

REGENERON PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Industry	Biotechnology & Medical Research
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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): August 2, 2018 (August 2, 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 August 2, 2018 , Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended June 30, 2018 . A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information included or incorporated in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated August 2, 2018 , Reporting Second 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: August 2, 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	<u>Press Release, dated August 2, 2018, Reporting Second Quarter 2018 Financial and Operating Results.</u>

REGENERON

Press Release

Regeneron Reports Second Quarter 2018 Financial and Operating Results

- Second quarter 2018 GAAP net income per diluted share increased by 44% to \$4.82 versus second quarter 2017 and second quarter 2018 non-GAAP net income per diluted share increased 31% to \$5.45 versus second quarter 2017
- Second quarter 2018 EYLEA[®] (aflibercept) Injection U.S. net sales increased 8% to \$992 million versus second quarter 2017 and second quarter 2018 EYLEA global net sales⁽¹⁾ increased 13% to \$1.66 billion versus second quarter 2017
- Positive results reported from Phase 3 trial of Dupixent[®] (dupilumab) in adolescents with inadequately controlled moderate-to-severe atopic dermatitis

Tarrytown, New York (August 2, 2018) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second quarter of 2018 and provided a business update.

"Regeneron made important commercial progress in the second quarter with continued strong U.S. sales growth for EYLEA in retinal diseases and Dupixent in atopic dermatitis. We are particularly pleased by U.S. launch progress with Dupixent for adults with moderate-to-severe atopic dermatitis, driven by a positive experience in the marketplace by patients and physicians in this serious disease; we anticipate continued robust growth as more physicians increase their experience with the product," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In the second half of the year, we anticipate two significant U.S. regulatory approvals: cemiplimab for advanced cutaneous squamous cell carcinoma and Dupixent for uncontrolled asthma. We also plan to submit regulatory applications for Dupixent in adolescent atopic dermatitis and to report Phase 3 results in nasal polyps, in addition to other advances across our innovative portfolio for serious diseases."

Financial Highlights

(\$ in millions, except per share data)

	Three Months Ended June 30,		
	2018	2017	% Change
Total revenues	\$ 1,608	\$ 1,470	9%
GAAP net income	\$ 551	\$ 388	42%
GAAP net income per share - diluted	\$ 4.82	\$ 3.34	44%
Non-GAAP net income ⁽²⁾	\$ 624	\$ 487	28%
Non-GAAP net income per share - diluted ⁽²⁾	\$ 5.45	\$ 4.17	31%

Net Product Sales of Regeneron-Discovered Products *

(\$ in millions)

	Three Months Ended June 30,								
	2018			2017			% Change		
	US	ROW	Total	US	ROW	Total	US	ROW	Total
EYLEA *	\$ 992	\$ 666	\$ 1,658	\$ 919	\$ 542	\$ 1,461	8%	23%	13%
ARCALYST	4	—	4	5	—	5	(20)%	—	(20%)
Net product sales recorded by Regeneron	\$ 996	—*	—*	\$ 924	—*	—*	8%	—*	**

Net product sales recorded by Sanofi * :

Dupixent	\$ 181	\$ 28	\$ 209	\$ 28	—	\$ 28	546%	**	**
Praluent	42	32	74	33	\$ 13	46	27%	146%	61%
Kevzara	19	5	24	1	—	1	**	**	**
ZALTRAP	3	25	28	2	18	20	50%	39%	40%

* 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 below 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.

** Percentage not meaningful

Second Quarter 2018 Business Highlights

Key Pipeline Progress

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

EYLEA® (afibercept) Injection

- The Company recently submitted a supplemental Biologics License Application (sBLA) for EYLEA for the treatment of diabetic retinopathy.
- In the second quarter of 2018, the Company submitted an sBLA for EYLEA in a pre-filled syringe.

Dupixent® (dupilumab) Injection

- Dupixent, an antibody that blocks signaling of IL-4 and IL-13, is being studied in asthma, adolescent and pediatric atopic dermatitis, nasal polyps, eosinophilic esophagitis (EoE), and grass immunotherapy, with additional studies planned in 2018.
- In May 2018, the Company and Sanofi reported that a Phase 3 trial evaluating Dupixent to treat moderate-to-severe atopic dermatitis in adolescents (12–17 years of age) met its primary and key secondary endpoints.
- In May 2018, the Company and Sanofi announced that the *New England Journal of Medicine* published detailed, positive results from two Phase 3 trials of Dupixent in moderate-to-severe asthma.
- In the second quarter of 2018, a Phase 2 study of Dupixent in grass immunotherapy was initiated.

