

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): May 7, 2019 (May 7, 2019)

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

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)

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.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock - par value \$.001 per share	REGN	NASDAQ Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2019. 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 May 7, 2019, Reporting First Quarter 2019 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: May 7, 2019

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	Press Release, dated May 7, 2019, Reporting First Quarter 2019 Financial and Operating Results.

REGENERON

Press Release

Regeneron Reports First Quarter 2019 Financial and Operating Results

- First quarter 2019 revenues increased 13% to \$1.71 billion versus first quarter 2018
- First quarter 2019 EYLEA® (afibercept) Injection U.S. net sales increased 9% to \$1.07 billion versus first quarter 2018
- First quarter 2019 EYLEA net sales outside the United States, which are recorded by the Company's collaborator Bayer⁽¹⁾, increased 7% to \$669 million versus first quarter 2018
- First quarter 2019 Dupixent® (dupilumab) global net sales, which are recorded by the Company's collaborator Sanofi, were \$374 million
- First quarter 2019 Libtayo® (cemiplimab) U.S. net sales were \$27 million; Libtayo was launched in October 2018
- First quarter 2019 GAAP diluted EPS was \$3.99 and non-GAAP diluted EPS was \$4.45
- FDA approved Dupixent for moderate-to-severe atopic dermatitis in adolescents

Tarrytown, New York (May 7, 2019) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2019 and provided a business update.

"In the first quarter, aggregate sales of all Regeneron-invented products, recorded by the Company and its collaborators, were \$2.27 billion, an increase of 23% over the same period last year. This was driven by an 8% increase in EYLEA net sales, 185% increase in Dupixent net sales, and a strong initial launch for Libtayo in advanced cutaneous squamous cell carcinoma," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We continue to unlock the full potential of Dupixent, which is now FDA-approved in atopic dermatitis and asthma in both adults and adolescents and is currently under Priority Review by the FDA for chronic rhinosinusitis with nasal polyps. Regeneron also continues to invest in a broad immuno-oncology portfolio. At the June European Hematology Association meeting, we look forward to presenting updated promising results of the Phase 1 study of REGN1979 in relapsed or refractory B-cell non-hodgkin lymphoma, including in patients who have failed previous CAR-T therapy."

Financial Highlights

(\$ in millions, except per share data)

	Three Months Ended March 31,		
	2019	2018	% Change
Total revenues	\$ 1,712	\$ 1,512	13%
GAAP net income	\$ 461	\$ 478	(4%)
GAAP net income per share - diluted	\$ 3.99	\$ 4.16	(4%)
Non-GAAP net income ⁽²⁾	\$ 518	\$ 537	(4%)
Non-GAAP net income per share - diluted ⁽²⁾	\$ 4.45	\$ 4.67	(5%)

Business Highlights

Key Pipeline Progress

Regeneron has twenty product candidates in clinical development, including five of the Company's U.S. Food and Drug Administration (FDA) approved products for which it is investigating additional indications. Updates from the clinical pipeline include:

EYLEA® (aflibercept) Injection

- In April 2019, the Company resubmitted a supplemental Biologics License Application (sBLA) for EYLEA in a pre-filled syringe.
- The EYLEA sBLA for the treatment of diabetic retinopathy has a target action date of May 13, 2019.

Dupixent® (dupilumab)

- In March 2019, the FDA approved Dupixent for adolescent patients 12 to 17 years of age with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- The FDA accepted for priority review the sBLA for Dupixent as an add-on maintenance treatment for adults with inadequately controlled severe chronic rhinosinusitis with nasal polyps (CRSwNP), with a target action date of June 26, 2019. The Company and Sanofi have also submitted a European Marketing Authorization Application (MAA) for CRSwNP.
- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Dupixent, recommending it be approved for use in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma.
- Initiated a Phase 3 study in chronic obstructive pulmonary disease (COPD).

Libtayo® (cemiplimab)

- The European Medicines Agency's CHMP recommended conditional approval for Libtayo for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation.

REGN1979, a bispecific antibody against CD20 and CD3

- The Company expects to begin a potentially pivotal Phase 2 study in advanced follicular lymphoma this quarter, and a potentially pivotal Phase 2 study in diffuse large B-cell lymphoma (DLBCL) later this year.
- At the June European Hematology Association meeting, the Company plans to present updated results of the Phase 1 study in relapsed or refractory B-cell non-hodgkin lymphoma, including in patients who have failed previous CAR-T therapy.

