

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): February 6, 2019 (February 6, 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.

Item 2.02 Results of Operations and Financial Condition.

On February 6, 2019, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and year ended December 31, 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 February 6, 2019, Reporting Fourth Quarter and Full Year 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: February 6, 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	<u>Press Release, dated February 6, 2019, Reporting Fourth Quarter and Full Year 2018 Financial and Operating Results.</u>

REGENERON

Press Release

Regeneron Reports Fourth Quarter and Full Year 2018 Financial and Operating Results

- *Fourth quarter 2018 revenues were \$1.93 billion, an increase of 22%*
 - *Fourth quarter 2018 EYLEA® (afibercept) Injection U.S. net sales increased 11% to \$1.08 billion versus fourth quarter 2017*
 - *Fourth quarter 2018 Libtayo® (cemiplimab-rwlc) Injection U.S. net sales were \$15 million in the first three months of launch*
 - *Fourth quarter revenues include a \$149 million cumulative catch-up adjustment primarily related to the modification of the Sanofi Immuno-oncology Discovery and Development Agreement*
- *Fourth quarter 2018 EYLEA net sales outside the United States, which are recorded by the Company's collaborator Bayer, increased 14% to \$724 million*
- *Fourth quarter 2018 Dupixent® (dupilumab) Injection global net sales, which are recorded by the Company's collaborator Sanofi, were \$319 million*
- *Fourth quarter 2018 GAAP diluted EPS was \$7.15; fourth quarter non-GAAP diluted EPS was \$6.84; full year 2018 GAAP diluted EPS was \$21.29; full year non-GAAP diluted EPS was \$22.84*

Tarrytown, New York (February 6, 2019) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2018 and provided a business update.

"2018 was marked by the diversification of our product revenue streams as well as exciting advances across our commercial and development portfolio," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In 2019, we plan to strengthen EYLEA's U.S. market leadership position with a potential approval in diabetic retinopathy. With the fourth quarter U.S. approval of Dupixent in asthma, and the potential 2019 approvals in adolescent atopic dermatitis and chronic rhinosinusitis with nasal polyposis in the U.S. and asthma in the EU, Dupixent continues to deliver on its potential as a pipeline in a product. Libtayo, our first approved immuno-oncology therapy, has begun its launch in advanced cutaneous squamous cell carcinoma and we continue to investigate multiple other potential indications, both as monotherapy and in combination. This year we plan to initiate two potentially pivotal lymphoma studies with our most advanced bispecific antibody, CD20xCD3, and to advance two innovative co-stimulatory bispecific antibodies into human clinical studies."

Financial Highlights

(\$ in millions, except per share data)

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	% Change	2018	2017	% Change
Total revenues	\$ 1,928	\$ 1,582	22%	\$ 6,711	\$ 5,872	14%
GAAP net income	\$ 820	\$ 174	371%	\$ 2,444	\$ 1,199	104%
GAAP net income per share - diluted	\$ 7.15	\$ 1.50	377%	\$ 21.29	\$ 10.34	106%
Non-GAAP net income ⁽²⁾	\$ 786	\$ 607	29%	\$ 2,622	\$ 1,901	38%
Non-GAAP net income per share - diluted ⁽²⁾	\$ 6.84	\$ 5.23	31%	\$ 22.84	\$ 16.32	40%

Business Highlights

Key Pipeline Progress

Regeneron has twenty-one 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

- The Company announced that the Phase 3 PANORAMA trial evaluating EYLEA in patients with moderately severe and severe non-proliferative diabetic retinopathy (NPDR) 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.

Dupixent® (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 have submitted a supplemental Biologics License Application (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.
- In December 2018, the Company and Sanofi submitted an sBLA for chronic rhinosinusitis with nasal polyposis.

REGN1979 is a bi-specific antibody against CD20 and CD3.

- The Company presented positive results from a Phase 1 proof-of-concept study in patients with relapsed or refractory B-cell non-Hodgkin lymphoma, including in follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL), at the American Society of Hematology (ASH) Annual Meeting.