Praluent® (alirocumab) Injection

- 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 has been chosen as the exclusive PCSK9 inhibitor therapy on the Express Scripts national formulary. The agreement took effect on July 1, 2018.
- An sBLA and a Marketing Authorization Application (MAA) for Praluent for cardiovascular risk reduction have been recently submitted.
- An sBLA for first-line treatment of hyperlipidemia has also been recently submitted.
- In the second quarter of 2018, a Phase 3 pediatric study in heterozygous familial hypercholesterolemia (HeFH) was initiated.

Cemiplimab, an antibody to 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 cutaneous squamous cell carcinoma (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 European Medicines Agency (EMA) also accepted for review the MAA for cemiplimab in patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery.
- In June 2018, the Company and Sanofi announced that pivotal data from two trials evaluating cemiplimab in advanced CSCC were published in the *New England Journal of Medicine*.
- In May 2018, the Company and Sanofi announced positive interim results from a Phase 1 study assessing cemiplimab as a potential treatment for advanced non-small cell lung cancer (NSCLC).

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

- In April 2018, 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 ongoing osteoarthritis trials have been modified accordingly. Since the Phase 3 clinical study in chronic low back pain in patients with concomitant osteoarthritis was only using higher doses, the Company is no longer actively dosing patients in this study.

Evinacumab is an antibody to ANGPTL3. In the second quarter of 2018, a Phase 3 study in severe hypertriglyceridemia was initiated.

REGN3500 is an antibody to IL-33. In the third quarter of 2018, a Phase 2 study in chronic obstructive pulmonary disease (COPD) was initiated.

REGN3918 (pozelimab) is an antibody to C5. The Company expects to report full data from its Phase 1 study in paroxysmal nocturnal hemoglobinuria (PNH) in the second half of 2018, and plans to initiate a Phase 2 study in PNH in early 2019.

REGN4018 is a bi-specific antibody targeting MUC16 and CD3. In the second quarter of 2018, a Phase 1 study in platinum-resistant ovarian cancer was initiated.

REGN4659 is an antibody against CTLA4. In the second quarter of 2018, a Phase 1 study in advanced NSCLC 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) • Report one-year data from Phase 3 PANORAMA study for the treatment of non-proliferative diabetic retinopathy in patients without diabetic macular edema (DME)
Dupilixent (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 • Submit sBLA and MAA for expanded indication in adolescent patients with atopic dermatitis (12–17 years of age) • Report data from Phase 3 studies in nasal polyps • Initiate Phase 3 study in EoE • Initiate Phase 2 study in peanut allergy
Praluent (alirocumab)	<ul style="list-style-type: none"> • FDA decision on sBLA for use with apheresis (target action date of August 24, 2018) • Initiate Phase 3 pediatric study in homozygous familial hypercholesterolemia (HoFH)
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 Phase 3 patient enrollment for the treatment of non-small cell lung cancer, as well as various other studies
Fasimumab (NGF Antibody)	<ul style="list-style-type: none"> • Report data from first Phase 3 efficacy study in osteoarthritis pain • Continue patient enrollment in Phase 3 long-term safety and efficacy studies in osteoarthritis
REGN3500 (IL-33 Antibody)	<ul style="list-style-type: none"> • Initiate Phase 2 study in atopic dermatitis
Bispecific Antibodies	<ul style="list-style-type: none"> • Initiate Phase 2 study for REGN1979 (CD20xCD3 Antibody) in follicular lymphoma • Submit Investigational New Drug Application (IND) for BCMAxCD3 antibody

Financial Results

Product Revenues: Net product sales were \$996 million in the second quarter of 2018 , compared to \$924 million in the second quarter of 2017 . EYLEA net product sales in the United States were \$992 million in the second quarter of 2018 , compared to \$919 million in the second 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 9% to \$1.608 billion in the second quarter of 2018 , compared to \$1.470 billion in the second quarter of 2017 . Total revenues include Sanofi and Bayer collaboration revenues of \$501 million in the second quarter of 2018 , compared to \$432 million in the second quarter of 2017 . Sanofi collaboration revenue in the second quarter of 2018 increased primarily due to the Company's share of higher net sales of Dupixent and an increase in reimbursable expenses in connection with late-stage clinical development activities for cemiplimab. These increases were partly offset by the Company's Discovery and Preclinical Development Agreement with Sanofi ending on December 31, 2017, lower reimbursement for Dupixent development activities, and an increase in the Company's share of the collaboration's Dupixent commercialization expenses. Bayer collaboration revenue increased in the second 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.

