

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): November 5, 2019 (November 5, 2019)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York (State or other jurisdiction of incorporation or organization) **000-19034** (Commission File Number) **13-3444607** (I.R.S. 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 (see General Instruction A.2. below):

- 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))

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

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

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 5, 2019, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 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 November 5, 2019, Reporting Third Quarter 2019 Financial and Operating Results.](#)

104 Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

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 5, 2019

REGENERON PHARMACEUTICALS, INC.

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

REGENERONPress Release

Regeneron Reports Third Quarter 2019 Financial and Operating Results

- *Third quarter 2019 revenues increased 23% to \$2.05 billion versus third quarter 2018*
- *Third quarter EYLEA® U.S. net sales increased 16% to \$1.19 billion versus third quarter 2018*
- *Dupixent® global net sales⁽⁵⁾, which increased 141% to \$633 million versus third quarter 2018, drove higher profitability from antibody collaboration with Sanofi*
- *Third quarter 2019 GAAP diluted EPS was \$5.86 and third quarter non-GAAP diluted EPS⁽¹⁾ was \$6.67*
- *Company announces \$1.0 billion share repurchase program*

Tarrytown, New York (November 5, 2019) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2019 and provided a business update.

"Regeneron delivered positive financial and operational results this quarter, marked by significant EYLEA and Dupixent sales growth and progress across our pipeline," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We are broadening our efforts in retinal and type 2 inflammatory diseases, including initiating late-stage trials of Dupixent in additional type 2 diseases in the coming months. Oncology is a major focus of our research and development efforts, and we are advancing important new potential treatments for patients with a variety of cancers. We currently have six bispecific antibodies in the clinic, and multiple pivotal trials with Libtayo in non-small cell lung, skin, and other cancers."

"This quarter, we realized improving profitability from the Sanofi antibody collaboration, which is contributing to a more diverse earnings base for the Company," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "Our financial results, strength of our balance sheet, and confidence in our business longer-term allow us to continue deploying capital by investing in internal and external innovation to expand our pipeline, while also returning cash to shareholders with the initiation of a \$1 billion share repurchase program."

Financial Highlights

(\$ in millions, except per share data)	Three Months Ended September 30,		% Change
	2019	2018	
Total revenues	\$ 2,048	\$ 1,663	23%
GAAP net income	\$ 670	\$ 595	13%
GAAP net income per share - diluted	\$ 5.86	\$ 5.17	13%
Non-GAAP net income ⁽¹⁾	\$ 762	\$ 675	13%
Non-GAAP net income per share - diluted ⁽¹⁾	\$ 6.67	\$ 5.87	14%

Business Highlights

Key Pipeline Progress

Regeneron has 24 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 August 2019, the FDA approved the EYLEA pre-filled syringe, which is expected to be launched before the end of this year.
- A Phase 2 study exploring less frequent dosing intervals using a high-dose formulation of aflibercept in wet AMD was initiated.
- A Phase 3 study in retinopathy of prematurity was initiated.

Dupixent® (dupilumab)

- In August 2019, the European Commission (EC) extended its approval of Dupixent in the European Union to include adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.
- In August 2019, the Company and Sanofi announced that the Phase 3 trial to treat severe atopic dermatitis in children 6 to 11 years of age met its primary and secondary endpoints. Submissions for a supplemental Biologics License Application (sBLA) and Marketing Authorization Application (MAA) for this expanded atopic dermatitis indication in pediatric patients are expected by the end of the year.
- In October 2019, the EC approved Dupixent in chronic rhinosinusitis with nasal polyposis (CRSwNP).
- The Company and Sanofi plan to initiate Phase 3 studies in bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, and additional type 2 inflammatory diseases.

Praluent® (alirocumab)

- In August 2019, the Company and Sanofi announced the U.S. District Court for the District of Delaware ruled in their favor and found as a matter of law that Amgen's asserted patent claims for antibodies targeting PCSK9 are invalid based on lack of enablement.