Praluent® (alirocumab) Injection

- In February 2019, the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Praluent, recommending a new indication to reduce cardiovascular risk by lowering low-density lipoprotein cholesterol (LDL-C) levels

as an adjunct to correction of other risk factors in adults with established atherosclerotic cardiovascular disease (ASCVD).

REGN3500 is an antibody to IL-33.

- A Phase 2 study in atopic dermatitis was initiated.

REGN5458 is a bi-specific antibody against BCMA and CD3.

- A Phase 1 study in multiple myeloma was initiated.

Business Development Update

- The Company and Sanofi entered into an agreement to restructure their Immuno-oncology Discovery and Development Agreement (Amended IO Discovery Agreement), which narrowed the scope of the existing discovery and development activities conducted by the Company to developing therapeutic bi-specific antibodies targeting BCMA and CD3 (BCMAxCD3) and MUC16 and CD3 (MUC16xCD3). The Company retains full rights to its other immuno-oncology programs that were part of the original Immuno-oncology Discovery and Development Agreement.

Select 2019 Milestones

Programs	Milestones
EYLEA	<ul style="list-style-type: none">• FDA decision on sBLA for the treatment of diabetic retinopathy (target action date of May 13, 2019)• Re-submission of Prior-Approval Supplement (PAS) for pre-filled syringe• Initiate a study of a high dose formulation of aflibercept
Dupixent	<ul style="list-style-type: none">• FDA decision on sBLA for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) (target action date of March 11, 2019)• Report results from Phase 3 study in pediatric patients (6–11 years of age) with atopic dermatitis• European Medicines Agency (EMA) decision on regulatory application for asthma• Initiate Phase 2/3 program in chronic obstructive pulmonary disease (COPD)
Libtayo	<ul style="list-style-type: none">• Regulatory agency decision for advanced cutaneous squamous cell carcinoma (CSCC) in the European Union (EU)• Continue patient enrollment in non-small cell lung cancer and various other studies
Praluent	<ul style="list-style-type: none">• FDA (target action date of April 28, 2019) and EMA decisions on applications for cardiovascular risk reduction• FDA decision on sBLA for first-line treatment of hyperlipidemia (target action date of April 29, 2019)
Fasimumab (NGF Antibody)	<ul style="list-style-type: none">• Continue patient enrollment in Phase 3 long-term safety study and Phase 3 efficacy studies in osteoarthritis
Evinacumab (ANGPTL3 Antibody)	<ul style="list-style-type: none">• Report results from Phase 3 study in homozygous familial hypercholesterolemia (HoFH)
REGN3500 (IL-33 Antibody)	<ul style="list-style-type: none">• Report results from Phase 2 study in asthma
Trevogrumab (GDF8 Antibody) in combination with garetosmab	<ul style="list-style-type: none">• Report results from multi-dose portion of Phase 1 study
REGN1979 (CD20 and CD3 Antibody)	<ul style="list-style-type: none">• Initiate potentially pivotal Phase 2 study in FL• Initiate potentially pivotal Phase 2 study in DLBCL
Pozelimab (C5 Antibody)	<ul style="list-style-type: none">• Initiate Phase 2 study in paroxysmal nocturnal hemoglobinuria (PNH)

Fourth Quarter and Full Year 2018 Financial Results

Product Revenues: Net product sales were \$1.096 billion in the fourth quarter and \$4.106 billion for the full year 2018, compared to \$979 million in the fourth quarter and \$3.719 billion for the full year 2017. EYLEA net product sales in the United States were \$1.079 billion in the fourth quarter and \$4.077 billion for the full year 2018, compared to \$975 million in the fourth quarter and \$3.702 billion for the full year 2017. Overall distributor inventory levels for EYLEA in the United States remained within the Company's one-to-two-week targeted range. Libtayo, which was approved by the FDA on September 28, 2018, had net product sales in the United States of \$15 million in the fourth quarter of 2018.

