

REGENERON

Regeneron Reports Third Quarter 2016 Financial and Operating Results

November 4, 2016

TARRYTOWN, N.Y., Nov. 4, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2016 and provided a business update.

Financial Highlights

(\$ in millions, except per share data)	Three Months Ended September 30,		
	2016	2015*	% Change
EYLEA U.S. net product sales	\$ 854	\$ 734	16 %
Total revenues	\$ 1,220	\$ 1,137	7 %
GAAP net income	\$ 265	\$ 210	26 %
GAAP net income per share - diluted	\$ 2.27	\$ 1.82	25 %
Non-GAAP net income ⁽²⁾	\$ 365	\$ 276	32 %
Non-GAAP net income per share - diluted ⁽²⁾	\$ 3.13	\$ 2.38	32 %

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

"In the third quarter, we saw continued U.S. sales growth with EYLEA in retinal diseases and with Praluent in hypercholesterolemia," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We are preparing for a potential approval and launch for Dupixent in atopic dermatitis and continuing to advance our pipeline at all stages."

Business Highlights

Marketed Product Update

EYLEA® (afibercept) Injection for Intravitreal Injection

- In the third quarter of 2016, net sales of EYLEA in the United States increased 16% to \$854 million from \$734 million in the third quarter of 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 third quarter of 2016, net sales of EYLEA outside of the United States⁽¹⁾ were \$471 million, compared to \$371 million in the third quarter of 2015. In the third quarter of 2016, Regeneron recognized \$171 million from its share of net profit from EYLEA sales outside the United States, compared to \$131 million in the third quarter of 2015.

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

- In the third quarter of 2016, global net sales of Praluent were \$38 million, compared to \$4 million in the third quarter of 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.
- In the second quarter of 2016, the U.S. Food and Drug Administration (FDA) accepted for review a supplemental Biologics License Application (sBLA) for a monthly dosing regimen of Praluent, with a target action date of January 24, 2017. In addition, a regulatory application for a monthly dosing regimen of Praluent was filed in the European Union.
- In July 2016, the Japanese Ministry of Health, Labour and Welfare granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk.
- In August 2016, the Company and Sanofi presented data from the Phase 3 ODYSSEY ESCAPE study in patients with heterozygous familial hypercholesterolemia (HeFH) who were undergoing LDL apheresis therapy. The trial demonstrated that adding Praluent to existing therapy reduced LDL cholesterol by approximately 50% from baseline (compared to a 2% increase for placebo). The trial also achieved its primary endpoint, demonstrating that patients who added Praluent to their existing treatment regimen significantly reduced the frequency of their apheresis therapy by 75%, compared to placebo.
- The ODYSSEY OUTCOMES trial remains ongoing, and is assessing the potential of Praluent to demonstrate cardiovascular benefit. An independent Data Monitoring Committee will conduct a second interim analysis for futility and

overwhelming efficacy (hazard ratio < 0.802 corresponding to $p < 0.0001$) for the primary endpoint with consistency across subgroups and regions, positive trends for secondary end points including all-cause mortality, and no excess non-cardiovascular mortality. This second interim analysis is expected by the end of this month.

Pipeline Progress

Regeneron has sixteen product candidates in clinical development. These consist of EYLEA and fifteen fully human monoclonal antibodies generated using the Company's *VelocImmune*[®] technology, including five 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, is currently being studied in the global Phase 3 SARIL-RA program.

- On October 28, 2016, the Company and Sanofi announced that the FDA issued a Complete Response Letter (CRL) regarding the Biologics License Application (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. Satisfactory resolution of these deficiencies is required before the BLA can be approved. Sanofi submitted a comprehensive corrective action plan to the FDA, is implementing the corrective actions, and is working closely with the FDA towards a timely resolution. The CRL does not identify any concerns relating to the safety or efficacy of sarilumab.
- 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.

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*.
- The pivotal Phase 3 LIBERTY ASTHMA QUEST study of dupilumab for the treatment of asthma completed enrollment during the third quarter of 2016.

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 after observing a case of adjudicated arthropathy in a patient receiving high dose fasinumab who had advanced osteoarthritis at study entry. 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 a pivotal Phase 3 study in chronic low back pain that excludes patients with advanced osteoarthritis.
- 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, the Company's antibody to Ang2 co-formulated with aflibercept for intravitreal injection, is currently being studied in patients with 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.

