

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): November 6, 2018 (November 6, 2018)

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On November 6, 2018, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2018. 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 November 6, 2018, Reporting Third Quarter 2018 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: November 6, 2018

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated November 6, 2018, Reporting Third Quarter 2018 Financial and Operating Results.</a>

**REGENERON**

Press Release

**Regeneron Reports Third Quarter 2018 Financial and Operating Results**

- *Third quarter 2018 EYLEA® (aflibercept) Injection U.S. net sales increased 7% to \$1.02 billion versus third quarter 2017, and third quarter 2018 EYLEA global net sales<sup>(1)</sup> increased 11% to \$1.68 billion versus third quarter 2017*
- *U.S. launch of Libtayo® (cemiplimab-rwlc) Injection for the treatment of patients with cutaneous squamous cell carcinoma (CSCC) underway*
- *U.S. launch of Dupixent® (dupilumab) Injection in patients with moderate-to-severe asthma underway*
- *FDA approval of EYLEA for an every 12-week dosing regimen in patients with wet age-related macular degeneration (wet AMD)*
- *Positive Phase 3 trial results showed that EYLEA improved diabetic retinopathy and reduced vision-threatening complications*
- *Positive results reported from Phase 3 Dupixent trials in patients with chronic rhinosinusitis with nasal polyps (CRSwNP) and Phase 3 fasinumab trial in patients with chronic pain from osteoarthritis of the knee or hip*

**Tarrytown, New York (November 6, 2018)** -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2018 and provided a business update.

"Regeneron continues to grow and diversify our business, while continuing to deliver very strong financial results. In addition to EYLEA reaching over \$1 billion in quarterly U.S. net sales, we also made significant progress with Dupixent, a key driver of future growth, and launched Libtayo, our first immuno-oncology therapy," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Dupixent is now approved in the U.S. for both atopic dermatitis and asthma and under regulatory review for the treatment of adolescents with atopic dermatitis - with another submission planned in chronic rhinosinusitis with nasal polyps. We also recently reported positive Phase 3 results for EYLEA in diabetic retinopathy, and expect an FDA action on our supplemental application for this indication in the first half of 2019."

**Financial Highlights**

	Three Months Ended September 30,		
	2018	2017	% Change
<i>(\$ in millions, except per share data)</i>			
Total revenues	\$ 1,663	\$ 1,501	11%
GAAP net income	\$ 595	\$ 388	53%
GAAP net income per share - diluted	\$ 5.17	\$ 3.32	56%
Non-GAAP net income <sup>(2)</sup>	\$ 675	\$ 470	44%
Non-GAAP net income per share - diluted <sup>(2)</sup>	\$ 5.87	\$ 3.99	47%

## **Third Quarter 2018 Business Highlights**

### **Key Pipeline Progress**

Regeneron has twenty product candidates in clinical development, which consist of EYLEA and fully human antibodies generated using the Company's *VelocImmune*<sup>®</sup> technology, including eight in collaboration with Sanofi. Updates from the clinical pipeline include:

#### **EYLEA<sup>®</sup> (aflibercept) Injection**

- The FDA approved EYLEA for an every 12-week dosing regimen option after one year of effective therapy in patients with wet AMD.
- The FDA accepted for review the supplemental Biologics License Application (sBLA) of EYLEA for the treatment of diabetic retinopathy, with a target action date of May 13, 2019.
- The Company announced that the Phase 3 PANORAMA trial evaluating EYLEA in patients with moderately severe and severe non-proliferative diabetic retinopathy met its one-year primary endpoint and key secondary endpoints, including both the improvement of diabetic retinopathy and a reduction in the rate of vision-threatening complications.
- The FDA issued a Complete Response Letter regarding the Chemistry, Manufacturing, and Controls Prior-Approval Supplement (PAS) for the EYLEA pre-filled syringe. The Company expects to compile all the requested information and resubmit the PAS in the first half of 2019.

#### **Dupixent<sup>®</sup> (dupilumab) Injection**

- In October 2018, the FDA approved Dupixent as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.
- The Company and Sanofi submitted an sBLA and a Marketing Authorization Application (MAA) for an expanded atopic dermatitis indication in adolescent patients (12–17 years of age). In November 2018, the FDA accepted for priority review the sBLA for atopic dermatitis in adolescent patients, with a target action date of March 11, 2019.
- The Company and Sanofi announced positive top-line results from both pivotal Phase 3 placebo-controlled trials evaluating Dupixent in adults with inadequately-controlled CRSwNP.
- A Phase 2/3 study in eosinophilic esophagitis and a Phase 2 study in peanut allergy were initiated.

