

REGENERON PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Address	777 OLD SAW MILL RIVER ROAD TARRYTOWN, NY, 10591
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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 3, 2018 (May 3, 2018)

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 May 3, 2018 , Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 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 May 3, 2018 , Reporting First Quarter 2018 Financial and Operating Results.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 3, 2018

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	Press Release, dated May 3, 2018, Reporting First Quarter 2018 Financial and Operating Results.

REGENERON

Press Release

Regeneron Reports First Quarter 2018 Financial and Operating Results

- First quarter 2018 GAAP net income per diluted share increased by 93% to \$4.16 versus first quarter 2017 and first quarter 2018 non-GAAP net income per diluted share increased 60% to \$4.67 versus first quarter 2017
- First quarter 2018 EYLEA[®] (afibercept) Injection U.S. net sales increased 15% to \$984 million versus first quarter 2017 and first quarter 2018 EYLEA global net sales⁽¹⁾ increased 20% to \$1.61 billion versus first quarter 2017
- Positive results reported from Praluent[®] (alirocumab) ODYSSEY OUTCOMES study
- Agreement reached with Express Scripts that provides patients with straightforward and more affordable patient access to Praluent
- Supplemental Biologics License Application for Dupixent[®] (dupilumab) in asthma accepted with a target action date of October 20, 2018
- Biologics License Application for cemiplimab for the treatment of advanced cutaneous squamous cell carcinoma (CSCC) accepted for priority review
- Positive Phase 3 results reported for EYLEA in non-proliferative diabetic retinopathy trial

Tarrytown, New York (May 3, 2018) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2018 and provided a business update.

"Regeneron's commercial business continues to advance with positive sales growth for EYLEA and strong underlying demand for Dupixent," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "This year, we have reported positive Phase 3 results for Praluent in cardiovascular risk reduction and for EYLEA in diabetic retinopathy - and look forward to continued progress with Dupixent, including a U.S. regulatory decision in uncontrolled asthma and Phase 3 results in both adolescents with atopic dermatitis and adults with nasal polyps. Our immuno-oncology portfolio is advancing rapidly, with a potential first approval for cemiplimab in advanced cutaneous squamous cell carcinoma, and a broad pivotal program in lung cancer."

Financial Highlights

(\$ in millions, except per share data)

	Three Months Ended March 31,		
	2018	2017	% Change
Total revenues	\$ 1,511	\$ 1,319	15%
GAAP net income	\$ 478	\$ 249	92%
GAAP net income per share - diluted	\$ 4.16	\$ 2.16	93%
Non-GAAP net income ⁽²⁾	\$ 537	\$ 337	59%
Non-GAAP net income per share - diluted ⁽²⁾	\$ 4.67	\$ 2.92	60%

Net Product Sales of Regeneron-Discovered Products *

(\$ in millions)

	Three Months Ended March 31,		
	2018	2017	% Change
EYLEA in the United States	\$ 984	\$ 854	15%
ARCALYST	4	4	—%
Net product sales recorded by Regeneron	\$ 988	\$ 858	15%
EYLEA outside of the United States *	\$ 624	\$ 484	29%
EYLEA global	\$ 1,608	\$ 1,338	20%
<i>Global net product sales recorded by Sanofi * :</i>			
Praluent in the United States	\$ 32	\$ 25	28%
Praluent outside of the United States	28	11	155%
Praluent global	60	36	67%
Dupixent in the United States	117	—	**
Dupixent outside of the United States	14	—	**
Dupixent global	131	—	**
Kevzara in the United States	9	—	**
Kevzara outside of the United States	3	—	**
Kevzara global	12	—	**
ZALTRAP global	26	17	53%
Net product sales recorded by Sanofi	\$ 229	\$ 53	**

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

** Percentage not meaningful

First Quarter 2018 Business Highlights

Key Pipeline Progress

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

EYLEA® (afibercept) Injection

- In the first quarter of 2018, the Company announced positive top-line results from the Phase 3 PANORAMA study of EYLEA in moderately severe to severe non-proliferative diabetic retinopathy (NPDR). PANORAMA will form the basis of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) by the end of the year.