Praluent® (alirocumab)

- In March 2019, the European Commission approved a new indication for Praluent to reduce cardiovascular risk in adults with established atherosclerotic cardiovascular disease (ASCVD) by lowering low-density lipoprotein cholesterol (LDL-C) levels as an adjunct to correction of other risk factors.
- In April 2019, the FDA approved a new indication for Praluent to reduce the risk of heart attack, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.

- Beginning in March 2019, Praluent was made available for both the 75 mg and 150 mg doses at a U.S. list price of \$5,850 annually, a 60% reduction from the original price.

Business Development Update

- In April 2019, the Company entered into a collaboration with Alnylam Pharmaceuticals, Inc. to discover, develop, and commercialize new RNA interference (RNAi) therapeutics for diseases of the eye and central nervous system, in addition to a select number of targets expressed in the liver. Under the terms of the agreement, the Company is obligated to make an up-front payment of \$400 million and purchase \$400 million of Alnylam common stock. In addition, the Company will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to \$200 million in clinical proof-of-principle milestones.

First Quarter 2019 Financial Results

Product Revenues: Net product sales were \$1.104 billion in the first quarter of 2019, compared to \$988 million in the first quarter of 2018. EYLEA net product sales in the United States were \$1.074 billion in the first quarter of 2019, compared to \$984 million in the first quarter of 2018. 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 13% to \$1.712 billion in the first quarter of 2019, compared to \$1.512 billion in the first quarter of 2018. Total revenues include Sanofi and Bayer collaboration revenues⁽⁶⁾ of \$523 million in the first quarter of 2019, compared to \$437 million in the first quarter of 2018. The increase in Sanofi collaboration revenue in the first quarter of 2019 was primarily due to the Company's share of lower losses of collaboration antibodies, primarily driven by higher net product sales of Dupixent. This increase was partly offset by a decrease in reimbursement of research and development costs under the Immuno-oncology Discovery and Development Agreement with Sanofi, as the amended agreement narrowed the scope of reimbursable activities to the BCMAXCD3 and MUC16xCD3 programs.

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

Research and Development (R&D) Expenses: GAAP R&D expenses were \$642 million in the first quarter of 2019, compared to \$499 million in the first quarter of 2018. The higher R&D expenses in the first quarter of 2019 were principally due to additional costs incurred in connection with our earlier-stage pipeline, an increase in Libtayo development expenses, higher clinical manufacturing costs, and higher headcount and headcount-related costs. In the first quarter of 2019, R&D-related non-cash share-based compensation expense was \$59 million, compared to \$41 million in the first quarter of 2018.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$411 million in the first quarter of 2019, compared to \$331 million in the first quarter of 2018. The higher SG&A expenses in the first quarter of 2019 were primarily due to higher headcount and headcount-related costs, higher contributions to independent not-for-profit patient assistance organizations, and an increase in commercialization-related expenses for Dupixent. In the first quarter of 2019, SG&A-related non-cash share-based compensation expense was \$44 million, compared to \$35 million in the first quarter of 2018.

Cost of Collaboration and Contract Manufacturing (COCM): GAAP COCM expenses were \$108 million in the first quarter of 2019, compared to \$46 million in the first quarter of 2018. The increase in COCM was primarily due to higher expenses in connection with process validation at our Limerick manufacturing facility, higher inventory write-offs and reserves, and the recognition of manufacturing costs associated with higher sales of Dupixent.

Other Income (Expense): GAAP other income (expense), net, in the first quarter of 2019 and 2018 includes the recognition of \$43 million and \$9 million, respectively, of net gains on equity securities.

Income Taxes: In the first quarter of 2019, GAAP income tax expense was \$85 million and the effective tax rate was 15.6%, compared to \$107 million and 18.3% in the first quarter of 2018. The effective tax rate for the first quarter of 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by the federal tax credit for research activities, stock-based compensation, the foreign-derived intangible income deduction, and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate.

GAAP and Non-GAAP Net Income⁽²⁾: GAAP net income was \$461 million, or \$4.23 per basic share and \$3.99 per diluted share, in the first quarter of 2019, compared to GAAP net income of \$478 million, or \$4.44 per basic share and \$4.16 per diluted share, in the first quarter of 2018.