#### **Praluent<sup>®</sup> (alirocumab) Injection**

- The FDA approved Praluent for the treatment of patients with heterozygous familial hypercholesterolemia (HeFH) undergoing apheresis.
- An sBLA for Praluent as a potential treatment to reduce major adverse cardiovascular events was accepted for review by the FDA, with a target action date of April 28, 2019.
- The FDA also accepted for review an sBLA for Praluent for first-line treatment of hyperlipidemia, with a target action date of April 29, 2019.
- A Phase 3 study in pediatric patients with homozygous familial hypercholesterolemia (HoFH) was initiated.

#### **Kevzara<sup>®</sup> (sarilumab) Injection**

- A Phase 3 study in polymyalgia rheumatica was initiated.

### Libtayo® (cemiplimab-rwlc) Injection

- On September 28, 2018, the FDA approved Libtayo (cemiplimab-rwlc) for the treatment of patients with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

### Fasinumab is an antibody targeting Nerve Growth Factor (NGF).

- The Company and Teva announced positive top-line results from a Phase 3 study of fasinumab in patients with chronic pain from osteoarthritis of the knee or hip.

### REGN3500 is an antibody to IL-33.

- A Phase 2 study in chronic obstructive pulmonary disease (COPD) was initiated.

### **Business Development Update**

- In the third quarter of 2018, the Company entered into a collaboration agreement with bluebird bio, Inc. to research, develop, and commercialize novel immune cell therapies for cancer.

### **Financial Results**

**Product Revenues:** Net product sales were \$1.025 billion in the third quarter of 2018, compared to \$957 million in the third quarter of 2017. EYLEA net product sales in the United States were \$1.022 billion in the third quarter of 2018, compared to \$953 million in the third quarter of 2017. Overall distributor inventory levels for EYLEA in the United States remained within the Company's one-to-two-week targeted range.

**Total Revenues:** Total revenues, which include product revenues described above, increased by 11% to \$1.663 billion in the third quarter of 2018, compared to \$1.501 billion in the third quarter of 2017. Total revenues include Sanofi and Bayer collaboration revenues of \$521 million in the third quarter of 2018, compared to \$482 million in the third quarter of 2017. The increase in Sanofi collaboration revenue in the third quarter of 2018 was primarily due to the Company's share of higher net sales of Dupixent and Praluent, partly offset by the ceasing of funding by Sanofi in connection with the Company's Discovery and Preclinical Development Agreement, which ended on December 31, 2017, and an increase in the collaboration's Dupixent commercialization expenses. Bayer collaboration revenue increased in the third quarter of 2018 primarily due to an increase in net profits in connection with higher sales of EYLEA outside the United States. The increase in other revenue in the third quarter of 2018 was partially due to the recognition of a portion of \$80 million in development milestones achieved in the third quarter of 2018 in connection with the Company's fasinumab collaboration with Teva and Mitsubishi Tanabe Pharma.

The Company adopted Accounting Standard Codification (ASC) 606, *Revenue from Contracts with Customers*, as of January 1, 2018. The Company adopted the standard using the modified retrospective method, and therefore prior period amounts have not been adjusted. A more complete description of the impact of adopting ASC 606 can be found in the Company's Form 10-Q for the quarterly period ended September 30, 2018.

Refer to Table 4 for a summary of collaboration and other revenue.

**Research and Development (R&D) Expenses:** GAAP R&D expenses were \$557 million in the third quarter of 2018, compared to \$530 million in the third quarter of 2017. The higher R&D expenses in the third quarter of 2018 were principally due to an increase in Libtayo development expenses and higher R&D headcount and facilities-related costs, partly offset by a decrease in Dupixent development expenses. In the third quarter of 2018, R&D-related non-cash share-based compensation expense was \$60 million, compared to \$70 million in the third quarter of 2017.

**Selling, General, and Administrative (SG&A) Expenses:** GAAP SG&A expenses were \$369 million in the third quarter of 2018, compared to \$307 million in the third quarter of 2017. The higher SG&A expenses in the third quarter of 2018 were primarily due to higher headcount and headcount-related costs and higher contributions to independent not-for-profit patient assistance organizations. In the third quarter of 2018, SG&A-related non-cash share-based compensation expense decreased to \$43 million, compared to \$48 million in the third quarter of 2017.