Dupixent® (dupilumab) Injection

- Dupixent, an antibody that blocks signaling of IL-4 and IL-13, is currently approved in atopic dermatitis for adults in the United States, European Union, and certain other countries outside the United States.

- Dupilumab is being studied in asthma, adolescent and pediatric atopic dermatitis, nasal polyps, and eosinophilic esophagitis (EoE), with additional studies planned in 2018. Data are expected to be reported from Phase 3 studies in patients with nasal polyps and adolescent patients with atopic dermatitis during 2018.
- In March 2018, the sBLA for Dupixent as an add-on maintenance treatment in certain adults and adolescents (12 years of age and older) with moderate-to-severe asthma was filed with the FDA, with a target action date of October 20, 2018. In the first quarter of 2018, regulatory applications were also accepted for review by the European Medicines Agency (EMA) and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for Dupixent in asthma.
- Dupixent for the treatment of atopic dermatitis in adults not adequately controlled with existing therapies was approved by the Ministry of Health, Labor and Welfare (MHLW) in Japan in the first quarter of 2018, and has recently been launched.
- In the first quarter of 2018, a Phase 2/3 study in younger pediatric patients (from six months to five years of age) with severe atopic dermatitis was initiated.

Praluent® (alirocumab) Injection

- In the first quarter of 2018, the Company and Sanofi announced that the ODYSSEY OUTCOMES trial met its primary endpoint, demonstrating that high-risk patients who added Praluent to maximally-tolerated statins experienced significantly fewer major adverse cardiovascular events compared to those on maximally-tolerated statins alone. In addition, in this study, adding Praluent to maximally-tolerated statins was associated with reduced death from any cause.
- In May 2018, the Company and Sanofi announced they will lower the net price of Praluent in exchange for straightforward, more affordable patient access from Express Scripts. Praluent will become the exclusive PCSK9 inhibitor therapy on the Express Scripts national formulary. The agreement takes effect on July 1, 2018 for commercial patients covered by the Express Scripts National Preferred Formulary (approximately 25 million individuals in total).

Cemiplimab, an antibody to programmed cell death protein 1 (PD-1), is being studied in patients with cancer.

- In April 2018, the FDA accepted for priority review the BLA for cemiplimab for the treatment of patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery. The target action date for the FDA decision is October 28, 2018.
- In April 2018, the EMA also accepted for review the Marketing Authorization Application (MAA) for cemiplimab in patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery.

Fasinumab, an antibody targeting Nerve Growth Factor (NGF), is being studied in patients with osteoarthritis of the knee or hip and chronic low back pain in patients with concomitant osteoarthritis of the knee or hip.

- An independent Data Monitoring Committee monitoring the ongoing safety and efficacy of the fasinumab clinical trials recommended that the higher dose-regimens be discontinued based on the risk benefit assessment and that the program may continue with the lower dose-regimens of fasinumab. The trials are being modified accordingly.

Evinacumab is an antibody to angiotensin-like protein 3 (ANGPTL3). A Phase 3 study in homozygous familial hypercholesterolemia (HoFH) was initiated in the first quarter of 2018.

REGN3500 is an antibody to interleukin-33 (IL-33). In the first quarter of 2018, a Phase 2 study in asthma was initiated.