Evinacumab, an antibody to ANGPTL3

- In August 2019, the Company announced positive top-line results from a Phase 3 trial of evinacumab in patients with homozygous familial hypercholesterolemia (HoFH). The Company plans to submit a BLA in mid-2020.

REGN-EB3, a multi-antibody therapy to Ebola virus infection

- In August 2019, the Company announced that a randomized, controlled trial evaluating four investigational therapies for Ebola virus infection was stopped early because REGN-EB3 was superior to ZMapp (the control arm of the trial since it was considered standard-of-care) in preventing death. REGN-EB3 and another investigational drug are being further studied as part of the Extension Phase of this trial.
- The FDA granted Breakthrough Therapy designation for the treatment of Ebola virus infection and the Company has initiated a rolling BLA submission.

REGN5678, a bispecific antibody targeting PSMA and CD28

- A Phase 1 study evaluating this first-in-class co-stimulatory bispecific antibody was initiated in prostate cancer.

REGN5093, a bispecific antibody targeting two distinct MET epitopes

- A Phase 1 study evaluating this first-in-class bispecific antibody was initiated in MET-altered advanced non-small cell lung cancer.

Share Repurchase Program

In November 2019, the Company's board of directors authorized a share repurchase program to repurchase up to \$1.0 billion of the Company's Common Stock. Repurchases may be made from time to time at management's discretion through a variety of methods. The program has no time limit and can be discontinued at any time. No shares have been repurchased under the program to date.

Third Quarter 2019 Financial Results

Total Revenues: Total revenues increased by 23% to \$2.048 billion in the third quarter of 2019, compared to \$1.663 billion in the third quarter of 2018.

Net product sales were \$1.238 billion in the third quarter of 2019, compared to \$1.025 billion in the third quarter of 2018. EYLEA net product sales in the United States were \$1.188 billion in the third quarter of 2019, compared to \$1.022 billion in the third 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 also include Sanofi and Bayer collaboration revenues⁽⁵⁾ of \$707 million in the third quarter of 2019, compared to \$521 million in the third quarter of 2018. Sanofi collaboration revenue in the third quarter of 2019 included the Company's share of profits from collaboration antibodies (Dupixent, Praluent, and Kevzara) of \$94 million, while Sanofi collaboration revenue in the third quarter of 2018 included the Company's share of losses from collaboration antibodies of \$39 million. The increase in the Company's share of profits from collaboration antibodies was primarily driven by higher Dupixent profits.

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

Research and Development (R&D) Expenses: GAAP R&D expenses were \$663 million in the third quarter of 2019, compared to \$557 million in the third quarter of 2018. The higher R&D expenses in the third quarter of 2019 were principally due to additional costs incurred in connection with fasinumab as well as our earlier-stage pipeline, and higher headcount and

headcount-related costs. In each of the third quarters of 2019 and 2018, R&D-related non-cash share-based compensation expense was \$60 million.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$420 million in the third quarter of 2019, compared to \$369 million in the third quarter of 2018. The higher SG&A expenses in the third quarter of 2019 were primarily due to higher headcount and related costs, as well as an increase in commercialization-related expenses for Dupixent and EYLEA. In the third quarter of 2019, SG&A-related non-cash share-based compensation expense was \$41 million, compared to \$43 million in the third quarter of 2018.

Cost of Goods Sold (COGS): GAAP COGS was \$116 million in the third quarter of 2019, compared to \$31 million in the third quarter of 2018. The increase in COGS was primarily due to the Company's obligation to pay Sanofi its share of Libtayo U.S. gross profits, higher period costs at the Company's Limerick manufacturing facility, and higher inventory reserves and write-offs.

Income Taxes: In the third quarter of 2019, GAAP income tax expense was \$99 million and the effective tax rate was 12.9%, compared to \$41 million and 6.5%, respectively, in the third quarter of 2018. The effective tax rate for the third quarter of 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by federal tax credits for research activities and the foreign-derived intangible income deduction, partly offset by the taxation of certain global intangible low-taxed income. The Company's 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 the U.S. Tax Reform Act and the federal tax credit for research activities.