Total Revenues: Total revenues, which include product revenues described above, increased by 22% to \$1.928 billion in the fourth quarter of 2018, compared to \$1.582 billion in the fourth quarter of 2017. Full year 2018 total revenues increased by 14% to \$6.711 billion, compared to \$5.872 billion for the full year 2017. Total revenues include Sanofi and Bayer collaboration revenues of \$729 million in the fourth quarter of 2018, compared to \$497 million in the fourth quarter of 2017. Total revenues include Sanofi and Bayer collaboration revenues of \$2.188 billion for the full year 2018, compared to \$1.815 billion for the full year 2017. The increase in Sanofi collaboration revenue in the fourth quarter and full year 2018 was primarily due to (i) an increase in clinical development activities for Libtayo, (ii) the Company's share of higher net sales of Dupixent, and, to a lesser extent, Praluent and Kevzara, and (iii) the recognition of a cumulative catch-up adjustment of \$149 million in the fourth quarter arising from a change in the estimate of the stage of completion of the collaborations' immuno-oncology programs primarily in connection with the Amended IO Discovery Agreement, partly offset by (i) a lower proportion of development reimbursements for Dupixent that Sanofi is required to fund under our License and Collaboration Agreement, and (ii) an increase in the collaborations' Dupixent commercialization expenses. Sanofi collaboration revenue for the full year of 2018, compared to the full year of 2017, was also negatively impacted by the ceasing of funding by Sanofi in connection with the Company's Antibody Discovery and Preclinical Development Agreement, which ended on December 31, 2017.

The change in Bayer collaboration revenue in the fourth quarter and full year 2018 was primarily due to an increase in net profits in connection with higher sales of EYLEA outside the United States. In addition, in the fourth quarter of 2017, the Company accelerated the recognition of deferred revenue from the up-front payment previously received from Bayer in connection with the discontinuation of the Ang2 development program.

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.

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

Research and Development (R&D) Expenses: GAAP R&D expenses were \$601 million in the fourth quarter and \$2.186 billion for the full year 2018, compared to \$528 million in the fourth quarter and \$2.075 billion for the full year 2017. The higher R&D expenses in the fourth quarter and full year 2018 were principally due to an increase in Libtayo development expenses, higher payroll and payroll-related costs, and higher facilities-related costs, partly offset by a decrease in Dupixent development expenses. The higher R&D expenses for full year 2018, compared to full year 2017, was also due to higher fasinumab development expenses, partly offset by lower total clinical manufacturing costs. R&D-related non-cash share-based compensation expense was \$68 million in the fourth quarter and \$229 million for the full year 2018, compared to \$59 million in the fourth quarter and \$272 million for the full year 2017. The decrease in total R&D-related non-cash compensation expense for the full year of 2018, compared to the full year of 2017, is largely attributable to a revision in our estimate of the number of stock options that are expected

to be forfeited, partly offset by the immediate recognition of non-cash compensation expense in connection with annual employee grants made in December 2018 to certain retirement-eligible employees.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$491 million in the fourth quarter and \$1.556 billion for the full year 2018, compared to \$410 million in the fourth quarter and \$1.320 billion for the full year 2017. The higher SG&A expenses in the fourth quarter and full year 2018 were primarily due to higher headcount and headcount-related costs, higher contributions to independent not-for-profit patient assistance organizations, an increase in commercialization-related expenses for Dupixent, and an accrual for loss contingencies associated with ongoing litigation. SG&A-related non-cash share-based compensation expense was \$51 million in the fourth quarter and \$169 million for the full year 2018, compared to \$62 million in the fourth quarter and \$208 million for the full year 2017. The decrease in SG&A-related non-cash share-based compensation expense for the full year of 2018, compared to the full year of 2017, was primarily due to a revision in our estimate of the number of stock options that are expected to be forfeited.

Other Income (Expense): GAAP other income (expense), net, in the fourth quarter and full year of 2018 includes the recognition of \$63 million and \$42 million, respectively, of net losses on equity securities. In the first quarter of 2018, we adopted Accounting Standards Update (ASU) 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*, which requires us to measure equity investments at fair value with changes in fair value recognized in net income; previously, such changes in fair value were recognized in Other comprehensive income (loss). In addition, GAAP other expenses in 2017 included the recognition of a \$30 million loss on debt extinguishment related to the Company's Tarrytown lease transaction.