Select Upcoming 2018 Milestones

Programs	Milestones
EYLEA	<ul style="list-style-type: none"> • FDA decision on sBLA for every 12-week dosing interval in wet AMD (target action date of August 11, 2018) • Submit sBLA for the treatment of NPDR in patients without DME • Submit sBLA for pre-filled syringe
Dupixent (dupilumab)	<ul style="list-style-type: none"> • FDA decision on sBLA for asthma in adult/adolescent patients (target action date of October 20, 2018) • Additional regulatory agency decisions on applications for atopic dermatitis in adults outside the United States • Report data from Phase 3 study in adolescent patients (12–17 years of age) with atopic dermatitis and submit sBLA and MAA for expanded indication • Report data from Phase 3 studies in nasal polyps • Initiate Phase 3 study in EoE • Initiate Phase 3 program in chronic obstructive pulmonary disease (COPD) • Initiate clinical program in co-morbid allergic conditions • Initiate Phase 2 studies in peanut allergy and grass allergy
Praluent (alirocumab)	<ul style="list-style-type: none"> • Submit for regulatory approval for cardiovascular risk reduction in the United States and EU and for first-line treatment of hyperlipidemia in the United States • FDA decision on sBLA for use with apheresis (target action date of August 24, 2018) • Initiate Phase 3 pediatric studies in HoFH and HeFH
Kevzara (sarilumab)	<ul style="list-style-type: none"> • Initiate Phase 3 study in giant cell arteritis • Initiate Phase 3 study in polymyalgia rheumatica
Cemiplimab (PD-1 Antibody)	<ul style="list-style-type: none"> • FDA decision on BLA for advanced CSCC (target action date of October 28, 2018) • Continue patient enrollment in Phase 3 study for first-line treatment of non-small cell lung cancer, as well as various other studies • Initiate additional studies in non-small cell lung cancer
Fasimumab (NGF Antibody)	<ul style="list-style-type: none"> • Report data from first Phase 3 efficacy study in osteoarthritis pain
Evinacumab (Angptl-3 Antibody)	<ul style="list-style-type: none"> • Initiate Phase 2 study in severe hypertriglyceridemia
REGN3500 (IL-33 Antibody)	<ul style="list-style-type: none"> • Initiate Phase 2 studies in COPD and atopic dermatitis
Bispecific Antibodies	<ul style="list-style-type: none"> • Initiate Phase 2 study for REGN1979 (CD20xCD3 Antibody) in Follicular Lymphoma • Initiate clinical study in REGN4018 (MUC16xCD3 antibody) • Submit Investigational New Drug Application (IND) for BCMAxCD3 antibody

Financial Results

Product Revenues: Net product sales were \$988 million in the first quarter of 2018 , compared to \$858 million in the first quarter of 2017 . EYLEA net product sales in the United States were \$984 million in the first quarter of 2018 , compared to \$854 million in the first quarter of 2017 . Overall distributor inventory levels remained within the Company's one- to two-week targeted range.

Total Revenues: Total revenues, which include product revenues described above, increased by 15% to \$1.511 billion in the first quarter of 2018 , compared to \$1.319 billion in the first quarter of 2017 . Total revenues include Sanofi and Bayer collaboration revenues of \$437 million in the first quarter of 2018 , compared to \$404 million in the first quarter of 2017 . Sanofi collaboration revenue in the first quarter of 2018 decreased primarily due to the Company's Discovery and Preclinical Development Agreement with Sanofi ending on December 31, 2017, lower reimbursement for Dupixent (dupilumab) development activities, and an increase in the Company's share of the collaborations' Dupixent commercialization expenses. These decreases were partly offset by the Company's share of higher net sales of Dupixent (as the product was launched at the end of March 2017), and an increase in reimbursement revenues in connection with late-stage clinical development activities for cemiplimab. Bayer collaboration revenue increased in the first quarter of 2018 primarily due to an increase in the Company's share of net profits in connection with higher sales of EYLEA outside the United States.

Other revenue in the first quarter of 2018 increased primarily due to higher reimbursements of the Company's fasinumab research and development expenses in connection with the Company's collaboration agreement with Teva.

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; prior period amounts have not been adjusted and the Company recognized a cumulative-effect adjustment to reduce Retained earnings and increase Deferred revenue on January 1, 2018 by \$143 million , net of tax. The adoption of the new standard did not have a material impact of the Company's total revenues in the first quarter of 2018.