GAAP and Non-GAAP Net Income⁽¹⁾: GAAP net income was \$670 million, or \$5.86 per diluted share, in the third quarter of 2019, compared to GAAP net income of \$595 million, or \$5.17 per diluted share, in the third quarter of 2018.

Non-GAAP net income was \$762 million, or \$6.67 per diluted share, in the third quarter of 2019, compared to non-GAAP net income of \$675 million, or \$5.87 per diluted share, in the third 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⁽²⁾

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	\$490 million–\$510 million <i>(previously \$500 million–\$530 million)</i>
Unreimbursed R&D ⁽⁴⁾	\$2.360 billion–\$2.410 billion <i>(previously \$2.300 billion–\$2.380 billion)</i>
Non-GAAP Unreimbursed R&D ⁽¹⁾⁽³⁾	\$1.680 billion–\$1.710 billion <i>(previously \$1.650 billion–\$1.710 billion)</i>
GAAP SG&A	\$1.730 billion–\$1.780 billion <i>(previously \$1.705 billion–\$1.785 billion)</i>
Non-GAAP SG&A ⁽¹⁾⁽³⁾	\$1.550 billion–\$1.580 billion <i>(previously \$1.530 billion–\$1.580 billion)</i>
GAAP effective tax rate	12%–14% <i>(previously 11%–13%)</i>
Capital expenditures	\$390 million–\$420 million <i>(previously \$380 million–\$420 million)</i>

⁽¹⁾ 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. 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.

⁽²⁾ 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.

⁽³⁾ A reconciliation of full year 2019 non-GAAP to GAAP financial guidance is included below:

<i>(In millions)</i>	Projected Range	
	Low	High
Unreimbursed R&D ⁽⁴⁾	\$ 2,360	\$ 2,410
R&D: Non-cash share-based compensation expense	(250)	(270)
R&D: Up-front payments related to license and collaboration agreements	(430)	(430)
Non-GAAP unreimbursed R&D	\$ 1,680	\$ 1,710
GAAP SG&A	\$ 1,730	\$ 1,780
SG&A: Non-cash share-based compensation expense	(160)	(180)
SG&A: Other	(20)	(20)
Non-GAAP SG&A	\$ 1,550	\$ 1,580

⁽⁴⁾ Unreimbursed R&D represents GAAP R&D expenses reduced by GAAP R&D expense reimbursements from the Company's collaborators and/or customers (refer to Table 4).

⁽⁵⁾ 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 third quarter 2019 financial and operating results on Tuesday, November 5, 2019, at 8:30 AM. To access this call, dial (800) 708-4540 (U.S.) or (847) 619-6397 (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 at least 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, infectious diseases, pain, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*[®] technologies, such as *VelociImmune*[®] which uses a unique genetically-humanized mouse to produce optimized fully-human antibodies and bispecific antibodies, and through 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; 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, evinacumab, and REGN-EB3; 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, unreimbursed R&D, 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 Dupixent and Praluent), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, 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 September 30, 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)

	September 30, 2019	December 31, 2018
Assets:		
Cash and marketable securities	\$ 5,990.5	\$ 4,564.9
Accounts receivable - trade, net	2,027.7	1,723.7
Accounts receivable from Sanofi and Bayer	632.3	519.5
Inventories	1,344.3	1,151.2
Property, plant, and equipment, net	2,771.4	2,575.8
Deferred tax assets	808.3	828.7
Other assets	364.8	370.7
Total assets	\$ 13,939.3	\$ 11,734.5
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 1,429.7	\$ 1,352.0
Deferred revenue	1,292.5	916.7
Finance lease liabilities	712.7	708.5
Stockholders' equity	10,504.4	8,757.3
Total liabilities and stockholders' equity	\$ 13,939.3	\$ 11,734.5