**Income Tax Expense:** In the third quarter of 2018, GAAP income tax expense was \$41 million and the effective tax rate was 6.5%, compared to \$177 million and 31.3% in the third quarter of 2017. The Company's effective tax rate for the third quarter of 2018 was significantly impacted by the law known as the Tax Cuts and Jobs Act (the "U.S. Tax Reform Act"), which reduced the U.S. federal corporate income tax rate from 35% to 21% effective January 1, 2018. The effective tax rate for the third quarter of 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with tax planning in connection with the U.S. Tax Reform Act, the federal tax credit for research activities, and, to a lesser extent, stock-based compensation and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate. During the third quarter of 2018, the Company recorded an income tax benefit of \$11.9 million as an adjustment to the provisional amount recorded as of December 31, 2017 for the U.S. Tax Reform Act, which was related to the re-measurement of the Company's U.S. net deferred tax assets.

**GAAP and Non-GAAP Net Income<sup>(2)</sup>:** GAAP net income was \$595 million, or \$5.50 per basic share and \$5.17 per diluted share, in the third quarter of 2018, compared to GAAP net income of \$388 million, or \$3.64 per basic share and \$3.32 per diluted share, in the third quarter of 2017.

Non-GAAP net income was \$675 million, or \$6.25 per basic share and \$5.87 per diluted share, in the third quarter of 2018, compared to non-GAAP net income of \$470 million, or \$4.41 per basic share and \$3.99 per diluted share, in the third quarter of 2017.

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

## 2018 Financial Guidance<sup>(3)</sup>

The Company's updated full year 2018 financial guidance consists of the following components:

Sanofi collaboration revenue: Sanofi reimbursement of Regeneron commercialization-related expenses	\$430 million–\$455 million <i>(previously \$455 million–\$485 million)</i>
Non-GAAP unreimbursed R&D <sup>(2)(4)</sup>	\$1.190 billion–\$1.225 billion <i>(previously \$1.210 billion–\$1.260 billion)</i>
Non-GAAP SG&A <sup>(2)(4)</sup>	\$1.330 billion–\$1.370 billion <i>(previously \$1.340 billion–\$1.390 billion)</i>
Effective tax rate	11%–13% <i>(previously 13%–16%)</i>
Capital expenditures	\$360 million–\$390 million <i>(previously \$410 million–\$450 million)</i>

<sup>(1)</sup> 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.

<sup>(2)</sup> 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 estimated 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 or changes in the fair value of the Company's equity investments) or items that are not associated with normal, recurring operations (such as changes in applicable laws and regulations). 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.

<sup>(3)</sup> The Company's 2018 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

<sup>(4)</sup> A reconciliation of full year 2018 non-GAAP to GAAP financial guidance is included below:

<i>(In millions)</i>	Projected Range	
	Low	High
GAAP unreimbursed R&D <sup>(5)</sup>	\$ 1,400	\$ 1,450
R&D: Non-cash share-based compensation expense	(210)	(225)
Non-GAAP unreimbursed R&D	\$ 1,190	\$ 1,225
GAAP SG&A	\$ 1,490	\$ 1,550
SG&A: Non-cash share-based compensation expense	(160)	(180)
Non-GAAP SG&A	\$ 1,330	\$ 1,370

<sup>(5)</sup> 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 2018 financial and operating results on Tuesday, November 6, 2018, at 8:30 AM. To access this call, dial (800) 708-4539 (U.S.) or (847) 619-6396 (International). A link to the webcast may be accessed from the "Investors and Media" 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 biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neuromuscular diseases, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*<sup>®</sup> technologies, such as *VelocImmune*<sup>®</sup> which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center<sup>®</sup>, which is conducting one of the largest genetics sequencing efforts in the world.

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 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> (aflibercept) Injection, Dupixent<sup>®</sup> (dupilumab) Injection, Praluent<sup>®</sup> (alirocumab) Injection, Kevzara<sup>®</sup> (sarilumab) Injection, Libtayo<sup>®</sup> (cemiplimab) Injection, fasinumab, and evinacumab; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing

regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo), 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; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's 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 financial projections or guidance and changes to the assumptions underlying those projections or guidance, including without limitation those relating to 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, 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, including without limitation the patent litigation proceedings relating to EYLEA, Dupixent, and Praluent, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. 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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**Contact Information:**