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

Research and Development (R&D) Expenses: GAAP R&D expenses were \$499 million in the first quarter of 2018 , compared to \$507 million in the first quarter of 2017 . The lower R&D expenses in the first quarter of 2018 were principally due to a decrease in clinical manufacturing costs and a decrease in dupilumab development costs. These decreases were partly offset by an increase in cemiplimab and fasinumab clinical trial costs. In the first quarter of 2018 , R&D-related non-cash share-based compensation expense was \$41 million , compared to \$74 million in the first quarter of 2017 . The decrease in total non-cash share-based compensation expense in the first quarter of 2018 was primarily attributable to a revision in the Company's estimate of the number of stock options that are expected to be forfeited.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$331 million in the first quarter of 2018 , compared to \$297 million in the first quarter of 2017 . The higher SG&A expenses in the first quarter of 2018 were primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses to support the launch of Dupixent. In the first quarter of 2018 , SG&A-related non-cash share-based compensation expense decreased to \$35 million , compared to \$54 million in the first quarter of 2017 , primarily due to the revision in the Company's estimate of stock option forfeitures as described under "R&D Expenses" above.

Income Tax Expense: In the first quarter of 2018 , GAAP income tax expense was \$107 million and the effective tax rate was 18.3% , compared to \$183 million and 42.4% in the first quarter of 2017 . The Company's effective tax rate for the first quarter of 2018 was significantly impacted by the bill known as the Tax Cuts and Jobs Act (the "U.S. Tax Reform Act"), which reduced the U.S. federal corporate income tax rate from 35% to 21% effective January 1, 2018. The effective tax rate for the first quarter of 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the foreign-derived intangible income deduction and the federal tax credit for research activities.

Other income, net: GAAP other income in the first quarter of 2018 included the recognition of unrealized gains on equity securities. In the first quarter of 2018, the Company adopted Accounting Standards Update ("ASU") 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* , as of January 1, 2018, which requires the Company 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). Refer to Table 3 for the non-GAAP adjustment related to these gains.

GAAP and Non-GAAP Net Income ⁽²⁾: GAAP net income was \$478 million , or \$4.44 per basic share and \$4.16 per diluted share, in the first quarter of 2018 , compared to GAAP net income of \$249 million , or \$2.36 per basic share and \$2.16 per diluted share, in the first quarter of 2017 .

Non-GAAP net income was \$537 million , or \$4.99 per basic share and \$4.67 per diluted share, in the first quarter of 2018 , compared to non-GAAP net income of \$337 million , or \$3.19 per basic share and \$2.92 per diluted share, in the first quarter of 2017 .

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

2018 Financial Guidance ⁽³⁾

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

Sanofi collaboration revenue: Sanofi reimbursement of Regeneron commercialization-related expenses	\$450 million–\$485 million <i>(previously \$450 million–\$500 million)</i>
Non-GAAP unreimbursed R&D ⁽²⁾⁽⁴⁾	\$1.230 billion – \$1.310 billion <i>(previously \$1.230 billion–\$1.330 billion)</i>
Non-GAAP SG&A ⁽²⁾⁽⁴⁾	\$1.325 billion–\$1.395 billion <i>(previously \$1.350 billion–\$1.450 billion)</i>
Effective tax rate	15%–18% <i>(previously 15%–19%)</i>
Capital expenditures	\$420 million – \$480 million <i>(previously \$420 million–\$500 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 2018 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 2018 non-GAAP to GAAP financial guidance is included below:

<i>(In millions)</i>	Projected Range	
	Low	High
GAAP unreimbursed R&D ⁽⁵⁾	\$ 1,445	\$ 1,545
R&D: Non-cash share-based compensation expense	(215)	(235)
Non-GAAP unreimbursed R&D	\$ 1,230	\$ 1,310
GAAP SG&A	\$ 1,490	\$ 1,590
SG&A: Non-cash share-based compensation expense	(165)	(195)
Non-GAAP SG&A	\$ 1,325	\$ 1,395

⁽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 first quarter 2018 financial and operating results on Thursday, May 3, 2018, 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 & Media" page of Regeneron's website at <http://investor.regeneron.com/events.cfm>. 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 six 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 disease, heart disease, allergic and inflammatory diseases, pain, cancer, 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 news release; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, cemiplimab, 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, and Kevzara), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance, including without limitation those relating to Sanofi reimbursement of Regeneron commercialization-related expenses, non-GAAP unreimbursed R&D, non-GAAP SG&A, effective tax rate, and capital expenditures; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation proceedings relating to Praluent, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

Non-GAAP Financial Measures

This press release and/or the financial results attached to this press release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of historical non-GAAP financial measures.

