total Bayer collaboration revenue	<u>181,484</u>	<u>164,809</u>	<u>744,270</u>	<u>580,488</u>
Total Sanofi and Bayer collaboration revenue	<u>\$ 312,649</u>	<u>\$ 330,481</u>	<u>\$ 1,402,935</u>	<u>\$ 1,339,361</u>

*Note: In addition to amounts noted in the table above, the Company recorded \$21.2 million and \$24.2 million for the three months and year ended December 31, 2016, respectively, related to reimbursements of Regeneron research and development expenses in connection with its collaboration agreement with Teva. The Company also recorded \$0.8 million and \$2.3 million for the three months and year ended December 31, 2016, respectively, and \$0.3 million and \$2.4 million for the three months and year ended December 31, 2015, respectively, related to reimbursements of Regeneron research and development expenses by other entities.*