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Net product sales	\$ 1,238.3	\$ 1,025.5	\$ 3,548.0	\$ 3,009.8
Sanofi collaboration revenue	404.2	256.3	999.7	683.5
Bayer collaboration revenue	302.8	264.4	868.0	775.2
Other revenue	103.1	117.3	278.2	314.5
	<u>2,048.4</u>	<u>1,663.5</u>	<u>5,693.9</u>	<u>4,783.0</u>
Expenses:				
Research and development	663.4	557.0	2,353.5	1,584.8
Selling, general, and administrative	419.9	369.2	1,248.0	1,064.9
Cost of goods sold	115.9	30.8	253.8	136.1
Cost of collaboration and contract manufacturing	110.7	79.6	304.5	180.9
	<u>1,309.9</u>	<u>1,036.6</u>	<u>4,159.8</u>	<u>2,966.7</u>
Income from operations	<u>738.5</u>	<u>626.9</u>	<u>1,534.1</u>	<u>1,816.3</u>
Other income (expense), net	<u>30.0</u>	<u>9.0</u>	<u>5.2</u>	<u>61.0</u>
Income before income taxes	768.5	635.9	1,539.3	1,877.3
Income tax expense	<u>(98.9)</u>	<u>(41.2)</u>	<u>(215.5)</u>	<u>(253.3)</u>
Net income	<u>\$ 669.6</u>	<u>\$ 594.7</u>	<u>\$ 1,323.8</u>	<u>\$ 1,624.0</u>
Net income per share - basic	\$ 6.12	\$ 5.50	\$ 12.12	\$ 15.06
Net income per share - diluted	\$ 5.86	\$ 5.17	\$ 11.54	\$ 14.14
Weighted average shares outstanding - basic	109.4	108.0	109.2	107.8
Weighted average shares outstanding - diluted	114.2	115.1	114.7	114.8

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net income	\$ 669.6	\$ 594.7	\$ 1,323.8	\$ 1,624.0
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	60.0	60.4	178.0	160.8
R&D: Up-front payments related to license and collaboration agreements	—	—	400.0	—
SG&A: Non-cash share-based compensation expense	40.8	42.9	122.3	118.4
SG&A: Litigation contingencies	—	—	10.0	—
COGS and COCM: Non-cash share-based compensation expense	16.3	8.1	30.5	21.4
Other income/expense: (Gains) losses on investments in equity securities	(3.4)	4.9	70.7	(21.0)
Income tax effect of reconciling items above	(21.5)	(23.7)	(165.8)	(55.8)
Income tax expense: Adjustment to previously recorded charge related to enactment of U.S. Tax Reform Act	—	(11.9)	—	(11.9)
Non-GAAP net income	<u>\$ 761.8</u>	<u>\$ 675.4</u>	<u>\$ 1,969.5</u>	<u>\$ 1,835.9</u>
Non-GAAP net income per share - basic	\$ 6.96	\$ 6.25	\$ 18.04	\$ 17.03
Non-GAAP net income per share - diluted	\$ 6.67	\$ 5.87	\$ 17.16	\$ 15.98
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	109.4	108.0	109.2	107.8
Non-GAAP net income per share - diluted	114.2	115.1	114.8	114.9