Non-GAAP net income was \$518 million, or \$4.75 per basic share and \$4.45 per diluted share, in the first quarter of 2019, compared to non-GAAP net income of \$537 million, or \$4.99 per basic share and \$4.67 per diluted share, in the first quarter of 2018.

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

2019 Financial Guidance⁽³⁾

The Company's updated full year 2019 financial guidance consists of the following components:

GAAP Sanofi collaboration revenue: Sanofi reimbursement of Regeneron commercialization-related expenses	\$500 million–\$535 million <i>(previously \$510 million–\$560 million)</i>
GAAP Unreimbursed R&D ⁽⁵⁾	\$1.880 billion–\$2.000 billion <i>(previously \$1.855 billion–\$2.000 billion)</i>
Non-GAAP Unreimbursed R&D ⁽²⁾⁽⁴⁾	\$1.610 billion–\$1.710 billion <i>(previously \$1.590 billion–\$1.710 billion)</i>
GAAP SG&A	\$1.690 billion–\$1.795 billion <i>(previously \$1.700 billion–\$1.830 billion)</i>
Non-GAAP SG&A ⁽²⁾⁽⁴⁾	\$1.500 billion–\$1.580 billion <i>(previously \$1.500 billion–\$1.600 billion)</i>
GAAP effective tax rate	11%–13% <i>(previously 14%–16%)</i>
Capital expenditures	\$410 million–\$475 million <i>(previously \$410 million–\$490 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 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.

- (3) The Company's 2019 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release (other than the collaboration with Alnylam Pharmaceuticals, Inc. discussed above).
- (4) A reconciliation of full year 2019 non-GAAP to GAAP financial guidance is included below:

<i>(In millions)</i>	Projected Range	
	Low	High
GAAP unreimbursed R&D ⁽⁵⁾	\$ 1,880	\$ 2,000
R&D: Non-cash share-based compensation expense	(270)	(290)
Non-GAAP unreimbursed R&D	\$ 1,610	\$ 1,710
GAAP SG&A	\$ 1,690	\$ 1,795
SG&A: Non-cash share-based compensation expense	(190)	(215)
Non-GAAP SG&A	\$ 1,500	\$ 1,580

- (5) Unreimbursed R&D represents R&D expenses reduced by R&D expense reimbursements from the Company's collaborators and/or customers.
- (6) The Company's collaborators provide it with estimates of the collaborators' respective sales and the Company's share of the profits or losses from commercialization of products for the most recent fiscal quarter. The Company's estimates for such quarter are reconciled to actual results in the subsequent fiscal quarter, and the Company's share of the profit or loss is adjusted on a prospective basis accordingly, if necessary.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its first quarter 2019 financial and operating results on Tuesday, May 7, 2019, 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. 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, musculoskeletal diseases, infectious diseases, and rare diseases.

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

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 press release and the impact of the recent and any potential future U.S. government shutdowns on the anticipated timing of any FDA regulatory action described in this press 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[®] (aflibercept) Injection, Dupixent[®] (dupilumab) Injection, Praluent[®] (alirocumab) Injection, Kevzara[®] (sarilumab) Injection, Libtayo[®] (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 (as applicable) to perform manufacturing, 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, GAAP and non-GAAP unreimbursed R&D, GAAP and 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 and other related proceedings relating to EYLEA, Dupixent, and Praluent, the ultimate outcome of any such 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, including its Form 10-K for the fiscal year ended December 31, 2018 and its Form 10-Q for the quarterly period ended March 31, 2019. 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 such non-GAAP financial measures.

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TABLE 1

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

	March 31, 2019	December 31, 2018
Assets:		
Cash and marketable securities	\$ 5,572.2	\$ 4,564.9
Accounts receivable - trade, net	1,728.4	1,723.7
Accounts receivable from Sanofi and Bayer	576.8	519.5
Inventories	1,208.8	1,151.2
Property, plant, and equipment, net	2,612.8	2,575.8
Deferred tax assets	829.3	828.7
Other assets	326.5	370.7
Total assets	\$ 12,854.8	\$ 11,734.5
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 1,357.0	\$ 1,352.0
Deferred revenue	1,343.2	916.7
Finance lease liabilities	709.9	708.5
Stockholders' equity	9,444.7	8,757.3
Total liabilities and stockholders' equity	\$ 12,854.8	\$ 11,734.5