Rinucumab, the Company's antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection, is currently being studied in patients with neovascular age-related macular degeneration (wet AMD). In September 2016, the Company announced top-line results from the Phase 2 CAPELLA study. These data showed that at 12 weeks, rinucumab in combination with aflibercept did not add to the improvement in best corrected visual acuity (BCVA) that was demonstrated with intravitreal aflibercept injection monotherapy, the primary endpoint of the study. Results in the EYLEA monotherapy arm of the CAPELLA study were consistent with the efficacy and safety seen in Phase 3 pivotal studies of EYLEA in wet AMD.

REGN3500 entered Phase 1 clinical development for the treatment of inflammatory diseases in the third quarter of 2016. Sanofi exercised its right to opt-in to co-develop REGN3500.

Business Development Update

- In July 2016, the Company and Adicet Bio, Inc. entered into a license and collaboration agreement to develop next-generation engineered immune-cell therapeutics with fully human chimeric antigen receptors and T-cell receptors directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells.
- In September 2016, the Company and Teva Pharmaceuticals International GmbH (Teva), a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., entered into a collaboration agreement to develop and commercialize fasinumab. Under the terms of the agreement, the Company will lead global development and commercialization in the United States, and Teva will lead development and commercialization in territories outside the United States (excluding certain Asian countries that are subject to a separate collaboration agreement previously entered into between the Company and Mitsubishi Tanabe Pharma Corporation).

Third Quarter 2016 Financial Results

Product Revenues: Net product sales were \$857 million in the third quarter of 2016, compared to \$738 million in the third quarter of 2015. EYLEA net product sales in the United States were \$854 million in the third quarter of 2016, compared to \$734 million in the third quarter of 2015.

Total Revenues: Total revenues, which include product revenues described above, increased by 7% to \$1,220 million in the third quarter of 2016, compared to \$1,137 million in the third quarter of 2015. Total revenues also include Sanofi and Bayer collaboration revenues of \$336 million in the third quarter of 2016, compared to \$382 million in the third quarter of 2015. Collaboration revenues in the third quarter of 2016 decreased primarily due to lower reimbursable research and development expenses and an increase in the Company's share of losses primarily from the commercialization of Praluent and pre-commercialization activities for sarilumab and Dupixent under the Company's antibody collaboration with Sanofi, partly offset by 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 \$543 million in the third quarter of 2016, compared to \$426 million in the third quarter of 2015. The higher R&D expenses in the third quarter of 2016 were principally due to 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, Dupixent, and REGN2810, and higher headcount to support the Company's increased R&D activities, partly offset by lower development costs primarily related to Praluent and sarilumab. In addition, in the third quarter of 2016, R&D-related non-cash share-based compensation expense was \$81 million, compared to \$64 million in the third quarter of 2015.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$270 million in the third quarter of 2016, compared to \$210 million in the third quarter of 2015. The increase was primarily due to higher commercialization-related expenses in connection with EYLEA and Praluent, and higher headcount. In addition, in the third quarter of 2016, SG&A-related non-cash share-based compensation expense was \$49 million, compared to \$36 million in the third quarter of 2015.

Cost of Goods Sold (COGS): GAAP COGS was \$30 million in the third quarter of 2016, compared to \$67 million in the third quarter of 2015. COGS primarily consists of costs in connection with producing U.S. EYLEA commercial supplies, various start-up costs in connection with the Company's Limerick, Ireland commercial manufacturing facility, and royalties. 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.

Cost of Collaboration and Contract Manufacturing (COCM): GAAP COCM was \$14 million in the third quarter of 2016, compared to \$42 million in the third quarter of 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 third quarter of 2016, GAAP income tax expense was \$101 million and the effective tax rate was 27.6%, compared to \$183 million and 46.5% in the third quarter of 2015. The effective tax rate for the third quarter of 2016 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, the federal tax credit for increased research activities, and changes to tax reserves, partly offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. 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 \$265 million, or \$2.53 per basic share and \$2.27 per diluted share, in the third quarter of 2016, compared to GAAP net income of \$210 million, or \$2.04 per basic share and \$1.82 per diluted share, in the third quarter of 2015.