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TABLE 1

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

	March 31, 2018	December 31, 2017
Assets:		
Cash and marketable securities	\$ 3,446,937	\$ 2,896,074
Accounts receivable - trade, net	1,531,936	1,538,642
Accounts receivable from Sanofi and Bayer	411,996	435,698
Inventories	820,397	726,138
Property, plant, and equipment, net	2,394,727	2,358,605
Deferred tax assets	532,268	506,291
Other assets	234,435	302,838
Total assets	<u>\$ 9,372,696</u>	<u>\$ 8,764,286</u>
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 1,043,749	\$ 967,418
Deferred revenue	1,056,658	949,337
Capital and facility lease obligations	704,645	703,453
Stockholders' equity	6,567,644	6,144,078
Total liabilities and stockholders' equity	<u>\$ 9,372,696</u>	<u>\$ 8,764,286</u>

TABLE 2

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

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Net product sales	\$ 987,909	\$ 858,245
Sanofi collaboration revenue	189,490	210,367
Bayer collaboration revenue	247,928	193,939
Other revenue	86,158	56,440
	<u>1,511,485</u>	<u>1,318,991</u>
Expenses:		
Research and development	498,586	507,435
Selling, general, and administrative	330,770	296,846
Cost of goods sold	69,243	61,253
Cost of collaboration and contract manufacturing	45,655	22,915
	<u>944,254</u>	<u>888,449</u>
Income from operations	567,231	430,542
Other income, net	18,167	1,747
Income before income taxes	585,398	432,289
Income tax expense	(107,418)	(183,358)
Net income	<u>\$ 477,980</u>	<u>\$ 248,931</u>
Net income per share - basic	\$ 4.44	\$ 2.36
Net income per share - diluted	\$ 4.16	\$ 2.16
Weighted average shares outstanding - basic	107,648	105,572
Weighted average shares outstanding - diluted	114,906	115,106

TABLE 3

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

	Three Months Ended March 31,	
	2018	2017
GAAP net income	\$ 477,980	\$ 248,931
<i>Adjustments:</i>		
R&D: Non-cash share-based compensation expense	40,835	73,523
SG&A: Non-cash share-based compensation expense	35,014	53,812
COGS and COCM: Non-cash share-based compensation expense	6,573	6,454
Other income/expense: Gains and losses on investments in equity securities ^(a)	(9,369)	—
Income tax effect of reconciling items above	(14,301)	(46,179)
Non-GAAP net income	<u>\$ 536,732</u>	<u>\$ 336,541</u>
Non-GAAP net income per share - basic	\$ 4.99	\$ 3.19
Non-GAAP net income per share - diluted	\$ 4.67	\$ 2.92
<i>Shares used in calculating:</i>		
Non-GAAP net income per share - basic	107,648	105,572
Non-GAAP net income per share - diluted	114,910	115,178

^(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 ASU 2016-01, unrealized gains and losses on equity securities during the three months ended March 31, 2018 were recorded in Other income, net.

TABLE 4

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

	Three Months Ended	
	March 31,	
	2018	2017
<i>Sanofi collaboration revenue:</i>		
Reimbursement of Regeneron research and development expenses	\$ 134,218	\$ 213,924
Reimbursement of Regeneron commercialization-related expenses	86,634	73,559
Regeneron's share of losses in connection with commercialization of antibodies	(74,874)	(108,402)
Other	43,512	31,286
Total Sanofi collaboration revenue	189,490	210,367
<i>Bayer collaboration revenue:</i>		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	232,068	174,876
Reimbursement of Regeneron development expenses	3,997	6,349
Other	11,863	12,714
Total Bayer collaboration revenue	247,928	193,939
Total Sanofi and Bayer collaboration revenue	\$ 437,418	\$ 404,306
<i>Other revenue:</i>		
Reimbursement of Regeneron research and development expenses - Teva	\$ 39,129	\$ 22,050
Reimbursement of Regeneron research and development expenses - other	2,695	2,650
Other	44,334	31,740
Total other revenue	\$ 86,158	\$ 56,440