Income Taxes: GAAP income tax benefit was \$(144) million and the effective tax rate was (21.3)% in the fourth quarter of 2018, compared to GAAP income tax expense of \$381 million and 68.7% in the fourth quarter of 2017. GAAP income tax expense was \$109 million and the effective tax rate was 4.3% for the full year 2018, compared to \$880 million and 42.3% for the full year 2017. The Company's effective tax rate for both the fourth quarter and full year 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 in 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the Company's fourth quarter sale of non-inventory related assets between foreign subsidiaries, which had a net impact on the rate by 24.0% and 6.3% for the fourth quarter and full year 2018, respectively. The effective tax rate for both the fourth quarter and full year 2018 was also positively impacted by tax planning in connection with the U.S. Tax Reform Act, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, stock-based compensation, and the federal tax credit for research activities. During the fourth quarter and full year 2018, the Company recorded an income tax benefit of \$56 million and \$68 million, respectively, as an adjustment to the provisional amount recorded as of December 31, 2017 for the U.S. Tax Reform Act.

GAAP and Non-GAAP Net Income⁽²⁾: GAAP net income was \$820 million, or \$7.58 per basic share and \$7.15 per diluted share, in the fourth quarter of 2018, compared to GAAP net income of \$174 million, or \$1.62 per basic share and \$1.50 per diluted share, in the fourth quarter of 2017. GAAP net income was \$2.444 billion, or \$22.65 per basic share and \$21.29 per diluted

share, for the full year 2018, compared to GAAP net income of \$1.199 billion, or \$11.27 per basic share and \$10.34 per diluted share, for the full year 2017.

Non-GAAP net income was \$786 million, or \$7.26 per basic share and \$6.84 per diluted share, in the fourth quarter of 2018, compared to non-GAAP net income of \$607 million, or \$5.67 per basic share and \$5.23 per diluted share, in the fourth quarter of 2017. Non-GAAP net income was \$2.622 billion, or \$24.30 per basic share and \$22.84 per diluted share, for the full year 2018, compared to non-GAAP net income of \$1.901 billion, or \$17.88 per basic share and \$16.32 per diluted share, for the full year 2017.

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 full year 2019 financial guidance consists of the following components:

GAAP Sanofi collaboration revenue: Sanofi reimbursement of Regeneron commercialization-related expenses	\$510 million–\$560 million
GAAP Unreimbursed R&D ⁽⁵⁾	\$1.855 billion–\$2.000 billion
Non-GAAP Unreimbursed R&D ⁽²⁾⁽⁴⁾	\$1.590 billion–\$1.710 billion
GAAP SG&A	\$1.700 billion–\$1.830 billion
Non-GAAP SG&A ⁽²⁾⁽⁴⁾	\$1.500 billion–\$1.600 billion
GAAP effective tax rate	14%–16%
Capital expenditures	\$410 million–\$490 million

⁽¹⁾ Regeneron records net product sales of EYLEA in the United States. Outside the United States, EYLEA net product sales comprise sales by Bayer in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within "Bayer collaboration revenue" in its Statements of Operations.

⁽²⁾ This press release uses non-GAAP net income, non-GAAP net income per share, non-GAAP unreimbursed R&D, and non-GAAP SG&A, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). These non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. Non-GAAP adjustments also include the 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.

⁽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⁾	\$ 1,855	\$ 2,000
R&D: Non-cash share-based compensation expense	(265)	(290)
Non-GAAP unreimbursed R&D	\$ 1,590	\$ 1,710
GAAP SG&A	\$ 1,700	\$ 1,830
SG&A: Non-cash share-based compensation expense	(200)	(230)
Non-GAAP SG&A	\$ 1,500	\$ 1,600

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

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2018 financial and operating results on Wednesday, February 6, 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, neuromuscular 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 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, 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 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 such non-GAAP financial measures.