The Company reported non-GAAP net income of \$365 million, or \$3.48 per basic share and \$3.13 per diluted share, in the third quarter of 2016, compared to non-GAAP net income of \$276 million, or \$2.67 per basic share and \$2.38 per diluted share, in the third quarter of 2015.

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

2016 Financial Guidance⁽³⁾

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

EYLEA U.S. net product sales	23% - 25% growth over 2015 (previously 20% - 25% growth over 2015)
Sanofi reimbursement of Regeneron commercialization-related expenses	\$310 million - \$335 million (previously \$310 million - \$340 million)

Non-GAAP unreimbursed R&D ⁽²⁾ (4)	\$945 million - \$975 million <i>(previously \$970 million - \$1.01 billion)</i>
Non-GAAP SG&A ⁽²⁾ (4)	\$965 million - \$995 million <i>(previously \$980 million - \$1.02 billion)</i>
Effective tax rate	29% - 33% <i>(previously 33% - 41%)</i>
Capital expenditures	\$480 million - \$510 million <i>(previously \$480 million - \$530 million)</i>

- (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 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) A reconciliation of full year 2016 non-GAAP to GAAP financial guidance is included below:

<i>(In millions)</i>	Projected Range	
	Low	High
GAAP unreimbursed R&D ⁽⁵⁾	\$ 1,355	\$ 1,400
R&D: Non-cash share-based compensation expense	(310)	(325)
R&D: Upfront payments related to license and collaboration agreements	(100)	(100)
Non-GAAP unreimbursed R&D	\$ 945	\$ 975
GAAP SG&A	\$ 1,185	\$ 1,240
SG&A: Non-cash share-based compensation expense	(220)	(245)
Non-GAAP SG&A	\$ 965	\$ 995

- (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 third quarter 2016 financial and operating results on Friday, November 4, 2016, 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. 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, asthma, atopic dermatitis, pain, cancer, and infectious diseases. For additional information about the Company, please visit 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 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® (afibercept) Injection, Praluent® (alirocumab) Injection, sarilumab, Dupixent® (dupilumab), fasinumab, nesvacumab, rinucumab, and REGN3500; 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; 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; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), 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, 2015 and its Form 10-Q for the quarterly period ended September 30, 2016. 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:

Manisha Narasimhan, Ph.D.

Investor Relations

914-847-5126

manisha.narasimhan@regeneron.com

Hala Mirza

Corporate Communications

914-847-3422

hala.mirza@regeneron.com

TABLE 1

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

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
Assets:		
Cash and marketable securities	\$ 2,186,297	\$ 1,677,385
Accounts receivable - trade, net	1,332,071	1,152,489
Accounts receivable from Sanofi and Bayer	311,801	315,304
Inventories	345,620	238,578
Deferred tax assets	655,552	461,945
Property, plant, and equipment, net	1,872,167	1,594,120
Other assets	124,511	169,311
Total assets	<u>\$ 6,828,019</u>	<u>\$ 5,609,132</u>
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 851,801	\$ 760,619
Deferred revenue	1,100,342	818,166
Facility lease obligations	384,381	364,708
Convertible senior notes	248	10,802
Stockholders' equity	4,491,247	3,654,837
Total liabilities and stockholders' equity	<u>\$ 6,828,019</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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Net product sales	\$ 857,468	\$ 737,562	\$ 2,475,869	\$ 1,939,954
Sanofi collaboration revenue	144,392	224,735	527,500	593,201
Bayer collaboration revenue	191,298	157,596	562,786	415,679
Other revenue	26,964	17,529	67,445	56,817
	<u>1,220,122</u>	<u>1,137,422</u>	<u>3,633,600</u>	<u>3,005,651</u>
Expenses:				
Research and development	543,047	425,924	1,573,089	1,159,367
Selling, general, and administrative	270,045	209,993	851,760	543,572
Cost of goods sold	29,901	67,199	150,090	170,624
Cost of collaboration and contract manufacturing	14,327	41,884	74,923	111,254
	<u>857,320</u>	<u>745,000</u>	<u>2,649,862</u>	<u>1,984,817</u>
Income from operations	<u>362,802</u>	<u>392,422</u>	<u>983,738</u>	<u>1,020,834</u>
Other income (expense), net	<u>3,079</u>	<u>867</u>	<u>4,550</u>	<u>(23,026)</u>
Income before income taxes	365,881	393,289	988,288	997,808
Income tax expense	<u>(101,077)</u>	<u>(182,891)</u>	<u>(345,881)</u>	<u>(516,746)</u>
Net income	<u>\$ 264,804</u>	<u>\$ 210,398</u>	<u>\$ 642,407</u>	<u>\$ 481,062</u>
Net income per share - basic	\$ 2.53	\$ 2.04	\$ 6.14	\$ 4.68
Net income per share - diluted	\$ 2.27	\$ 1.82	\$ 5.51	\$ 4.18
Weighted average shares outstanding - basic	104,833	103,348	104,586	102,825
Weighted average shares outstanding - diluted	116,466	115,944	116,567	115,144