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 adoption of the new standard did not have a material impact on the Company's total revenues in the second 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 \$529 million in the second quarter of 2018 , compared to \$510 million in the second quarter of 2017 . The higher R&D expenses in the second quarter of 2018 were principally due to an increase in cemiplimab and fasinumab clinical trial costs and higher R&D headcount and facilities-related costs, partly offset by a decrease in Dupixent development expenses and the discontinuation of certain development programs. In the second quarter of 2018 , R&D-related non-cash share-based compensation expense was \$60 million , compared to \$70 million in the second quarter of 2017 .

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$365 million in the second quarter of 2018 , compared to \$307 million in the second quarter of 2017 . The higher SG&A expenses in the second quarter of 2018 were primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses for EYLEA and Dupixent, and, to a lesser extent, for cemiplimab. In the second quarter of 2018 , SG&A-related non-cash share-based compensation expense decreased to \$40 million , compared to \$45 million in the second quarter of 2017 .

Income Tax Expense: In the second quarter of 2018 , GAAP income tax expense was \$105 million and the effective tax rate was 16.0% , compared to \$138 million and 26.3% in the second quarter of 2017 . The Company's effective tax rate for the second 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 second quarter of 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, the foreign-derived intangible income deduction, and the federal tax credit for research activities.

Other income (expense), net: GAAP other income in the second quarter of 2018 included the recognition of \$17 million of net 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 gains and losses on investments in equity securities.

GAAP other expenses in the second quarter of 2017 included a \$30 million loss on debt extinguishment related to the 2017 Tarrytown lease transaction.

GAAP and Non-GAAP Net Income⁽²⁾: GAAP net income was \$551 million, or \$5.12 per basic share and \$4.82 per diluted share, in the second quarter of 2018, compared to GAAP net income of \$388 million, or \$3.66 per basic share and \$3.34 per diluted share, in the second quarter of 2017.

Non-GAAP net income was \$624 million, or \$5.79 per basic share and \$5.45 per diluted share, in the second quarter of 2018, compared to non-GAAP net income of \$487 million, or \$4.59 per basic share and \$4.17 per diluted share, in the second 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	\$455 million–\$485 million <i>(previously \$450 million–\$485 million)</i>
Non-GAAP unreimbursed R&D ⁽²⁾⁽⁴⁾	\$1.210 billion – \$1.260 billion <i>(previously \$1.230 billion–\$1.310 billion)</i>
Non-GAAP SG&A ⁽²⁾⁽⁴⁾	\$1.340 billion–\$1.390 billion <i>(previously \$1.325 billion–\$1.395 billion)</i>
Effective tax rate	13%–16% <i>(previously 15%–18%)</i>
Capital expenditures	\$410 million – \$450 million <i>(previously \$420 million–\$480 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⁾	\$ 1,425	\$ 1,495
R&D: Non-cash share-based compensation expense	(215)	(235)
Non-GAAP unreimbursed R&D	\$ 1,210	\$ 1,260
GAAP SG&A	\$ 1,505	\$ 1,585
SG&A: Non-cash share-based compensation expense	(165)	(195)
Non-GAAP SG&A	\$ 1,340	\$ 1,390

⁽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 second quarter 2018 financial and operating results on Thursday, August 2, 2018, at 8:30 AM. To access this call, dial (800) 708-4539 (U.S.) or (847) 619-6396 (International). A link to the webcast may be accessed from the "Investors and Media" page of Regeneron's website at www.regeneron.com. 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 EYLEA, Dupixent, and Praluent, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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