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TABLE 1

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

	December 31,	
	2018	2017
Assets:		
Cash and marketable securities	\$ 4,564.9	\$ 2,896.0
Accounts receivable - trade, net	1,723.7	1,538.6
Accounts receivable from Sanofi and Bayer	519.5	435.7
Inventories	1,151.2	726.1
Property, plant, and equipment, net	2,575.8	2,358.6
Deferred tax assets	828.7	506.3
Other assets	370.7	303.0
Total assets	\$ 11,734.5	\$ 8,764.3
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 1,352.0	\$ 967.4
Deferred revenue	916.7	949.3
Capital and facility lease obligations	708.5	703.5
Stockholders' equity	8,757.3	6,144.1
Total liabilities and stockholders' equity	\$ 11,734.5	\$ 8,764.3

TABLE 2

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Net product sales	\$ 1,096.4	\$ 978.7	\$ 4,106.2	\$ 3,718.5
Sanofi collaboration revenue	427.6	199.5	1,111.1	877.2
Bayer collaboration revenue	301.5	297.1	1,076.7	938.1
Other revenue	102.3	107.1	416.8	338.4
	<u>1,927.8</u>	<u>1,582.4</u>	<u>6,710.8</u>	<u>5,872.2</u>
Expenses:				
Research and development	601.2	528.0	2,186.1	2,075.1
Selling, general, and administrative	491.3	409.9	1,556.2	1,320.4
Cost of goods sold	44.0	52.7	180.0	202.5
Cost of collaboration and contract manufacturing	73.2	53.0	254.1	194.6
	<u>1,209.7</u>	<u>1,043.6</u>	<u>4,176.4</u>	<u>3,792.6</u>
Income from operations	<u>718.1</u>	<u>538.8</u>	<u>2,534.4</u>	<u>2,079.6</u>
Other income (expense), net	<u>(41.9)</u>	<u>16.0</u>	<u>19.1</u>	<u>(1.1)</u>
Income before income taxes	676.2	554.8	2,553.5	2,078.5
Income tax benefit (expense)	<u>144.2</u>	<u>(381.3)</u>	<u>(109.1)</u>	<u>(880.0)</u>
Net income	<u>\$ 820.4</u>	<u>\$ 173.5</u>	<u>\$ 2,444.4</u>	<u>\$ 1,198.5</u>
Net income per share - basic	\$ 7.58	\$ 1.62	\$ 22.65	\$ 11.27
Net income per share - diluted	\$ 7.15	\$ 1.50	\$ 21.29	\$ 10.34
Weighted average shares outstanding - basic	108.2	107.0	107.9	106.3
Weighted average shares outstanding - diluted	114.8	115.9	114.8	115.9

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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
GAAP net income	\$ 820.4	\$ 173.5	\$ 2,444.4	\$ 1,198.5
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	68.2	58.7	229.0	271.9
R&D: Up-front payments related to license and collaboration agreements	—	25.0	—	25.0
SG&A: Non-cash share-based compensation expense	50.8	62.2	169.2	208.4
SG&A: Litigation contingencies	30.0	—	30.0	—
COGS and COCM: Non-cash share-based compensation expense	7.8	6.2	29.2	27.0
Other income/expense: Loss on extinguishment of debt	—	—	—	30.1
Other income/expense: Gains and losses on investments in equity securities ^(a)	62.9	—	41.9	—
Income tax effect of reconciling items above	(36.2)	(44.6)	(92.1)	(186.0)
Income tax (benefit) expense: Impact of sale of assets between foreign subsidiaries	(162.1)	—	(162.1)	—
Income tax (benefit) expense: (Adjustment) charge related to enactment of U.S. Tax Reform Act	(56.1)	326.2	(68.0)	326.2
Non-GAAP net income	<u>\$ 785.7</u>	<u>\$ 607.2</u>	<u>\$ 2,621.5</u>	<u>\$ 1,901.1</u>
Non-GAAP net income per share - basic	\$ 7.26	\$ 5.67	\$ 24.30	\$ 17.88
Non-GAAP net income per share - diluted	\$ 6.84	\$ 5.23	\$ 22.84	\$ 16.32
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	108.2	107.0	107.9	106.3
Non-GAAP net income per share - diluted	114.9	116.2	114.8	116.5

^(a) 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 months and year ended December 31, 2018 were recorded in Other income (expense), net.