TABLE 3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
GAAP net income	\$ 264,804	\$ 210,398	\$ 642,407	\$ 481,062
Adjustments:				
R&D: Non-cash share-based compensation expense	80,572	63,590	237,991	183,137
R&D: Upfront payment related to license and collaboration agreements	25,000	—	100,000	—
SG&A: Non-cash share-based compensation expense	49,369	36,481	157,181	110,814
COGS and COCM: Non-cash share-based compensation expense	1,438	2,571	10,148	6,706
Other expense: Non-cash interest and loss on extinguishment related to convertible senior notes	37	215	615	19,704
Income tax effect of reconciling items above ^(c)	<u>(56,223)</u>	<u>(36,889)</u>	<u>(181,612)</u>	<u>(115,111)</u>
Non-GAAP net income ^(c)	<u>\$ 364,997</u>	<u>\$ 276,366</u>	<u>\$ 966,730</u>	<u>\$ 686,312</u>
Non-GAAP net income per share - basic	\$ 3.48	\$ 2.67	\$ 9.24	\$ 6.67
Non-GAAP net income per share - diluted ^(a)	\$ 3.13	\$ 2.38	\$ 8.28	\$ 5.89

Shares used in calculating:

Non-GAAP net income per share - basic	104,833	103,348	104,586	102,825
Non-GAAP net income per share - diluted ^(b)	116,644	116,014	116,764	116,559

- (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 were excluded since these securities were dilutive. Such interest expense was not material for the three and nine-month periods ended September 30, 2016 and 2015.
- (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:

	<u>Three Months Ended September 30, 2015</u>	<u>Nine Months Ended September 30, 2015</u>
Non-GAAP net income - as revised (see above)	\$ 276,366	\$ 686,312
Income tax effect of reconciling items (see above)	36,889	115,111
Non-cash income taxes (as previously reported)	89,616	275,521
Non-GAAP net income - as previously reported	<u>\$ 402,871</u>	<u>\$ 1,076,944</u>

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

TABLE 4

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<i>Sanofi collaboration revenue:</i>				
Reimbursement of Regeneron research and development expenses	\$ 167,615	\$ 223,698	\$ 567,074	\$ 604,720
Reimbursement of Regeneron commercialization-related expenses	65,703	53,341	224,862	89,145
Regeneron's share of losses in connection with commercialization of antibodies	(112,001)	(74,865)	(333,530)	(143,583)
Other	23,075	22,561	69,094	42,919
Total Sanofi collaboration revenue	<u>144,392</u>	<u>224,735</u>	<u>527,500</u>	<u>593,201</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	170,854	130,510	484,181	326,567
Sales milestones	—	—	—	15,000
Cost-sharing of Regeneron development expenses	9,652	3,335	21,351	15,636
Other	10,792	23,751	57,254	58,476
Total Bayer collaboration revenue	<u>191,298</u>	<u>157,596</u>	<u>562,786</u>	<u>415,679</u>

Total Sanofi and Bayer collaboration revenue	<u>\$ 335,690</u>	<u>\$ 382,331</u>	<u>\$ 1,090,286</u>	<u>\$ 1,008,880</u>
--	-------------------	-------------------	---------------------	---------------------

Note: In addition to amounts noted in the table above, the Company recorded \$3.9 million and \$4.5 million for the three and nine months ended September 30, 2016, respectively, related to reimbursements of Regeneron research and development expenses by other entities.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/regeneron-reports-third-quarter-2016-financial-and-operating-results-300357345.html>

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media