TABLE 2

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Net product sales	\$ 1,104.4	\$ 987.9
Sanofi collaboration revenue	246.4	189.5
Bayer collaboration revenue	276.2	247.9
Other revenue	84.8	86.2
	<u>1,711.8</u>	<u>1,511.5</u>
Expenses:		
Research and development	641.8	498.6
Selling, general, and administrative	410.8	330.8
Cost of goods sold	70.9	69.2
Cost of collaboration and contract manufacturing	108.3	45.7
	<u>1,231.8</u>	<u>944.3</u>
Income from operations	480.0	567.2
Other income (expense), net	66.1	18.2
Income before income taxes	546.1	585.4
Income tax expense	(85.0)	(107.4)
Net income	<u>\$ 461.1</u>	<u>\$ 478.0</u>
Net income per share - basic	\$ 4.23	\$ 4.44
Net income per share - diluted	\$ 3.99	\$ 4.16
Weighted average shares outstanding - basic	108.9	107.6
Weighted average shares outstanding - diluted	115.5	114.9

TABLE 3

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

	Three Months Ended March 31,	
	2019	2018
GAAP net income	\$ 461.1	\$ 478.0
<i>Adjustments:</i>		
R&D: Non-cash share-based compensation expense	58.7	40.8
SG&A: Non-cash share-based compensation expense	43.8	35.0
SG&A: Litigation contingencies	5.0	—
COGS and COCM: Non-cash share-based compensation expense	5.4	6.6
Other income/expense: Gains and losses on investments in equity securities	(42.8)	(9.4)
Income tax effect of reconciling items above	(13.5)	(14.3)
Non-GAAP net income	<u>\$ 517.7</u>	<u>\$ 536.7</u>
Non-GAAP net income per share - basic	\$ 4.75	\$ 4.99
Non-GAAP net income per share - diluted	\$ 4.45	\$ 4.67
<i>Shares used in calculating:</i>		
Non-GAAP net income per share - basic	108.9	107.6
Non-GAAP net income per share - diluted	116.3	114.9

TABLE 4

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

	Three Months Ended March 31,	
	2019	2018
<i>Sanofi collaboration revenue:</i>		
Reimbursement of Regeneron research and development expenses	\$ 120.9	\$ 134.2
Reimbursement of Regeneron commercialization-related expenses	118.9	86.6
Regeneron's share of losses in connection with commercialization of antibodies	(27.8)	(74.8)
Other	34.4	43.5
Total Sanofi collaboration revenue	<u>246.4</u>	<u>189.5</u>
<i>Bayer collaboration revenue:</i>		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	249.3	232.1
Reimbursement of Regeneron development expenses	2.6	4.0
Other	24.3	11.8
Total Bayer collaboration revenue	<u>276.2</u>	<u>247.9</u>
Total Sanofi and Bayer collaboration revenue	<u>\$ 522.6</u>	<u>\$ 437.4</u>
<i>Other revenue:</i>		
Reimbursement of Regeneron research and development expenses - Teva	\$ 32.2	\$ 39.1
Reimbursement of Regeneron research and development expenses - other	8.4	2.7
Other	44.2	44.4
Total other revenue	<u>\$ 84.8</u>	<u>\$ 86.2</u>

TABLE 5

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

	Three Months Ended March 31,					
	2019			2018		
	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA*	\$ 1,074.1	\$ 669.4	\$ 1,743.5	\$ 984.0	\$ 624.0	\$ 1,608.0
Libtayo	26.8	—	26.8	—	—	—
ARCALYST	3.5	—	3.5	3.9	—	3.9
Net product sales recorded by Regeneron	<u>\$ 1,104.4</u>			<u>\$ 987.9</u>		
<i>Net product sales recorded by Sanofi*:</i>						
Dupixent	\$ 303.0	\$ 70.7	\$ 373.7	\$ 116.8	\$ 14.6	\$ 131.4
Praluent	\$ 22.9	\$ 41.0	\$ 63.9	\$ 31.7	\$ 28.2	\$ 59.9
Kevzara	\$ 20.7	\$ 13.0	\$ 33.7	\$ 9.3	\$ 3.1	\$ 12.4
ZALTRAP	\$ 0.5	\$ 24.0	\$ 24.5	\$ 2.4	\$ 23.9	\$ 26.3

* 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.