Non-GAAP Financial Measures

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

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TABLE 1

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

	June 30, 2018	December 31, 2017
Assets:		
Cash and marketable securities	\$ 3,728,221	\$ 2,896,074
Accounts receivable - trade, net	1,534,324	1,538,642
Accounts receivable from Sanofi and Bayer	504,923	435,698
Inventories	928,553	726,138
Property, plant, and equipment, net	2,461,614	2,358,605
Deferred tax assets	545,077	506,291
Other assets	249,268	302,838
Total assets	<u>\$ 9,951,980</u>	<u>\$ 8,764,286</u>
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 1,032,635	\$ 967,418
Deferred revenue	1,027,016	949,337
Capital and facility lease obligations	705,903	703,453
Stockholders' equity	7,186,426	6,144,078
Total liabilities and stockholders' equity	<u>\$ 9,951,980</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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Net product sales	\$ 996,382	\$ 924,133	\$ 1,984,291	\$ 1,782,378
Sanofi collaboration revenue	237,753	222,128	427,243	432,495
Bayer collaboration revenue	262,863	210,355	510,791	404,294
Other revenue	111,024	113,500	197,182	169,940
	<u>1,608,022</u>	<u>1,470,116</u>	<u>3,119,507</u>	<u>2,789,107</u>
Expenses:				
Research and development	529,289	509,975	1,027,875	1,017,410
Selling, general, and administrative	364,884	306,908	695,654	603,754
Cost of goods sold	35,950	42,133	105,193	103,386
Cost of collaboration and contract manufacturing	55,711	60,788	101,366	83,703
	<u>985,834</u>	<u>919,804</u>	<u>1,930,088</u>	<u>1,808,253</u>
Income from operations	622,188	550,312	1,189,419	980,854
Other income (expense), net	33,886	(24,462)	52,053	(22,715)
Income before income taxes	656,074	525,850	1,241,472	958,139
Income tax expense	(104,662)	(138,106)	(212,080)	(321,464)
Net income	<u>\$ 551,412</u>	<u>\$ 387,744</u>	<u>\$ 1,029,392</u>	<u>\$ 636,675</u>
Net income per share - basic	\$ 5.12	\$ 3.66	\$ 9.56	\$ 6.02
Net income per share - diluted	\$ 4.82	\$ 3.34	\$ 8.97	\$ 5.51
Weighted average shares outstanding - basic	107,800	106,034	107,724	105,804
Weighted average shares outstanding - diluted	114,477	116,137	114,697	115,607

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net income	\$ 551,412	\$ 387,744	\$ 1,029,392	\$ 636,675
<i>Adjustments:</i>				
R&D: Non-cash share-based compensation expense	59,602	69,528	100,437	143,051
SG&A: Non-cash share-based compensation expense	40,467	44,708	75,481	98,520
COGS and COCM: Non-cash share-based compensation expense	6,726	7,022	13,299	13,476
Other expense: Loss on extinguishment of debt	—	30,100	—	30,100
Other income/expense: Gains and losses on investments in equity securities ^(a)	(16,520)	—	(25,889)	—
Income tax effect of reconciling items above	(18,035)	(52,310)	(32,336)	(98,500)
Non-GAAP net income	<u>\$ 623,652</u>	<u>\$ 486,792</u>	<u>\$ 1,160,384</u>	<u>\$ 823,322</u>
Non-GAAP net income per share - basic	\$ 5.79	\$ 4.59	\$ 10.77	\$ 7.78
Non-GAAP net income per share - diluted	\$ 5.45	\$ 4.17	\$ 10.12	\$ 7.10
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	107,800	106,034	107,724	105,804
Non-GAAP net income per share - diluted	114,478	116,832	114,700	115,903

^(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 and six months ended June 30, 2018 were recorded in Other income, net.

TABLE 4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
<i>Sanofi collaboration revenue:</i>				
Reimbursement of Regeneron research and development expenses	\$ 141,536	\$ 205,352	\$ 275,754	\$ 419,276
Reimbursement of Regeneron commercialization-related expenses	105,727	87,853	192,361	161,412
Regeneron's share of losses in connection with commercialization of antibodies	(68,797)	(122,281)	(143,671)	(230,683)
Other	59,287	51,204	102,799	82,490
Total Sanofi collaboration revenue	<u>237,753</u>	<u>222,128</u>	<u>427,243</u>	<u>432,495</u>
<i>Bayer collaboration revenue:</i>				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	246,302	190,883	478,370	365,759
Reimbursement of Regeneron development expenses	3,867	6,720	7,864	13,069
Other	12,694	12,752	24,557	25,466
Total Bayer collaboration revenue	<u>262,863</u>	<u>210,355</u>	<u>510,791</u>	<u>404,294</u>
Total Sanofi and Bayer collaboration revenue	<u>\$ 500,616</u>	<u>\$ 432,483</u>	<u>\$ 938,034</u>	<u>\$ 836,789</u>
<i>Other revenue:</i>				
Reimbursement of Regeneron research and development expenses - Teva	\$ 34,310	\$ 31,481	\$ 73,439	\$ 53,531
Reimbursement of Regeneron research and development expenses - other	3,889	762	6,584	3,412
Other	72,825	81,257	117,159	112,997
Total other revenue	<u>\$ 111,024</u>	<u>\$ 113,500</u>	<u>\$ 197,182</u>	<u>\$ 169,940</u>