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TABLE 1

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

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
<b>Assets:</b>		
Cash and marketable securities	\$ 4,065,721	\$ 2,896,074
Accounts receivable - trade, net	1,665,737	1,538,642
Accounts receivable from Sanofi and Bayer	537,208	435,698
Inventories	1,039,679	726,138
Property, plant, and equipment, net	2,524,446	2,358,605
Deferred tax assets	562,818	506,291
Other assets	410,004	302,838
<b>Total assets</b>	<b>\$ 10,805,613</b>	<b>\$ 8,764,286</b>
<b>Liabilities and stockholders' equity:</b>		
Accounts payable, accrued expenses, and other liabilities	\$ 1,148,318	\$ 967,418
Deferred revenue	1,081,792	949,337
Capital and facility lease obligations	707,203	703,453
Stockholders' equity	7,868,300	6,144,078
<b>Total liabilities and stockholders' equity</b>	<b>\$ 10,805,613</b>	<b>\$ 8,764,286</b>

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,	
	2018	2017	2018	2017
<b>Revenues:</b>				
Net product sales	\$ 1,025,488	\$ 957,367	\$ 3,009,779	\$ 2,739,745
Sanofi collaboration revenue	256,265	245,175	683,508	677,670
Bayer collaboration revenue	264,373	236,625	775,164	640,919
Other revenue	117,370	61,506	314,552	231,446
	<u>1,663,496</u>	<u>1,500,673</u>	<u>4,783,003</u>	<u>4,289,780</u>
<b>Expenses:</b>				
Research and development	556,972	529,749	1,584,847	1,547,159
Selling, general, and administrative	369,232	306,766	1,064,886	910,520
Cost of goods sold	30,817	46,388	136,010	149,774
Cost of collaboration and contract manufacturing	79,552	57,844	180,918	141,547
	<u>1,036,573</u>	<u>940,747</u>	<u>2,966,661</u>	<u>2,749,000</u>
Income from operations	<u>626,923</u>	<u>559,926</u>	<u>1,816,342</u>	<u>1,540,780</u>
Other income (expense), net	<u>8,938</u>	<u>5,679</u>	<u>60,991</u>	<u>(17,036)</u>
Income before income taxes	635,861	565,605	1,877,333	1,523,744
Income tax expense	<u>(41,206)</u>	<u>(177,288)</u>	<u>(253,286)</u>	<u>(498,752)</u>
Net income	<u>\$ 594,655</u>	<u>\$ 388,317</u>	<u>\$ 1,624,047</u>	<u>\$ 1,024,992</u>
Net income per share - basic	\$ 5.50	\$ 3.64	\$ 15.06	\$ 9.66
Net income per share - diluted	\$ 5.17	\$ 3.32	\$ 14.14	\$ 8.84
Weighted average shares outstanding - basic	108,033	106,706	107,828	106,108
Weighted average shares outstanding - diluted	115,088	117,028	114,843	115,994

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,	
	2018	2017	2018	2017
GAAP net income	\$ 594,655	\$ 388,317	\$ 1,624,047	\$ 1,024,992
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	60,404	70,123	160,841	213,174
SG&A: Non-cash share-based compensation expense	42,898	47,672	118,379	146,192
COGS and COCM: Non-cash share-based compensation expense	8,133	7,302	21,432	20,778
Other income/expense: Loss on extinguishment of debt	—	—	—	30,100
Other income/expense: Gains and losses on investments in equity securities <sup>(a)</sup>	4,852	—	(21,037)	—
Income tax effect of reconciling items above	(23,560)	(42,958)	(55,896)	(141,458)
Income tax expense: Adjustment to previously recorded charge related to enactment of U.S. Tax Reform Act	(11,886)	—	(11,886)	—
Non-GAAP net income	<u>\$ 675,496</u>	<u>\$ 470,456</u>	<u>\$ 1,835,880</u>	<u>\$ 1,293,778</u>
Non-GAAP net income per share - basic	\$ 6.25	\$ 4.41	\$ 17.03	\$ 12.19
Non-GAAP net income per share - diluted	\$ 5.87	\$ 3.99	\$ 15.98	\$ 11.09
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	108,033	106,706	107,828	106,108
Non-GAAP net income per share - diluted	115,142	117,819	114,855	116,616

<sup>(a)</sup> Prior to the quarter ended March 31, 2018, unrealized gains and losses on equity securities were recorded in Other comprehensive income (loss). In connection with the adoption of Accounting Standards Update 2016-01, unrealized gains and losses on equity securities during the three and nine months ended September 30, 2018 were recorded in Other income (expense), net.