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
<i>Sanofi collaboration revenue:</i>				
Antibody:				
Reimbursement of Regeneron research and development expenses	\$ 60.2	\$ 76.2	\$ 216.5	\$ 201.0
Reimbursement of Regeneron commercialization-related expenses	111.6	103.7	349.3	292.8
Reimbursement for Regeneron's manufacturing of commercial supplies	78.5	40.3	133.3	94.4
Regeneron's share of profits (losses) in connection with commercialization of antibodies	94.2	(38.9)	105.2	(182.6)
Other	4.8	(7.2)	(0.6)	(12.3)
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses	38.0	74.8	120.9	225.7
Reimbursement of Regeneron commercialization-related expenses	3.0	3.2	7.0	6.5
Amounts recognized in connection with up-front payments received	18.5	7.9	73.8	65.2
Other	(4.6)	(3.7)	(5.7)	(7.2)
Total Sanofi collaboration revenue	404.2	256.3	999.7	683.5
<i>Bayer collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	275.0	243.2	793.3	721.5
Reimbursement of Regeneron development expenses	5.0	0.5	15.6	8.3
Other	22.8	20.7	59.1	45.4
Total Bayer collaboration revenue	302.8	264.4	868.0	775.2
<i>Other revenue:</i>				
Reimbursement of Regeneron research and development expenses - Teva	34.2	27.6	102.9	101.1
Reimbursement of Regeneron research and development expenses - other	24.9	6.3	37.0	12.9
Other	44.0	83.4	138.3	200.5
Total other revenue	\$ 103.1	\$ 117.3	\$ 278.2	\$ 314.5

TABLE 5

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

	Three Months Ended September 30,							% Change (Total Sales)
	2019			2018				
	U.S.	ROW	Total	U.S.	ROW	Total		
EYLEA*	\$ 1,187.7	\$ 730.2	\$ 1,917.9	\$ 1,021.8	\$ 654.6	\$ 1,676.4	14%	
Libtayo*	47.6	3.9	51.5	—	—	—	**	
ARCALYST	3.0	—	3.0	3.7	—	3.7	(19%)	
Net product sales recorded by Regeneron	<u>\$ 1,238.3</u>			<u>\$ 1,025.5</u>				
<i>Global net product sales recorded by Sanofi*:</i>								
Dupixent	\$ 508.3	\$ 124.8	\$ 633.1	\$ 219.6	\$ 43.0	\$ 262.6	141%	
Praluent	\$ 33.5	\$ 36.2	\$ 69.7	\$ 48.4	\$ 31.8	\$ 80.2	(13%)	
Kevzara	\$ 36.5	\$ 18.3	\$ 54.8	\$ 19.9	\$ 5.0	\$ 24.9	120%	
ZALTRAP	\$ 3.1	\$ 25.3	\$ 28.4	\$ 1.5	\$ 23.9	\$ 25.4	12%	

	Nine Months Ended September 30,							% Change (Total Sales)
	2019			2018				
	U.S.	ROW	Total	U.S.	ROW	Total		
EYLEA*	\$ 3,422.1	\$ 2,114.9	\$ 5,537.0	\$ 2,997.8	\$ 1,944.5	\$ 4,942.3	12%	
Libtayo*	115.2	3.9	119.1	—	—	—	**	
ARCALYST	10.7	—	10.7	12.0	—	12.0	(11%)	
Net product sales recorded by Regeneron	<u>\$ 3,548.0</u>			<u>\$ 3,009.8</u>				
<i>Global net product sales recorded by Sanofi*:</i>								
Dupixent	\$ 1,266.0	\$ 298.1	\$ 1,564.1	\$ 517.7	\$ 85.4	\$ 603.1	159%	
Praluent	\$ 82.9	\$ 124.4	\$ 207.3	\$ 121.5	\$ 92.0	\$ 213.5	(3%)	
Kevzara	\$ 91.4	\$ 55.6	\$ 147.0	\$ 48.1	\$ 13.3	\$ 61.4	139%	
ZALTRAP	\$ 4.9	\$ 74.6	\$ 79.5	\$ 6.6	\$ 73.5	\$ 80.1	(1%)	

* Bayer records net product sales of EYLEA outside the U.S., and Sanofi records net product sales of Libtayo outside the U.S. and global net product sales of Dupixent, Praluent, Kevzara, and ZALTRAP. The Company records its share of profits/losses in connection with sales of EYLEA and Libtayo outside the U.S., and global sales of Dupixent, Praluent, and Kevzara, within collaboration revenue (see Table 4). Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP.

** Percentage not meaningful