TABLE 4

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
<i>Sanofi collaboration revenue:</i>				
Reimbursement of Regeneron research and development expenses	\$ 150.4	\$ 138.9	\$ 577.1	\$ 748.4
Reimbursement of Regeneron commercialization-related expenses	126.8	122.9	426.1	375.8
Regeneron's share of losses in connection with commercialization of antibodies	(44.4)	(113.6)	(227.0)	(442.6)
Other	194.8	51.3	334.9	195.6
Total Sanofi collaboration revenue	<u>427.6</u>	<u>199.5</u>	<u>1,111.1</u>	<u>877.2</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	270.8	231.2	992.3	802.3
Reimbursement of Regeneron development expenses	2.4	4.7	10.8	31.1
Other	28.3	61.2	73.6	104.7
Total Bayer collaboration revenue	<u>301.5</u>	<u>297.1</u>	<u>1,076.7</u>	<u>938.1</u>
Total Sanofi and Bayer collaboration revenue	<u>\$ 729.1</u>	<u>\$ 496.6</u>	<u>\$ 2,187.8</u>	<u>\$ 1,815.3</u>
<i>Other revenue:</i>				
Reimbursement of Regeneron research and development expenses - Teva	\$ 28.4	\$ 33.1	\$ 129.5	\$ 115.1
Reimbursement of Regeneron research and development expenses - other	4.7	2.9	17.6	6.5
Other	69.2	71.1	269.7	216.8
Total other revenue	<u>\$ 102.3</u>	<u>\$ 107.1</u>	<u>\$ 416.8</u>	<u>\$ 338.4</u>

TABLE 5

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

	Three Months Ended December 31,					
	2018			2017		
	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA*	\$ 1,078.9	\$ 724.4	\$ 1,803.3	\$ 974.8	\$ 636.9	\$ 1,611.7
Libtayo	14.8	—	14.8	—	—	—
ARCALYST	2.7	—	2.7	4.0	—	4.0
Net product sales recorded by Regeneron	<u>\$ 1,096.4</u>			<u>\$ 978.8</u>		

Net product sales recorded by Sanofi:*

Dupixent	\$ 258.6	\$ 60.2	\$ 318.8	\$ 136.9	\$ 2.0	\$ 138.9
Praluent	\$ 59.7	\$ 33.5	\$ 93.2	\$ 41.6	\$ 21.7	\$ 63.3
Kevzara	\$ 26.6	\$ 8.6	\$ 35.2	\$ 8.2	\$ 1.3	\$ 9.5
ZALTRAP	\$ 2.4	\$ 25.4	\$ 27.8	\$ 3.1	\$ 22.1	\$ 25.2

	Year Ended December 31,					
	2018			2017		
	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA*	\$ 4,076.7	\$ 2,668.9	\$ 6,745.6	\$ 3,701.9	\$ 2,226.9	\$ 5,928.8
Libtayo	14.8	—	14.8	—	—	—
ARCALYST	14.7	—	14.7	16.6	—	16.6
Net product sales recorded by Regeneron	<u>\$ 4,106.2</u>			<u>\$ 3,718.5</u>		

Net product sales recorded by Sanofi:*

Dupixent	\$ 776.3	\$ 145.7	\$ 922.0	\$ 253.8	\$ 2.7	\$ 256.5
Praluent	\$ 181.3	\$ 125.5	\$ 306.8	\$ 131.4	\$ 63.3	\$ 194.7
Kevzara	\$ 74.7	\$ 21.9	\$ 96.6	\$ 11.6	\$ 1.7	\$ 13.3
ZALTRAP	\$ 9.0	\$ 98.8	\$ 107.8	\$ 10.7	\$ 73.1	\$ 83.8

* 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.