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<i>Sanofi collaboration revenue:</i>				
Reimbursement of Regeneron research and development expenses	\$ 150,947	\$ 190,188	\$ 426,701	\$ 609,464
Reimbursement of Regeneron commercialization-related expenses	106,902	91,454	299,263	252,866
Regeneron's share of losses in connection with commercialization of antibodies	(38,924)	(98,315)	(182,595)	(328,998)
Other	37,340	61,848	140,139	144,338
Total Sanofi collaboration revenue	<u>256,265</u>	<u>245,175</u>	<u>683,508</u>	<u>677,670</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	243,152	205,367	721,522	571,126
Reimbursement of Regeneron development expenses	457	13,378	8,321	26,447
Other	20,764	17,880	45,321	43,346
Total Bayer collaboration revenue	<u>264,373</u>	<u>236,625</u>	<u>775,164</u>	<u>640,919</u>
Total Sanofi and Bayer collaboration revenue	<u>\$ 520,638</u>	<u>\$ 481,800</u>	<u>\$ 1,458,672</u>	<u>\$ 1,318,589</u>
<i>Other revenue:</i>				
Reimbursement of Regeneron research and development expenses - Teva	\$ 27,648	\$ 28,537	\$ 101,087	\$ 82,068
Reimbursement of Regeneron research and development expenses - other	6,291	150	12,875	3,562
Other	83,431	32,819	200,590	145,816
Total other revenue	<u>\$ 117,370</u>	<u>\$ 61,506</u>	<u>\$ 314,552</u>	<u>\$ 231,446</u>

**REGENERON PHARMACEUTICALS, INC.**  
**NET PRODUCT SALES OF REGENERON-DISCOVERED PRODUCTS (Unaudited)**  
*(In thousands)*

	<b>Three Months Ended September 30,</b>					
	<b>2018</b>			<b>2017</b>		
	<b>U.S.</b>	<b>ROW</b>	<b>Total</b>	<b>U.S.</b>	<b>ROW</b>	<b>Total</b>
EYLEA*	\$ 1,021,782	\$ 654,563	\$ 1,676,345	\$ 953,279	\$ 563,705	\$ 1,516,984
ARCALYST	3,706	—	3,706	4,088	—	4,088
Net product sales recorded by Regeneron	<u>\$ 1,025,488</u>			<u>\$ 957,367</u>		
<i>Net product sales recorded by Sanofi*:</i>						
Dupixent	\$ 219,605	\$ 42,957	\$ 262,562	\$ 88,509	\$ 470	\$ 88,979
Praluent	\$ 48,386	\$ 31,778	\$ 80,164	\$ 31,789	\$ 17,613	\$ 49,402
Kevzara	\$ 19,894	\$ 4,950	\$ 24,844	\$ 2,666	\$ 319	\$ 2,985
ZALTRAP	\$ 1,512	\$ 23,863	\$ 25,375	\$ 2,982	\$ 18,710	\$ 21,692

  

	<b>Nine Months Ended September 30,</b>					
	<b>2018</b>			<b>2017</b>		
	<b>U.S.</b>	<b>ROW</b>	<b>Total</b>	<b>U.S.</b>	<b>ROW</b>	<b>Total</b>
EYLEA*	\$ 2,997,829	\$ 1,944,482	\$ 4,942,311	\$ 2,727,132	\$ 1,590,043	\$ 4,317,175
ARCALYST	11,950	—	11,950	12,613	—	12,613
Net product sales recorded by Regeneron	<u>\$ 3,009,779</u>			<u>\$ 2,739,745</u>		
<i>Net product sales recorded by Sanofi*:</i>						
Dupixent	\$ 517,672	\$ 85,470	\$ 603,142	\$ 116,887	\$ 743	\$ 117,630
Praluent	\$ 121,561	\$ 91,964	\$ 213,525	\$ 89,782	\$ 41,661	\$ 131,443
Kevzara	\$ 48,118	\$ 13,249	\$ 61,367	\$ 3,429	\$ 399	\$ 3,828
ZALTRAP	\$ 6,637	\$ 73,431	\$ 80,068	\$ 7,575	\$ 50,991	\$ 58,566

\* Bayer records net product sales of EYLEA outside the United States and Sanofi records global net product sales of Dupixent, Praluent, Kevzara, and ZALTRAP. Refer to Table 4 for the Company's share of profits/losses recorded in connection with sales of EYLEA outside the United States and global sales of Dupixent, Praluent, and Kevzara. Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP.