REGENERON PHARMACEUTICALS INC
Form 10-Q
August 02, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark One)

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road, Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 847-7000
(Registrant's telephone number, including area code)

Yes ý No ¨

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer”, “accelerated filer”, “smaller reporting company” and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company	Emerging growth company
ý	¨	¨	¨	¨

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. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

The number of shares outstanding of each of the registrant’s classes of common stock as of July 20, 2018:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,911,354
Common Stock, $.001 par value	106,144,994

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"ARCALYST®", "EYLEA®", "Regeneron®", "Regeneron Genetics Center®", "VelociGene®", "VelociMab®", "VelocImmune®", "VelociMouse®", "VelociSuite®", and "ZALTRAP®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$917,876	$812,733
Marketable securities	765,642	596,847
Accounts receivable - trade, net	1,534,324	1,538,642
Accounts receivable from Sanofi	243,238	193,684
Accounts receivable from Bayer	261,685	242,014
Inventories	928,553	726,138
Prepaid expenses and other current assets	163,599	224,972
Total current assets	4,814,917	4,335,030
Marketable securities	2,044,703	1,486,494
Property, plant, and equipment, net	2,461,614	2,358,605
Deferred tax assets	545,077	506,291
Other noncurrent assets	85,669	77,866
Total assets	$9,951,980	$8,764,286
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$171,906	$178,183
Accrued expenses and other current liabilities	670,709	637,162
Deferred revenue from Sanofi	308,179	177,746
Deferred revenue - other	180,396	142,392
Total current liabilities	1,331,190	1,135,483
Capital and facility lease obligations	705,903	703,453
Deferred revenue from Sanofi	339,040	379,936
Deferred revenue - other	199,401	249,263
Other noncurrent liabilities	190,020	152,073
Total liabilities	2,765,554	2,620,208
Stockholders' equity:		
Preferred Stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,911,354 in 2018 and 2017	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 109,929,629 in 2018 and 109,477,222 in 2017	110	110
Additional paid-in capital	3,712,599	3,512,833

Retained earnings	3,839,179	2,946,733
Accumulated other comprehensive (loss) income	(11,612)	640
Treasury Stock, at cost; 3,885,469 shares in 2018 and 3,763,868 shares in 2017	(353,852)	(316,240)
Total stockholders' equity	7,186,426	6,144,078
Total liabilities and stockholders' equity	$9,951,980	$8,764,286

The accompanying notes are an integral part of the financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Statements of Operations				
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
	1,608,022	1,470,116	3,119,507	2,789,107
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
	985,834	919,804	1,930,088	1,808,253
Income from operations	622,188	550,312	1,189,419	980,854
Other income (expense):				
Other income (expense), net	40,804	(19,061)	65,410	(9,813)
Interest expense	(6,918)	(5,401)	(13,357)	(12,902)
	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	$551,412	$387,744	$1,029,392	$636,675
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
Statements of Comprehensive Income				
Net income	$551,412	$387,744	$1,029,392	$636,675
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on marketable securities	3,374	8,204	(7,706)	15,160
Unrealized gain on cash flow hedges	608	28	2,047	28
Comprehensive income	$555,394	$395,976	$1,023,733	$651,863

The accompanying notes are an integral part of the financial statements.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net income	$1,029,392	$636,675
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	70,000	73,241
Non-cash compensation expense	189,217	255,047
Other non-cash items, net	(54,980)	37,631
Deferred taxes	(15,487)	(57,737)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer, and trade accounts receivable	(64,907)	(232,927)
Increase in inventories	(182,100)	(151,544)
Decrease (increase) in prepaid expenses and other assets	59,432	(77,168)
Decrease in deferred revenue	(84,238)	(10,655)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	66,979	(147,232)
Total adjustments	(16,084)	(311,344)
Net cash provided by operating activities	1,013,308	325,331
Cash flows from investing activities:		
Purchases of marketable and other securities	(1,181,205)	(477,408)
Sales or maturities of marketable securities	462,212	272,166
Capital expenditures	(191,392)	(105,310)
Net cash used in investing activities	(910,385)	(310,552)
Cash flows from financing activities:		
Proceeds in connection with capital and facility lease obligations	—	57,000
Payments in connection with capital and facility lease obligations	—	(19,925)
Proceeds from issuance of Common Stock	34,073	188,693
Payments in connection with Common Stock tendered for employee tax obligations	(31,853)	(31,437)
Net cash provided by financing activities	2,220	194,331
Net increase in cash, cash equivalents, and restricted cash	105,143	209,110
Cash, cash equivalents, and restricted cash at beginning of period	825,233	547,703
Cash, cash equivalents, and restricted cash at end of period	$930,376	$756,813

The accompanying notes are an integral part of the financial statements.

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REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron," "Company," "we," "us," and "our") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim period are not necessarily indicative of the results for the full year. The December 31, 2017 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

We adopted Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, as of January 1, 2018. The Company adopted the standard using the modified retrospective method, and thus recognized a cumulative-effect adjustment to reduce Retained earnings and increase Deferred revenue on January 1, 2018 by $143.4 million, net of tax. Prior period amounts have not been adjusted in connection with the adoption of this standard.

The new standard did not have an impact on the recognition of revenue from product sales (see Note 2). However, the new standard has resulted in certain changes to the timing of revenue recognition related to our collaboration agreements (see Note 3). As a result of adopting ASC 606, non-refundable upfront payments, which were previously recognized ratably over the performance period, and substantive development milestones, which were previously recognized in the period when the milestone was achieved, will be recognized over the remaining performance period based on the Company's progress towards satisfying its identified performance obligation.

The following tables summarize the impacts of adopting ASC 606 on the Company's condensed consolidated financial statements as of and for the three and six months ended June 30, 2018 compared with the guidance that was in effect before the change.

	June 30, 2018		
Balance Sheet Data	As Reported	Adjustments	Balance Without Adoption of ASC 606
Deferred tax assets	$545,077	$(16,293)	$528,784
Total assets	$9,951,980	$(16,293)	$9,935,687
Accrued expenses and other current liabilities	$670,709	$(1,513)	$669,196
Deferred revenue from Sanofi (current)	$308,179	$(82,983)	$225,196
Deferred revenue - other (current)	$180,396	$(49,819)	$130,577
Total current liabilities	$1,331,190	$(134,315)	$1,196,875
Deferred revenue from Sanofi (noncurrent)	$339,040	$6,671	$345,711
Deferred revenue - other (noncurrent)	$199,401	$28,734	$228,135
Total liabilities	$2,765,554	$(98,910)	$2,666,644
Retained earnings	$3,839,179	$82,617	$3,921,796

Total stockholders' equity	$7,186,426	$82,617	$7,269,043
Total liabilities and stockholders' equity	$9,951,980	$(16,293)	$9,935,687

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(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months Ended June 30, 2018			Six Months Ended June 30, 2018		
Consolidated Statement of Operations Data	As Reported	Adjustments	Balance Without Adoption of ASC 606	As Reported	Adjustments	Balance Without Adoption of ASC 606
Sanofi collaboration revenue	$237,753	$ (8,924)	$228,829	$427,243	$ (17,331)	$409,912
Other revenue	$111,024	$ (29,879)	$81,145	$197,182	$ (47,189)	$149,993
Total revenues	$1,608,022	$ (38,803)	$1,569,219	$3,119,507	$ (64,520)	$3,054,987
Income from operations	$622,188	$ (38,803)	$583,385	$1,189,419	$ (64,520)	$1,124,899
Income before income taxes	$656,074	$ (38,803)	$617,271	$1,241,472	$ (64,520)	$1,176,952
Income tax expense	$(104,662)	$ 1,914	$(102,748)	$(212,080)	$ 3,702	$(208,378)
Net income	$551,412	$ (36,889)	$514,523	$1,029,392	$ (60,818)	$968,574

The Company also adopted Accounting Standards Update ("ASU") 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, as of January 1, 2018. The amendments require companies to measure equity investments at fair value with changes in fair value recognized in net income. We have elected the measurement alternative for equity investments we hold that do not have readily determinable fair values. Therefore, we will measure such investments at cost minus impairment, if any, and adjust for observable price changes in orderly transactions for identical or similar investments of the same issuer. Upon adoption, the Company recognized a cumulative-effect adjustment, related to unrealized gains on equity securities, to reduce Accumulated other comprehensive income and increase Retained earnings on January 1, 2018 by $6.6 million. See Note 5 and Note 6.

2. Product Sales

Net product sales consist of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
Net Product Sales in the United States	2018	2017	2018	2017
EYLEA®	$991,998	$919,466	$1,976,047	$1,773,853
ARCALYST®	4,384	4,667	8,244	8,525
	$996,382	$924,133	$1,984,291	$1,782,378

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the three and six months ended June 30, 2018 and 2017. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Besse Medical, a subsidiary of AmerisourceBergen Corporation	56%	50%	55%	51%
McKesson Corporation	35%	29%	37%	28%
Curascript SD Specialty Distribution, a subsidiary of Express Scripts	**	20%	**	20%

** Sales to Curascript SD Specialty Distribution represented less than 10% of total gross product revenue during the period.

Revenue from product sales is recognized at a point in time when our customer is deemed to have obtained control of the product, which generally occurs upon receipt by our distributors and specialty pharmacies. The Company's written contracts with its customers stipulate product is shipped freight on board destination (FOB destination).

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The amount of revenue we recognize varies due to rebates, chargebacks, and discounts provided under governmental and other programs, distribution-related fees, and other sales-related deductions. We estimate the amount of variable consideration that we will be entitled to, in order to determine the transaction price, based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, estimated payer mix, and other relevant factors.

The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the six months ended June 30, 2018 and 2017.

	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2017	$ 29,840	$ 34,142	$ 21,320	$85,302
Provisions	97,698	102,133	19,892	219,723
Credits/payments	(91,108)	(98,532)	(24,431)	(214,071)
Balance as of June 30, 2018	$ 36,430	$ 37,743	$ 16,781	$90,954
Balance as of December 31, 2016	$ 12,712	$ 29,465	$ 3,674	$45,851
Provisions	78,250	90,077	20,531	188,858
Credits/payments	(67,850)	(90,519)	(21,312)	(179,681)
Balance as of June 30, 2017	$ 23,112	$ 29,023	$ 2,893	$55,028

Accruals for chargebacks and discounts are recorded as a direct reduction to accounts receivable. Accruals for rebates, distribution-related fees, and other sales-related deductions are recorded within accrued liabilities.

3. Collaboration Agreements

We have entered into various agreements related to our activities to research, develop, manufacture, and commercialize product candidates and utilize our technology platforms. The Company earns collaboration revenue in connection with collaboration agreements to utilize our technology platforms and develop and/or commercialize product candidates. As described in Note 1, during the first quarter of 2018, we adopted ASC 606. Under the terms of the new standard, revenue is measured as the amount of consideration we expect to be entitled to in exchange for transferring promised goods or providing services to a customer, and is recognized when (or as) we satisfy performance obligations under the terms of a contract. Depending on the terms of the arrangement, we may defer the recognition of all or a portion of the consideration received because the performance obligations are satisfied over time.

Our collaboration agreements may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In agreements involving multiple goods or services promised to be transferred to a customer, we must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation.

The terms of these agreements typically include consideration to be provided to the Company in the form of non-refundable up-front payments, development milestones, payments for development activities, as well as payments for commercialization activities, sales milestones, and sharing of profits or losses arising from the commercialization of products.

At the inception of the contract, the transaction price reflects the amount of consideration we expect to be entitled to in exchange for transferring promised goods or services to our customer. We review our estimate of the transaction price

each period, and make revisions to such estimates as necessary. In arrangements where we satisfy performance obligation(s) during the development phase over time, we recognize collaboration revenue over time typically using an input method on the basis of our research and development costs incurred relative to the total expected cost which determines the extent of our progress toward completion.

Under the Company's collaboration agreements, product sales and cost of sales for products which are currently approved are recorded by the Company's collaborators as they are deemed to be the principal in the transaction. The Company shares in any profits or losses arising from the commercialization of such products, and records its share of the variable consideration, representing

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net product sales less cost of goods sold and shared commercialization and other expenses, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborator.

In arrangements where the collaborator records product sales, the Company may be obligated to use commercially reasonable efforts to supply commercial bulk product to its collaborators, and may be reimbursed for its manufacturing costs as commercial product is shipped to its collaborators; however, recognition of such cost reimbursements as collaboration revenue is deferred until the product is sold by the Company's collaborators to third-party customers. In addition, we may also be reimbursed for a portion of costs incurred for other commercial-related activities, which are recorded as collaboration revenue in the period in which such costs are incurred.

a. Sanofi

The collaboration revenue we earned from Sanofi is detailed below:

	Three Months Ended June 30,		Six Months Ended June 30,	
Sanofi Collaboration Revenue	2018	2017	2018	2017
Antibody:				
Reimbursement of Regeneron research and development expenses	$64,482	$137,272	$124,876	$292,517
Reimbursement of Regeneron commercialization-related expenses	103,666	87,104	189,090	160,663
Regeneron's share of losses in connection with commercialization of antibodies	(68,797)	(122,281)	(143,671)	(230,683)
Other	31,654	31,204	48,984	42,490
Total Antibody	131,005	133,299	219,279	264,987
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses	77,054	68,080	150,878	126,759
Reimbursement of Regeneron commercialization-related expenses	2,061	749	3,271	749
Other	27,633	20,000	53,815	40,000
Total Immuno-oncology	106,748	88,829	207,964	167,508
	$237,753	$222,128	$427,243	$432,495

Antibodies

In November 2007, the Company entered into a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). The Antibody Collaboration was governed by the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended). Pursuant to the Antibody Discovery Agreement, Sanofi agreed to fund up to $130.0 million of the Company's research activities in 2017. The Company's Antibody Discovery Agreement with Sanofi ended on December 31, 2017 without any extension and, therefore, funding from Sanofi under the Antibody Discovery Agreement ceased after 2017. Under the License and Collaboration Agreement, agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. Consequently, during the three months ended June 30, 2018 and 2017, the Company recognized as research and development expense $9.9 million and $20.6 million, respectively, and during the six months ended June 30, 2018 and 2017, the Company recognized as research and development expense $23.8 million and $45.6 million, respectively, its share of antibody development expenses that Sanofi incurred related to Praluent® (alirocumab), Kevzara® (sarilumab), and Dupixent® (dupilumab).

Effective January 7, 2018, the Company and Sanofi entered into a letter agreement (the "Letter Agreement") in connection with, among other matters, the allocation of additional funds to certain activities relating to dupilumab and REGN3500 (collectively,

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(Unless otherwise noted, dollars in thousands, except per share data)

the "Dupilumab/REGN3500 Eligible Investments"). Refer to the "Immuno-Oncology" section below for further details regarding the Letter Agreement.

In March 2017, the U.S. Food and Drug Administration ("FDA") approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis, and in September 2017, the European Commission granted marketing authorization for Dupixent for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. In May 2017, the FDA approved Kevzara for the treatment of adult patients with moderately to severely active rheumatoid arthritis, and in June 2017, the European Commission granted marketing authorization for Kevzara for the treatment of rheumatoid arthritis in adult patients.

Sanofi leads commercialization activities for products developed under the Antibody Collaboration, subject to the Company's right to co-promote such products. In addition to profit and loss sharing, the Company is entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling twelve-month basis. The amount of variable consideration related to such share of profits and losses and sales milestones is deemed to be constrained as of June 30, 2018, and therefore has not been included in the transaction price.

The Company's significant promised goods and services consist of providing research and development services, including the manufacturing of clinical supplies, and providing commercial-related services, including the manufacturing of commercial supplies. As it relates to the Antibody Collaboration, "Reimbursement of Regeneron commercialization-related expenses" in the table above represents reimbursement of internal and external costs in connection with commercializing Praluent, Kevzara, and Dupixent. As we recognize Sanofi antibody collaboration revenue in an amount equal to the amount we have the right to invoice and such amount corresponds directly with the value to Sanofi of our performance to date, we do not disclose the value of the transaction price allocated to our remaining unsatisfied performance obligations.

The following table summarizes accounts receivable and deferred revenue information in connection with the Company's Antibody Collaboration with Sanofi:

	June 30, 2018	December 31, 2017
Accounts receivable, net	$160,954	$121,001
Deferred revenue	$170,906	$117,682

Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2018
Increase due to shipments of commercial supplies to Sanofi	$108,359
Revenue recognized that was included in deferred revenue at the beginning of the period	$(55,135)

Immuno-Oncology

In July 2015, the Company and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement ("IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to the Company.

The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date our budget for IO Discovery activities, which has been agreed to with Sanofi, is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to the Company. Under the terms of the IO License and Collaboration Agreement, the parties are co-developing the Company's

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antibody product candidate (cemiplimab) targeting the receptor known as programmed cell death protein 1 (PD-1). The parties share equally, on an ongoing basis, development expenses for cemiplimab up to a total of $1.640 billion, an increase of $990.0 million over the budget set forth in the original IO License and Collaboration Agreement. Pursuant to the Letter Agreement, the cemiplimab development budget has been increased and the Company has agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to cemiplimab development and Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares of our Common Stock directly or indirectly owned by Sanofi through September 30, 2020. If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the cemiplimab development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. During the second quarter of 2018, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 121,601 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to cemiplimab development costs incurred during the first quarter of 2018. Consequently, we recorded the cost of the shares received, or $37.6 million, as Treasury Stock during the three months ended June 30, 2018.

The Company has principal control over the development of cemiplimab and will lead commercialization activities in the United States, subject to Sanofi’s right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. The Company will be entitled to a milestone payment of $375.0 million in the event that global sales of certain licensed products targeting PD-1 (including cemiplimab), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with any of such licensed products targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period. The amount of variable consideration related to such milestone is deemed to be constrained as of June 30, 2018, and therefore has not been included in the transaction price.

At the inception of the IO Collaboration, the Company's significant promised goods and services consisted of a license to certain rights and intellectual property and providing research and development services, including the manufacturing of clinical supplies. The Company concluded that the license was not distinct, primarily as a result of (i) Sanofi being unable to benefit from the license on its own or together with other resources that are readily available as the license provides access to Regeneron's complex and specialized know-how and (ii) the research and development services, including manufacturing in support of such services, were expected to significantly modify the initial license. Therefore the promised goods and services were considered a single performance obligation. Consequently, the $640.0 million in aggregate up-front payments made by Sanofi during 2015 in connection with the execution of the IO Collaboration has been recorded as deferred revenue and has been included in the transaction price at the inception of the contract. "Other" Sanofi immuno-oncology revenue in the Sanofi Collaboration Revenue table above primarily includes recognition of deferred revenue from the $640.0 million of up-front payments.

As it relates to the IO Collaboration, "Reimbursement of Regeneron commercialization-related expenses" in the table above represents reimbursement of costs by Sanofi in connection with the commercialization of cemiplimab outside of the United States.

The following table summarizes accounts receivable and deferred revenue information in connection with the Company's IO Collaboration with Sanofi:

	June 30, 2018	December 31, 2017
Accounts receivable, net	$76,522	$59,274

Deferred revenue	$476,312	$440,000

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Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2018
Increase as a result of cumulative-effect adjustment arising from the adoption of ASC 606	$93,643
Revenue recognized that was included in deferred revenue at the beginning of the period	$(57,331)

The aggregate amount of the transaction price under the IO Collaboration allocated to the Company's performance obligation that was unsatisfied (or partially unsatisfied) as of June 30, 2018 was $1,550.1 million. This amount is expected to be recognized as revenue over the remaining period the Company is obligated to satisfy its performance obligation in connection with performing development activities.

b. Bayer

EYLEA outside the United States

Revenue earned in connection with our Bayer EYLEA collaboration is detailed below:

	Three Months Ended June 30,		Six Months Ended June 30,	
Bayer EYLEA Collaboration Revenue	2018	2017	2018	2017
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 EYLEA development expenses	3,678	2,329	7,135	4,780
Other	12,694	10,593	24,557	21,196
	$262,674	$203,805	$510,062	$391,735

Under the terms of the license and collaboration agreement with Bayer for the global development and commercialization outside the United States of EYLEA, Bayer markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, the Company is entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales. In addition, the Company and Bayer share the funding of agreed-upon EYLEA development costs.

The following table summarizes accounts receivable and deferred revenue information in connection with the Company's EYLEA collaboration with Bayer:

	June 30, 2018	December 31, 2017
Accounts receivable, net	$261,646	$241,153
Deferred revenue	$73,750	$68,734

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Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2018
Increase due to shipments of commercial supplies to Bayer	$ 24,666
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (19,650)

Ang2 antibody and PDGFR-beta antibody outside the United States

In 2016, the Company entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to angiopoietin-2 (Ang2), including REGN910-3 (Ang2 in combination with aflibercept), for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a non-refundable up-front payment and paid a portion of our global development costs and development costs exclusively for the territory outside the United States. In the fourth quarter of 2017, the Company reported that results from two Phase 2 studies of REGN910-3 did not provide sufficient differentiation to warrant Phase 3 development. Therefore, during the fourth quarter of 2017, the Company accelerated and recognized the remaining amount of deferred revenue from the $50.0 million up-front payment (which was initially recorded as deferred revenue) received from Bayer as the Company deemed its performance obligation to be satisfied.

In 2014, the Company entered into a license and collaboration agreement with Bayer governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), including REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept. Effective in the first quarter of 2017, the Company discontinued clinical development of REGN2176-3, and on July 31, 2017, the Company and Bayer agreed to terminate this collaboration agreement.

c. Teva

In September 2016, the Company and Teva entered into a collaboration agreement (the "Teva Collaboration Agreement") to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with Mitsubishi Tanabe Pharma Corporation. In connection with the Teva Collaboration Agreement, Teva made a $250.0 million non-refundable up-front payment in September 2016. The Company leads global development activities, and the parties share development costs equally, on an ongoing basis, under a global development plan. The Company is also responsible for the manufacture and supply of fasinumab globally.

During the second and fourth quarters of 2017, the Company earned, and recognized as substantive milestones, development milestones of $25.0 million and $35.0 million, respectively, from Teva upon initiation of two Phase 3 trials. In addition, the Company is entitled to receive up to an aggregate of $400.0 million in development milestones and up to an aggregate of $1,890.0 million in contingent payments upon achievement of specified annual net sales amounts. The amount of variable consideration related to such milestones is deemed to be constrained as of June 30, 2018, and therefore has not been included in the transaction price.

At the inception of the Teva Collaboration Agreement, the Company's significant promised goods and services consisted of a license to certain rights and intellectual property and providing research and development services, including the manufacturing of clinical supplies. The Company concluded that the license was not distinct, primarily as a result of (i) Teva being unable to benefit from the license on its own or together with other resources that are

readily available as the license providing access to Regeneron's complex and specialized know-how and (ii) the research and development services, including manufacturing in support of such services, were expected to significantly modify the initial license. Therefore the promised goods and services were considered a single performance obligation. Consequently, the $250.0 million up-front payment and development milestones received from Teva, as described above, have been recorded as deferred revenue and have been included in the transaction price.

The Company recognized $68.8 million and $67.7 million of revenue for the three months ended June 30, 2018 and 2017, respectively, and $127.4 million and $100.8 million of revenue for the six months ended June 30, 2018 and 2017, respectively, in connection with the Teva Collaboration Agreement.

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The following tables summarize accounts receivable and deferred revenue information in connection with the Teva Collaboration Agreement:

	June 30, 2018	December 31, 2017
Accounts receivable, net (recorded within Prepaid expenses and other current assets)	$35,504	$71,297
Deferred revenue	$194,564	$197,357

Significant changes in deferred revenue balances are as follows:

	Six Months Ended June 30, 2018
Increase as a result of cumulative-effect adjustment arising from the adoption of ASC 606	$48,216
Revenue recognized that was included in deferred revenue at the beginning of the period	$(52,826)

The aggregate amount of the transaction price under the Teva Collaboration Agreement allocated to the Company's performance obligation that was unsatisfied (or partially unsatisfied) as of June 30, 2018 was $525.3 million. This amount is expected to be recognized as revenue over the remaining period the Company is obligated to satisfy its performance obligation in connection with performing development activities.

4. Net Income Per Share

The Company's basic net income per share amounts have been computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net income - basic and diluted	$551,412	$387,744	$1,029,392	$636,675
(Shares in thousands)				
Weighted average shares - basic	107,800	106,034	107,724	105,804
Effect of dilutive securities:				
Stock options	6,664	9,602	6,959	9,310
Restricted stock	13	501	14	493
Dilutive potential shares	6,677	10,103	6,973	9,803
Weighted average shares - diluted	114,477	116,137	114,697	115,607
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

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Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive include the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
(Shares in thousands)	2018	2017	2018	2017
Stock options	14,865	7,959	14,872	11,055
Restricted stock	60	—	57	16

5. Marketable Securities

Marketable securities as of June 30, 2018 and December 31, 2017 consist of both available-for-sale debt securities of investment grade issuers (see below and Note 6) as well as equity securities of publicly traded companies (see Note 6).

The following tables summarize the Company's investments in available-for-sale debt securities:

As of June 30, 2018	Amortized Cost Basis	Unrealized Gains	Losses	Fair Value
Available-for-sale debt securities:				
Corporate bonds	$2,497,276	$2,282	$(18,987)	$2,480,571
U.S. government and government agency obligations	126,395	30	(1,589)	124,836
Municipal bonds	2,572	—	(8)	2,564
Commercial paper	76,013	—	—	76,013
Certificates of deposit	40,773	—	—	40,773
	$2,743,029	$2,312	$(20,584)	$2,724,757

As of December 31, 2017				
Available-for-sale debt securities:				
Corporate bonds	$1,717,976	$2,176	$(7,672)	$1,712,480
U.S. government and government agency obligations	186,699	34	(1,241)	185,492
Municipal bonds	4,600	—	(13)	4,587
Commercial paper	106,973	—	—	106,973
Certificates of deposit	11,024	—	—	11,024
	$2,027,272	$2,210	$(8,926)	$2,020,556

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of June 30, 2018 mature at various dates through March 2023. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	June 30, 2018	December 31, 2017
Maturities within one year	$765,642	$593,783
Maturities after one year through five years	1,959,115	1,426,773
	$2,724,757	$2,020,556

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The following table shows the fair value of the Company's available-for-sale debt securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
As of June 30, 2018	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$1,588,876	$(15,052)	$218,109	$(3,935)	$1,806,985	$(18,987)
U.S. government and government agency obligations	45,936	(656)	71,864	(933)	117,800	(1,589)
Municipal bonds	2,061	(8)	—	—	2,061	(8)
	$1,636,873	$(15,716)	$289,973	$(4,868)	$1,926,846	$(20,584)
As of December 31, 2017						
Corporate bonds	$930,970	$(4,924)	$256,750	$(2,748)	$1,187,720	$(7,672)
U.S. government and government agency obligations	110,532	(409)	67,921	(832)	178,453	(1,241)
Municipal bonds	2,582	(10)	2,005	(3)	4,587	(13)
	$1,044,084	$(5,343)	$326,676	$(3,583)	$1,370,760	$(8,926)

There were no realized losses on sales of marketable securities, and realized gains were not material, for the three and six months ended June 30, 2018 and 2017.

With respect to marketable securities, for the three and six months ended June 30, 2018 and 2017, amounts reclassified from Accumulated other comprehensive (loss) income into Other income, net were related to realized gains on sales. The Company adopted ASU 2016-01 (see Note 1) during the first quarter of 2018; as a result, there were $16.5 million and $25.9 million of net unrealized gains on equity securities recognized in Other income, net for the three and six months ended June 30, 2018, respectively. For the three and six months ended June 30, 2017, there were $5.8 million and $11.2 million, respectively, of net unrealized gains on equity securities that were recorded in Other comprehensive income (loss).

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6. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis consist of the following:

As of June 30, 2018	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Available-for-sale debt securities:			
Corporate bonds	$2,480,571	—	$2,480,571
U.S. government and government agency obligations	124,836	—	124,836
Municipal bonds	2,564	—	2,564
Commercial paper	76,013	—	76,013
Certificates of deposit	40,773	—	40,773
Equity securities	85,588	$85,588	—
	$2,810,345	$85,588	$2,724,757
As of December 31, 2017			
Available-for-sale debt securities:			
Corporate bonds	$1,712,480	—	$1,712,480
U.S. government and government agency obligations	185,492	—	185,492
Municipal bonds	4,587	—	4,587
Commercial paper	106,973	—	106,973
Certificates of deposit	11,024	—	11,024
Equity securities	62,785	$62,785	—
	$2,083,341	$62,785	$2,020,556

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and six months ended June 30, 2018 and 2017. There were no transfers of marketable securities between Levels 1 or 2 classifications during the three and six months ended June 30, 2018 and 2017.

The fair value of interest rate swap and interest rate cap contracts, which were recorded within Other noncurrent assets, was not material as of June 30, 2018 and December 31, 2017 (see Note 8). The fair value of these contracts was

determined based on Level 2 inputs, using significant inputs that are observable either directly or indirectly, including London Interbank Offered Rate ("LIBOR") and interest rate swap rates.

As of June 30, 2018 and December 31, 2017, the Company had $45.5 million and $37.5 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded at cost within Other noncurrent assets.

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7. Inventories

Inventories consist of the following:

	June 30, 2018	December 31, 2017
Raw materials	$205,463	$190,045
Work-in-process	400,834	302,042
Finished goods	26,571	21,791
Deferred costs	295,685	212,260
	$928,553	$726,138

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

8. Derivative Instruments and Hedging Activities

The Company is exposed to market fluctuations in interest rates, including those in connection with its March 2017 lease of laboratory and office facilities in Tarrytown, New York. Commencing in the second quarter of 2017, the Company entered into interest rate swap and interest rate cap agreements to manage a portion of such interest rate risk; no new agreements of this nature were entered into during the six months ended June 30, 2018. All of the Company's derivative instruments are utilized for risk management purposes, and are not used for trading or speculative purposes.

The Company's derivative instruments are designated as cash flow hedges for accounting purposes. Since the specific terms of the derivative instruments match those of the item being hedged, the derivative instruments are deemed to be highly effective in offsetting the changes in cash flows of the hedged item. As such, changes in the fair value of these derivatives are recorded in accumulated other comprehensive income (loss) until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. The Company would record any gain or loss related to the ineffectiveness directly to earnings.

The Company assesses, both at inception and on an ongoing basis, whether derivatives used continue to be highly effective in offsetting changes in cash flows of the hedged items. The Company does not exclude any portion of the cash flow hedge contracts from the assessment of hedge effectiveness. If and when a derivative is no longer expected to be highly effective, hedge accounting would be discontinued.

The following table summarizes the notional amounts of the Company's outstanding interest rate swap and cap agreements:

	June 30, 2018	December 31, 2017
Interest rate swap contracts	$75,000	$ 75,000
Interest rate cap contracts	$75,000	$ 75,000

As it relates to cash flow hedges, for the three and six months ended June 30, 2018 and 2017, amounts of gains and losses recognized in Other comprehensive income (loss), and amounts reclassified from Accumulated other comprehensive (loss) income into Interest expense were not material. As of June 30, 2018, the amounts expected to be reclassified out of Accumulated other comprehensive income into Interest expense over the next 12 months are not expected to be material. For the three and six months ended June 30, 2018 and 2017, there were no gains or losses recorded related to the ineffective portion of the derivative instruments.

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9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of $104.7 million and $138.1 million for the three months ended June 30, 2018 and 2017, respectively, and $212.1 million and $321.5 million for the six months ended June 30, 2018 and 2017, respectively. The Company's effective tax rate was 16.0% and 26.3% for the three months ended June 30, 2018 and 2017, respectively, and 17.1% and 33.6% for the six months ended June 30, 2018 and 2017, respectively. On December 22, 2017, the bill known as the "Tax Cuts and Jobs Act" (the "Act") was signed into law. The Act, which became effective with respect to most of its provisions as of January 1, 2018, significantly revised U.S. corporate income tax laws by, among other things, reducing the U.S. federal corporate income tax rate from 35% to 21%, changing the taxation of foreign earnings (including taxation of certain global intangible low-taxed income ("GILTI")), allowing for a foreign-derived intangible income deduction and immediate expensing for qualified assets, repealing the deduction for domestic manufacturing, and imposing further limitations on the deductibility of executive compensation. As a result of the Act being signed into law, we recognized a provisional charge of $326.2 million in the fourth quarter of 2017 related to the re-measurement of the Company's U.S. net deferred tax assets at the lower enacted corporate tax rates; such amount was not adjusted during the six months ended June 30, 2018. The provisional charge recorded in the fourth quarter of 2017 is an estimate, and the measurement of deferred tax assets is subject to further analysis, such as developing interpretations and clarifications of the provisions of the Act, which could result in changes to this estimate during 2018. In addition, we have not yet elected an accounting method regarding whether to record deferred tax assets and liabilities for expected amounts of GILTI inclusions or whether to treat such amounts as a period cost.

The Company's effective tax rate for the three and six months ended June 30, 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. The Company's effective tax rate for the three and six months ended June 30, 2017 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for research activities, partly offset by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee.

Income tax provisions recorded in the Statement of Comprehensive Income for the three and six months ended June 30, 2018 and 2017 were not material.

10. Statement of Cash Flows

The Company adopted ASU 2016-18, Statement of Cash Flows - Restricted Cash, during the first quarter of 2018, and the standard has been retrospectively applied to all periods presented. The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheet to the total of the same such amounts shown in the Condensed Consolidated Statement of Cash Flows:

	June 30, 2018	June 30, 2017
Cash and cash equivalents	$917,876	$744,313
Restricted cash included in Other noncurrent assets	12,500	12,500
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$930,376	$756,813

Restricted cash consists of amounts held by financial institutions pursuant to contractual arrangements.

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Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable, accrued expenses, and other liabilities as of June 30, 2018 and December 31, 2017 were $38.4 million and $41.8 million, respectively, of accrued capital expenditures. Included in accounts payable, accrued expenses, and other liabilities as of June 30, 2017 and December 31, 2016 were $30.9 million and $28.2 million, respectively, of accrued capital expenditures.

As described in Note 3, during the six months ended June 30, 2018, we purchased (by issuing a credit towards the amount owed by Sanofi) 121,601 shares of our Common Stock from Sanofi, and recorded the cost of the shares received, or $37.6 million, as Treasury Stock.

The Company recognized an additional capital lease obligation of $201.2 million in connection with the Company's lease of additional premises at its Tarrytown, New York facility during the six months ended June 30, 2017.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted.

Proceedings Relating to '287 Patent, '163 Patent, and '018 Patent

The Company is a party to patent infringement litigation initiated by the Company involving its European Patent No. 1,360,287 (the "'287 Patent"), its European Patent No. 2,264,163 (the "'163 Patent"), and its U.S. Patent No. 8,502,018 (the "'018 Patent"). Each of these patents concerns genetically engineered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings, the Company claims infringement of several claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable).

On September 25, 2013, the Company commenced patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting the '287 Patent and '163 Patent. A trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent was held from November 16, 2015 through December 8, 2015. On February 1, 2016, the court issued a final judgment, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. The hearing for the Company's appeal and Kymab's cross-appeal was held on October 17–20, 2017. On March 28, 2018, the Court of Appeal (Civil Division of England and Wales) reversed the English High Court's decision and held that the '287 Patent and '163 Patent are both valid and infringed by Kymab. On June 5, 2018, the Court of Appeal issued a final order, which enjoins Kymab from infringing the '287 Patent and '163 Patent (subject to certain exceptions) and requires Kymab to destroy or deliver to a third party all products and antibodies and cells engineered to produce antibodies which infringe the '287 Patent and '163 Patent (subject to certain exceptions). The provisions of the final order are stayed pending final determination of Kymab's application for permission to appeal to the Supreme Court of the United Kingdom and, if permission is granted, Kymab's appeal. The Company has also been awarded a portion of the legal fees incurred by it in connection with the proceedings in the English High Court of Justice and the Court of Appeal described above.

On March 11, 2014, the Company commenced '287 Patent infringement litigation and '018 Patent infringement litigation against Merus N.V., a company based in Utrecht, The Netherlands, in the District Court of The Hague (currently stayed by agreement of the parties) and the United States District Court for the Southern District of New York, respectively. On November 21, 2014, the United States District Court for the Southern District of New York issued its Opinion and Order on Claim Construction in the '018 Patent infringement litigation, in which it held the '018 Patent invalid and not infringed. On November 2, 2015, the United States District Court for the Southern District of New York issued an opinion and order finding that the '018 Patent was procured by inequitable conduct, thus rendering it unenforceable. On July 27, 2017, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") affirmed the District Court's decision regarding inequitable conduct without deciding the issues of validity and infringement; and, on December 26, 2017, the Federal Circuit denied the Company's petition for panel rehearing and rehearing en banc. On May 25, 2018, the Company filed a petition for a writ of certiorari with the United States Supreme Court.

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On July 8 and July 13, 2016, notices of opposition against the '163 Patent were filed in the European Patent Office (the "EPO") by Merus N.V. and Kymab and Novo Nordisk A/S, respectively. The notices assert, as applicable, lack of novelty, lack of inventive step, and insufficiency. The Company's response to the oppositions was filed on December 30, 2016. Following an oral hearing before the Opposition Division of the EPO on February 5–7, 2018, the Opposition Division upheld the '163 Patent without amendments. Kymab, Merus, and Novo Nordisk each filed a notice of appeal of the Opposition Division's decision on February 9, 2018, May 25, 2018, and June 26, 2018, respectively.

With respect to the '018 Patent infringement litigation against Merus N.V., on June 25, 2018, the United States District Court for the Southern District of New York granted Merus's motion for attorneys' fees and costs in the amount of $10.5 million, plus pre- and post-judgment interest. On July 25, 2018, the Company filed a notice of appeal with the Federal Circuit. If the Company is ultimately required to pay such amounts, this payment is not expected to have a material impact on the Company's financial statements.

Other than as noted above, the Company is not at this time able to predict the outcome of, or estimate possible gain or a range of possible loss, if any, related to, the '287 Patent, '163 Patent, and '018 Patent proceedings.

Proceedings Relating to Praluent (alirocumab) Injection

As described in greater detail below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. against the Company and Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent, which the Company is jointly developing and commercializing with Sanofi.

In the United States, Amgen has asserted a number of U.S. patents, which were subsequently narrowed to U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and seeks a permanent injunction to prevent the Company and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, "Commercializing") Praluent. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. A jury trial in this litigation was held in the United States District Court for the District of Delaware (the "District Court") from March 8 to March 16, 2016. During the course of the trial, the District Court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of the Company and the Sanofi defendants that there was no willful infringement of the asserted patent claims by the Company or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On January 3, 2017, the District Court issued a final opinion and judgment, denying the Company and the Sanofi defendants' motions for new trial and judgment as a matter of law. The District Court also denied as moot Amgen's motion to strike the Company and the Sanofi defendants' request to obtain a judgment as a matter of law, which allowed the Federal Circuit to address the Company and the Sanofi defendants' patent invalidity arguments on appeal. On January 12, 2017, the Company and the Sanofi defendants filed a notice of appeal with the Federal Circuit. On April 19, 2017, the District Court granted Amgen's motion to amend the judgment on an accounting of supplemental damages and enhancement of such damages if deemed appropriate, but deferred the order until after the Federal Circuit issued a decision on the appeal. Oral argument on the appeal was held on June 6, 2017. On October 5, 2017, the Federal Circuit reversed in part the District Court's decision, remanded for a new trial on the issues of written description and enablement, and, as discussed below, vacated the District Court's permanent injunction. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious. The Federal Circuit further concluded the Company and the Sanofi defendants were not entitled to judgment as a matter of law on the issues of written description and enablement on this record. On February 23, 2018, the Federal Circuit denied Amgen's petition for rehearing en banc, and on March 2, 2018 the Federal Circuit issued a mandate to transfer jurisdiction of the case

back to the District Court. On July 23, 2018, Amgen filed a petition for a writ of certiorari with the United States Supreme Court. A new jury trial is currently scheduled to begin on February 19, 2019.

On January 5, 2017, the District Court granted a permanent injunction prohibiting Regeneron and the Sanofi defendants from Commercializing Praluent in the United States but subsequently delayed its imposition until February 21, 2017. The Federal Circuit stayed the injunction pending appeal on February 8, 2017 and vacated it on October 5, 2017.

On July 25, 2016, Amgen filed a lawsuit against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of Amgen's European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, by Praluent. The lawsuit also seeks a permanent injunction,

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damages, an accounting of profits, and costs and interest. On February 8, 2017, the court temporarily stayed this litigation on terms mutually agreed by the parties.

Also on July 25, 2016, Amgen filed a lawsuit for infringement of the '124 Patent against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf, Germany (the "Düsseldorf Regional Court"), seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages. On November 14, 2017, the Düsseldorf Regional Court issued a decision staying the infringement proceedings until a decision of the Opposition Division of the EPO concerning the pending opposition filed by the Company, Sanofi, and several other opponents against the '124 Patent (as discussed below). Following Amgen's request to reopen the proceedings in light of the issuance of the Preliminary Opinion (as defined below), the Düsseldorf Regional Court has scheduled an oral hearing for September 11, 2018.

On July 12, 2018, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie S.A. filed an action in the Federal Patents Court (the "FPC") in Munich, Germany, seeking a compulsory license from Amgen based on the '124 Patent for the continued commercializing of Praluent in Germany. This compulsory license action included a request for a provisional compulsory license. The FPC has issued a summons for oral hearing scheduled for September 6, 2018 in the provisional compulsory license proceedings.

On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie, and Sanofi Chimie (subsequently added as a defendant). Amgen is seeking the prohibition of allegedly infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time. On April 10, 2017, the Company and the Sanofi parties filed briefs seeking invalidation of certain of the claims of the '124 Patent, and Amgen filed a response on July 28, 2017. Oral hearing on this infringement lawsuit is currently scheduled for February 12, 2019.

The '124 Patent is also subject to opposition proceedings in the EPO seeking to invalidate certain of its claims, which were initiated by Sanofi on February 24, 2016 and, separately, by the Company, Sanofi, and several other opponents on November 24, 2016. On December 13, 2017, the Opposition Division of the EPO issued a preliminary, non-binding opinion (the "Preliminary Opinion") regarding the validity of the '124 Patent, indicating that it currently considers the claims of a new request filed by Amgen in response to the opposition to satisfy the requirements for patentability. The Preliminary Opinion was accompanied by a summons to oral hearing to be held on November 28–30, 2018.

On May 19, 2017, Amgen filed a lawsuit for infringement of Amgen's Japanese Patent Nos. 5,906,333 (the "'333 Patent") and 5,705,288 (the "'288 Patent") in the Tokyo District Court Civil Division against Sanofi K.K. Amgen's complaint alleges that manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) infringe the '333 and '288 Patents. The complaint further seeks a permanent injunction, disposal of product, and court costs. The Company has not been named as a defendant in this litigation.

At this time, the Company is not able to predict the outcome of, or estimate a range of possible loss, if any, related to, these proceedings.

Proceedings Relating to Dupixent (dupilumab) Injection

On March 20, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation filed a lawsuit against Amgen and Immunex Corporation, a wholly owned subsidiary of Amgen, in the United States District Court for the District of Massachusetts seeking a declaratory judgment that the Company's and the other plaintiffs' Commercializing of Dupixent does not directly or indirectly infringe U.S. Patent No. 8,679,487 (the "'487 Patent") owned by Immunex Corporation relating to antibodies that bind the human interleukin-4 receptor. On May 1, 2017, the Company and the other plaintiffs filed a notice of voluntary dismissal of this action without prejudice.

On March 23, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation initiated an inter partes review ("IPR") in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of the '487 Patent. On July 28 and 31, 2017, the same parties filed two additional IPR petitions in the USPTO seeking declarations of invalidity of the '487 Patent

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based on different grounds (the "Additional IPR Petitions"). On October 4, 2017, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a decision on the first IPR petition and declined to institute an IPR proceeding to review the validity of the '487 Patent. On February 15, 2018, the PTAB issued two decisions instituting the Company's and Sanofi's Additional IPR Petitions on all claims of the '487 Patent for which review had been requested. Oral hearing on the Additional IPR Petitions has been scheduled for November 14, 2018.

On April 5, 2017, Immunex Corporation filed a lawsuit against the Company, Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation, and Aventisub LLC in the United States District Court for the Central District of California seeking a judgment of patent infringement of the '487 Patent and a declaratory judgment of infringement of the '487 Patent, in each case by the Company's and the other defendants' Commercializing of Dupixent; monetary damages (together with interest); an order of willful infringement of the '487 Patent, which would allow the court in its discretion to award damages up to three times the amount assessed; costs and expenses of the lawsuit; and attorneys' fees. Immunex is not seeking an injunction in this proceeding at this time. On June 21, 2017, the court denied a motion to dismiss Immunex's complaint previously filed by the Company and the Sanofi parties. On June 28, 2017, the Company and the Sanofi parties filed an answer to Immunex's complaint and counterclaims against Immunex and Amgen (which was amended on October 31, 2017 to, among other things, add an inequitable conduct allegation), and Immunex and Amgen filed an answer to the counterclaims on July 28, 2017. A combined hearing on the construction of certain disputed claim terms of the '487 Patent and summary judgment on the issue of indefiniteness of the '487 Patent claims was held on July 12, 2018. The issues of claim construction and summary judgment, among others, are still pending with the court. A jury trial has been scheduled to start on July 23, 2019.

On September 30, 2016, Sanofi initiated a revocation proceeding in the United Kingdom to invalidate the U.K. counterpart of European Patent No. 2,292,665 (the "'665 Patent"), another patent owned by Immunex relating to antibodies that bind the human interleukin-4 receptor. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the currently pending EPO opposition proceedings initiated by the Company and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions occurred on November 20, 2017, at which the claims of the '665 Patent were found invalid and the patent was revoked. A final written decision of revocation of the '665 Patent was issued by the EPO on January 4, 2018. Immunex filed a notice of appeal of the EPO's decision on January 31, 2018. On September 20, 2017 and September 21, 2017, respectively, the Company and Sanofi initiated opposition proceedings in the EPO against Immunex's European Patent No. 2,990,420 (the "'420 Patent"), a divisional patent of the '665 Patent (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). An oral hearing before the EPO on the '420 Patent opposition proceedings has been scheduled for January 24–25, 2019. The original patent term of the Immunex patents is set to expire in 2021.

At this time, the Company is not able to predict the outcome of, or estimate a range of possible loss, if any, related to, these proceedings.

Proceedings Relating to EYLEA (aflibercept) Injection and ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion

On March 19, 2018, Novartis Vaccines and Diagnostics, Inc., Novartis Pharma AG, and Grifols Worldwide Operations Limited (collectively, the "Novartis Parties") filed a lawsuit against the Company in the United States District Court for the Southern District of New York, seeking a judgment of patent infringement of U.S. Patent No. 5,688,688 (the "'688 Patent") by the Company's manufacture of aflibercept (the active ingredient used in both EYLEA and ZALTRAP); monetary damages (together with interest) for a limited period prior to the '688 Patent expiration; an order of willful infringement of the '688 Patent, which would allow the court in its discretion to award damages up to

three times the amount assessed; costs and expenses of the lawsuit; and attorneys' fees. The '688 Patent expired on November 18, 2014. The Novartis Parties are not seeking an injunction in these proceedings. At this time, the Company is not able to predict the outcome of, or estimate a range of possible loss, if any, related to, these proceedings.

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Proceedings Relating to Shareholder Derivative Claims

On December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the then current and certain former non-employee members of the Company's board of directors, the Chairman of the board of directors, the Company's Chief Executive Officer, and the Company's Chief Scientific Officer as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2013 and 2014. The complaint seeks damages in favor of the Company for the alleged breaches of fiduciary duties and unjust enrichment; changes to Regeneron's corporate governance and internal procedures; invalidation of the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan with respect to the individual defendants' compensation and a shareholder vote regarding the individual defendants' equity compensation; equitable relief, including an equitable accounting with disgorgement; and award of the costs of the action, including attorneys' fees. On June 28, 2017, the court dismissed the plaintiff's claims with respect to certain compensation awarded in 2013 but denied the defendants' motion to dismiss the other claims set forth in the complaint. On November 8, 2017, another alleged shareholder filed a second shareholder derivative complaint in the New York Supreme Court, naming the then current and certain former non-employee members of the Company's board of directors, the Chairman of the board of directors, the Company's Chief Executive Officer, the Company's Chief Scientific Officer, and Regeneron as defendants. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2014, 2015, and 2016. The complaint seeks damages in favor of Regeneron for the alleged breaches of fiduciary duties and unjust enrichment; changes to Regeneron's corporate governance and internal procedures; invalidation of Regeneron's 2014 Long-Term Incentive Plan with respect to the individual defendants' compensation and the imposition of meaningful limits on the amount of equity payable to the individual defendants; a shareholder vote regarding the individual defendants' equity compensation; equitable relief, including an equitable accounting with disgorgement; and award of the costs of the action, including attorneys' fees. On December 4, 2017, the plaintiff in the second action moved to consolidate both actions, to be appointed lead plaintiff, and to have its counsel be appointed lead counsel in the proposed consolidated action. The court heard oral argument on March 7, 2018 and denied the motion. The parties in both the first derivative action and the second derivative action have agreed to a schedule for document discovery and the filing of defendants' appeal of the court's June 28, 2017 decision, as well as a stay of all non-document discovery pending a decision on defendants' appeal. On March 19, 2018, the defendants appealed the court's June 28, 2017 decision to the Appellate Division of the Supreme Court, First Judicial Department. On April 19, 2018, the Appellate Division granted the second plaintiff's motion to intervene in this appeal. On July 26, 2018, the parties to the second shareholder derivative action filed with the court a stipulation of compromise and settlement. The settlement is subject to court approval. Under the terms of the stipulation, final approval of the settlement would release the claims asserted in the original suit as well. The court has scheduled a hearing for August 8, 2018 to determine whether to preliminarily approve the settlement and schedule a final approval hearing. Pursuant to the Company's By-Laws and the New York Business Corporation Law, expenses in connection with the foregoing are being advanced by the Company for the individual defendants.

On or about December 15, 2015, the Company received a shareholder litigation demand upon the Company's board of directors made by a purported Regeneron shareholder. On or about November 3, 2017, the Company received a second shareholder litigation demand upon the Company's board of directors made by another purported Regeneron shareholder, which was substantially similar to the December 15, 2015 shareholder litigation demand. The demands asserted that the then current and certain former non-employee members of the board of directors and the Chairman of the board of directors excessively compensated themselves in 2013 and 2014. The demands requested that the board

of directors investigate and bring legal action against these directors for breach of fiduciary duty, unjust enrichment, and corporate waste, and implement internal controls and systems designed to prohibit and prevent similar actions in the future. On December 20, 2017, the parties to the shareholder derivative action filed on December 30, 2015 entered into a stipulation with the second demanding shareholder. The stipulation provides that the purported shareholder will intervene as a plaintiff in the action, and that the purported shareholder's litigation demand will be withdrawn and deemed null and void. The stipulation was approved by the court on January 18, 2018. The first shareholder litigation demand has also since been withdrawn.

While the Company is unable at this time to predict the ultimate outcome of these proceedings, any possible loss related to these proceedings is not expected to have a material impact on the Company's financial statements.

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Department of Justice Investigation

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST, and ZALTRAP); and certain other related documents and communications. The Company is cooperating with this investigation. The Company cannot predict the outcome or duration of this investigation or any other legal proceedings or any enforcement actions or other remedies that may be imposed on the Company arising out of this investigation.

12. Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02, Leases. The new standard requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. We plan to adopt this standard in the first quarter of 2019 and are evaluating the impact that this guidance will have on our financial statements, including related disclosures. The new standard will result in the Company recording additional assets and corresponding liabilities related to operating leases; however, we do not expect the standard to have a material impact to our Consolidated Balance Sheets. The ultimate impact that the new standard will have will depend on the total amount of the Company's lease commitments as of the adoption date. We are in process of implementing a new lease accounting software system, and expect the implementation of the new standard to have a significant impact on our internal controls and processes.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "Regeneron," "Company," "we," "us," and "our"), 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 our products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, cemiplimab, fasinumab, and evinacumab; the likelihood and timing of achieving any of our anticipated clinical development milestones; 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 our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation EYLEA, Dupixent, Praluent, Kevzara, cemiplimab, fasinumab, and evinacumab; the extent to which the results from the research and development programs conducted by us or our collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting our 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 our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and

commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; the ability of our collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to our 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; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our 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 described further in Note 11 to our Condensed Consolidated Financial Statements included in this report. These statements are made based on management's current beliefs and

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judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. Our commercialized medicines and product candidates in development are designed to help patients with eye disease, allergic and inflammatory diseases, heart disease, pain, cancer, and infectious and other serious medical conditions.

Our total revenues were $1,608.0 million in the second quarter and $3,119.5 million in the first half of 2018, compared to $1,470.1 million in the second quarter and $2,789.1 million in the first half of 2017. Our net income was $551.4 million, or $4.82 per diluted share, in the second quarter and $1,029.4 million, or $8.97 per diluted share, in the first half of 2018, compared to net income of $387.7 million, or $3.34 per diluted share, in the second quarter and $636.7 million, or $5.51 per diluted share, in the first half of 2017. Refer to the "Results of Operations" section below for further details of our financial results, including amounts incurred related to research and development activities.

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We currently have six products that have received marketing approval:

Product	Disease Area[1]	Territory			
		U.S.	EU	Japan	Certain other countries outside the U.S.
EYLEA (aflibercept) Injection[2]	Neovascular age-related macular degeneration (wet AMD)	a	a	a	a
	Diabetic macular edema (DME)	a	a	a	a
	Macular edema following retinal vein occlusion (RVO), which includes macular edema following central retinal vein occlusion (CRVO) and macular edema following branch retinal vein occlusion (BRVO)	a	a	a	a
	Myopic choroidal neovascularization (mCNV)		a	a	a
	Diabetic retinopathy in patients with DME	a			
Dupixent (dupilumab) Injection[3]	Atopic dermatitis (in adults)	a	a	a	a
Praluent (alirocumab) Injection[3]	Heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) (in adults)	a	a	a	a
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	Rheumatoid arthritis (RA) (in adults)	a	a	a	a
ARCALYST® (rilonacept) Injection for Subcutaneous Use	Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	a			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[4]	Metastatic colorectal cancer (mCRC)	a	a		a

[1] Refer to label information in each territory for specific indication
[2] In collaboration with Bayer (outside the United States)
[3] In collaboration with Sanofi
[4] Pursuant to a 2015 amended and restated ZALTRAP agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP, and Sanofi pays us a percentage of aggregate net sales of ZALTRAP.

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Marketed Products

Net Product Sales of Regeneron-Discovered Products[2]

(In millions)	Three Months Ended June 30, 2018			2017		
	U.S.	ROW[1]	Total	U.S.	ROW[1]	Total
EYLEA[2]	$992.0	$665.9	$1,657.9	$919.5	$542.4	$1,461.9
ARCALYST	4.3	—	4.3	4.6	—	4.6
Net product sales recorded by Regeneron	$996.3	—[2]	—[2]	$924.1	—[2]	—[2]
Net product sales recorded by Sanofi[2]:						
Dupixent	$180.9	$28.3	$209.2	$28.4	$0.2	$28.6
Praluent	41.4	32.1	73.5	32.6	13.5	46.1
Kevzara	18.8	5.3	24.1	0.8	—	0.8
ZALTRAP	2.7	25.7	28.4	2.0	17.5	19.5

	Six Months Ended June 30, 2018			2017		
	U.S.	ROW[1]	Total	U.S.	ROW[1]	Total
EYLEA[2]	$1,976.0	$1,289.9	$3,265.9	$1,773.9	$1,026.3	$2,800.2
ARCALYST	8.3	—	8.3	8.5	—	8.5
Net product sales recorded by Regeneron	$1,984.3	—[2]	—[2]	$1,782.4	—[2]	—[2]
Net product sales recorded by Sanofi[2]:						
Dupixent	$298.1	$42.5	$340.6	$28.4	$0.3	$28.7
Praluent	73.2	60.2	133.4	58.0	24.0	82.0
Kevzara	28.2	8.3	36.5	0.8	—	0.8
ZALTRAP	5.1	49.6	54.7	4.6	32.3	36.9

[1] Rest of world

[2] 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 "Overview" above and "Collaboration Agreements" below for further details.

Marketed Products - Recent Developments

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 for commercial patients covered by the Express Scripts National Preferred Formulary.

Programs in Clinical Development

All 19 of our product candidates in clinical development were discovered in our research laboratories and are summarized below. We used our VelocImmune® technology to generate each of the antibodies in the table below. There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, and changes in the competitive landscape affecting a product candidate. Refer to Part II, Item 1A, "Risk Factors" for a description of these and other risks and uncertainties that may affect our clinical programs.

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Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
EYLEA			Non-proliferative diabetic retinopathy (NPDR) in patients without DME	Every 12-week dosing interval in wet AMD (U.S.) Pre-filled syringe (U.S.) Diabetic retinopathy (U.S.) Vial-only presentation (U.S.)
Dupixent (dupilumab)[a] Antibody to IL-4R alpha subunit		Eosinophilic esophagitis (EOE)[c] Grass immunotherapy	Atopic dermatitis in adolescents and pediatrics (6–17 years of age) Atopic dermatitis in pediatrics (6 months–5 years of age) (Phase 2/3) Asthma in pediatrics (6–11 years of age) Nasal polyps	Asthma in adults and adolescents (U.S., EU, and Japan)
Praluent (alirocumab)[a] Antibody to PCSK9			Homozygous familial hypercholesterolemia (HoFH)[c] in adults HeFH in pediatrics	Use with apheresis (U.S.) Cardiovascular risk reduction (U.S. and EU) First-line treatment of hyperlipidemia (U.S.)
Kevzara (sarilumab)[a] Antibody to IL-6R		Polyarticular-course juvenile idiopathic arthritis (pcJIA)		
Cemiplimab[a] (REGN2810) Antibody to PD-1[h]	Solid tumors and advanced hematologic malignancies	Metastatic or locally advanced and unresectable cutaneous squamous cell carcinoma (CSCC) (pivotal study)[d]	First-line and second-line non-small cell lung cancer (NSCLC) Second-line cervical cancer	Metastatic or locally advanced CSCC (U.S. and EU)
Fasinumab[b][f]		Basal cell carcinoma (BCC) (potentially pivotal study)		

(REGN475) Antibody to NGF			Osteoarthritis of knee and hip[e]
Evinacumab[f] (REGN1500) Antibody to ANGPTL3		Refractory hypercholesterolemia (both HeFH and non-FH) Severe hypertriglyceridemia	HoFH[c][d]
Trevogrumab[f] (REGN1033) Antibody to myostatin (GDF8)	Muscle-wasting diseases (in combination with garetosmab)		

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Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
REGN1908-1909[f] Multi-antibody therapy to Feld1	Allergic disease			
REGN1979 Bispecific antibody against CD20 and CD3	Certain B-cell malignancies (monotherapy and in combination with cemiplimab)[c]			
REGN-EB3[g] (REGN3470-3471-3479) Multi-antibody therapy to Ebola virus	Ebola virus infection[c]			
REGN3048-3051[g] Multi-antibody therapy to Middle East Respiratory Syndrome (MERS) virus	MERS virus infection			
Garetosmab[f] (REGN2477) Antibody to Activin A	Muscle-wasting diseases (in combination with trevogrumab)	Fibrodysplasia ossificans progressiva (FOP)[c][e] (potentially pivotal study)		
REGN3500[a] Antibody to IL-33. Studied as monotherapy and in combination with Dupixent.		Asthma Chronic obstructive pulmonary disease (COPD)		
REGN3767[a] Antibody to LAG-3 protein	Advanced cancers (administered alone or in combination with cemiplimab)			
Pozelimab[f] (REGN3918) Antibody to C5	Paroxysmal nocturnal hemoglobinuria (PNH)			
REGN4461 Agonist antibody to leptin receptor (LEPR)	Lipodystrophy and obesity			
REGN4018[a] Bispecific antibody targeting MUC16 and CD3	Platinum-resistant ovarian cancer (administered alone or in combination with cemiplimab)			
REGN4659[a] Antibody to CTLA4	Advanced NSCLC (administered alone or in combination with cemiplimab)			

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[a] In collaboration with Sanofi
[b] In collaboration with Teva and Mitsubishi Tanabe Pharma
[c] FDA granted orphan drug designation
[d] FDA granted Breakthrough Therapy designation
[e] FDA granted Fast Track designation
[f] Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future global sales of the product candidate.
[g] Sanofi did not opt-in to the product candidate. Under the terms of our agreement, Sanofi is

entitled to receive royalties on any future sales of the product candidate. We and the Biomedical Advanced Research Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) are parties to agreements whereby HHS provides certain funding to support research, development, and manufacturing of these antibodies.

(h) Studied as monotherapy and in combination with other antibodies and treatments

(i) Regulatory application submitted. Information in this column relates to U.S., EU, and Japan submissions only.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to be an integrated, multi-product biopharmaceutical company that provides

patients and medical professionals with important options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our VelociSuite® technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our VelociGene® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human antibody technology (VelocImmune) and cell line expression technologies (VelociMab®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using VelocImmune. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

General

Developing and commercializing new medicines entails significant risk and expense. Before significant revenues from the commercialization of our antibody candidates or new indications for our marketed products can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of EYLEA, Dupixent, Praluent, and Kevzara, as well as preparation for potential commercialization of cemiplimab and other indications of Dupixent. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, the continuation of our collaborations, in particular with Sanofi and Bayer, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators, and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

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The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2018 to date were, and plans for the next twelve months are, as follows:

Clinical Program	2018 Events to Date	2018–2019 Plans (next 12 months)
EYLEA	Chinese State Food and Drug Administration (CFDA) approved EYLEA for DME and wet AMD	FDA decision on sBLA for every 12-week dosing interval in wet AMD (target action date of August 11, 2018)
	Reported 24-week positive top-line results from Phase 3 PANORAMA study for the treatment of NPDR in patients without DME	FDA decision on sBLA for vial-only presentation (target action date of August 16, 2018)
	Submitted sBLA for vial-only presentation	FDA decision on sBLA for the treatment of diabetic retinopathy
	Submitted sBLA for the treatment of diabetic retinopathy	Report one-year data from Phase 3 PANORAMA study for the treatment of NPDR in patients without DME
	Submitted sBLA for pre-filled syringe	FDA decision on sBLA for pre-filled syringe
	Treat and Extend dosing regimen approved in the EU for wet AMD	
Dupixent (dupilumab; IL-4R Antibody)	Ministry of Health, Labor and Welfare (MHLW) in Japan approved Dupixent for the treatment of atopic dermatitis in adults not adequately controlled with existing therapies	Submit sBLA and Marketing Authorization Application (MAA) for expanded atopic dermatitis indication in adolescent patients (12–17 years of age)
	Initiated Phase 2/3 study in pediatric patients (6 months–5 years of age) with severe atopic dermatitis	FDA decision on sBLA for asthma in adult and adolescent patients (target action date of October 20, 2018)
	sBLA for asthma in adult and adolescent patients (12 years of age and older) filed with FDA	Report data from Phase 3 studies in nasal polyps
	Regulatory application for asthma accepted for review by the European Medicines Agency (EMA) and Pharmaceuticals and Medical Devices Agency (PMDA) in Japan	Initiate Phase 3 study in eosinophilic esophagitis
	Reported positive results from Phase 3 study in adolescent patients (12–17 years of age) with atopic dermatitis	Initiate Phase 2 study in peanut allergy
	Positive results from two Phase 3 trials for the treatment of moderate-to-severe asthma published in the New England Journal of Medicine	Initiate Phase 2/3 program in COPD
	Initiated Phase 2 study in grass immunotherapy	Initiate clinical program in co-morbid allergic conditions
Praluent (alirocumab; PCSK9 Antibody)	Reported positive results from ODYSSEY OUTCOMES study	FDA decision on sBLA for use with apheresis (target action date of August 24, 2018)
	Submitted sBLA and MAA for cardiovascular risk reduction	FDA and EMA decisions on applications for cardiovascular risk reduction
	Submitted sBLA for first-line treatment of hyperlipidemia	FDA decision on application for first-line treatment of hyperlipidemia
	Initiated Phase 3 pediatric study in HeFH	Initiate Phase 3 pediatric study in HoFH

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Clinical Program (continued)	2018 Events to Date	2018–2019 Plans (next 12 months)
Kevzara (sarilumab; IL-6R Antibody)	FDA approved single-dose pre-filled pen presentation	Continue patient enrollment in Phase 2 study in pcJIA Initiate Phase 3 study in giant cell arteritis Initiate Phase 3 study in polymyalgia rheumatica
Cemiplimab (REGN2810; PD-1 Antibody)	FDA accepted for priority review BLA for advanced CSCC	FDA decision on BLA for advanced CSCC (target action date of October 28, 2018)
	EMA accepted for review MAA for advanced CSCC	Regulatory agency decision for advanced CSCC in the EU
	Positive results from two pivotal trials in advanced CSCC published in the New England Journal of Medicine	Initiate additional studies in various indications
	Reported positive results from Phase 1 study in advanced NSCLC	Continue patient enrollment in NSCLC and various other studies
	Initiated additional Phase 3 studies in advanced NSCLC	
Fasinumab (NGF Antibody)	Completed patient enrollment in the efficacy sub-study of the Phase 3 long-term safety study in osteoarthritis	Report data from first Phase 3 efficacy study in osteoarthritis
	Independent Data Monitoring Committee (DMC) recommended higher dose-regimens be discontinued, and osteoarthritis trials modified accordingly	Continue patient enrollment in Phase 3 long-term safety study in osteoarthritis
	Discontinued dosing in chronic low back pain in patients with concomitant osteoarthritis of the knee and hip	
Evinacumab (ANGPTL3 Antibody)	Initiated Phase 3 study in HoFH	
	Initiated Phase 2 study in severe hypertriglyceridemia	
Trevogrumab (GDF8 Antibody) in combination with REGN2477	Reported positive results from single-dose portion of Phase 1 study	Report results from multi-dose portion of Phase 1 study Initiate Phase 2 programs in type 2 diabetes, sarcopenia, and sporadic inclusion body myositis (sIBM)
REGN1908-1909 (Feld1 Antibody)		Initiate Phase 2 study in cat allergic asthmatics
REGN1979 (CD20 and CD3 Antibody)	FDA granted orphan drug designation in Follicular Lymphoma (FL)	Continue evaluation in non-Hodgkin lymphomas Initiate Phase 2 studies in FL and diffuse large B-cell lymphoma

REGN-EB3 (REGN3470-3471-3479; Multi-antibody therapy to Ebola virus)	Approved for investigational use in the Democratic Republic of the Congo in Ebola virus infection outbreak	Initiate pivotal healthy volunteer safety study
REGN3048-3051 (Multiple-antibody therapy to MERS)	Initiated Phase 1 study in healthy volunteers	Complete Phase 1 study in healthy volunteers
Garetosmab (REGN2477; Activin A Antibody)	Initiated Phase 2 study in patients with FOP	
REGN3500 (IL-33 Antibody)	Initiated Phase 2 study in asthma	Initiate Phase 2 study in atopic dermatitis
	Initiated Phase 2 study in COPD	
REGN3767 (LAG-3 Antibody)		Open monotherapy expansion cohorts as well as in combination with cemiplimab in multiple indications

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Clinical Program (continued)	2018 Events to Date	2018–2019 Plans (next 12 months)
Pozelimab (REGN3918; C5 Antibody)		Complete Phase 1 study in healthy volunteers Initiate Phase 2 study in PNH
REGN4461 (LEPR Agonist Antibody)	Initiated Phase 1 study in healthy volunteers	Initiate Phase 2 study in generalized lipodystrophy
REGN4018 (MUC16 and CD3 Antibody)	Initiated Phase 1 study in platinum-resistant ovarian cancer	
REGN4659 (CTLA4 Antibody)	Initiated Phase 1 study in advanced NSCLC	

Clinical Programs - Additional Information on 2018 Developments

EYLEA

In March 2018, we announced that the Phase 3 PANORAMA trial evaluating EYLEA in NPDR met its 24-week primary endpoint. PANORAMA is an ongoing, pivotal, double-masked, randomized two-year trial that enrolled 402 patients and is designed to investigate EYLEA for the improvement of moderately severe to severe NPDR without DME, compared to sham injection.

Dupixent

In May 2018, we and Sanofi announced that a pivotal Phase 3 trial evaluating Dupixent to treat moderate-to-severe atopic dermatitis in adolescents (ages 12–17) met its primary and key secondary endpoints. In the trial, treatment with Dupixent as monotherapy significantly improved measures of overall disease severity, skin clearing, itching and certain health-related quality of life measures. Patients treated with Dupixent had significant improvement in disease severity at 16 weeks. The primary endpoints were the proportion of patients achieving Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and 75% improvement in Eczema Area and Severity Index (EASI-75, co-primary endpoint outside of the U.S.) at 16 weeks.

Praluent

In March 2018, we 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. For the first time, adding a lipid-lowering therapy to maximally-tolerated statins was associated with reduced death from any cause. A more pronounced effect was observed in patients with baseline LDL-cholesterol (LDL-C) levels at or above 100 mg/dL despite maximally-tolerated statins, who are at high risk of suffering a future event; in this group, Praluent reduced risk of major adverse cardiovascular events by 24% and was associated with a 29% reduced death from any cause. In this 18,924-patient, long-term trial, the safety profile of Praluent was consistent with previous trials and no new safety issues were observed.

Based on the positive results from this trial, an sBLA and an MAA for cardiovascular risk reduction have been recently submitted.

Cemiplimab

CSCC is the second most common type of skin cancer and it is estimated that about 750,000 patients are diagnosed in the United States each year. The vast majority of these patients are cured by surgery; however, there are still many patients with an unmet need. While estimates of the death rate from CSCC vary, it is estimated that between 4,000 to 8,000 patients in the United States die from the disease each year. Currently, there are no FDA- or EMA-approved treatments for advanced CSCC.

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 MAA for cemiplimab in patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery.

Fasinumab

We have several ongoing Phase 3 clinical studies of fasinumab in patients with pain due to osteoarthritis of the knee or hip. In April 2018, an independent DMC 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 using only higher doses, we are no longer actively dosing patients in this study.

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Other Research and Development Technologies and Programs

Our preclinical research programs include the areas of oncology and immuno-oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain and neurobiology, cardiovascular diseases, and infectious diseases.

In January 2018, we announced the formation of a consortium to fund the generation of genetic exome sequence data from 500,000 volunteer participants who make up the UK Biobank health resource. The current members of the consortium consist of AbbVie Inc., Alnylam Pharmaceuticals Inc., AstraZeneca PLC, Biogen Inc., Pfizer Inc., Millennium Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Unlimited), and Bristol-Meyers Squibb. The consortium members have each committed up to $10.0 million in funding for Regeneron to sequence the UK Biobank's samples, which will be performed at the Regeneron Genetics Center® (RGC) facility. Consortium members will have a limited period of exclusive access to the sequencing data before the data will be made available to other health researchers by UK Biobank.

Researchers from the RGC discovered a potential new therapeutic target to reduce the risk of chronic liver disease and progression to more advanced stages of disease, such as nonalcoholic steatohepatitis (NASH), by analyzing extensive genetic sequencing data linked with electronic health records. In March 2018, we announced a publication describing this discovery in the New England Journal of Medicine, which identified for the first time a variant in the HSD17B13 gene that is associated with reduced risk of, or protection from, various chronic liver diseases for which there are currently no approved therapeutics.

Collaboration Agreements

Collaborations with Sanofi

Antibodies. We are collaborating with Sanofi on the global development and commercialization of various antibodies and antibody product candidates (as described above). Under the terms of the Antibody License and Collaboration Agreement (LCA), development costs for the drug candidate are shared between the companies, with Sanofi funding these costs as they are incurred by us, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

Effective January 7, 2018, we and Sanofi entered into a letter agreement (Letter Agreement) amending the LCA in connection with, among other matters, the allocation of additional funds to certain proposed activities relating to dupilumab and REGN3500 (collectively, the Dupilumab/REGN3500 Eligible Investments). Pursuant to the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to the Dupilumab/REGN3500 Eligible Investments for the quarterly periods commencing on January 1, 2018 and ending on September 30, 2020 by selling up to an aggregate of 600,000 shares of our Common Stock directly or indirectly owned by Sanofi. Refer to the "Immuno-Oncology" section below for further details regarding the Letter Agreement.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-promote such products on a country-by-country basis. We have exercised our option to co-promote Dupixent, Praluent, and Kevzara in the United States. We have not exercised any of our options to co-promote these antibodies outside the United States; however, we retain the right to do so at a future date subject to the terms of the collaboration agreement. We and Sanofi equally share profits and losses from sales within the United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Immuno-Oncology. In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO

Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million (IO Discovery Budget) to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected

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ongoing programs. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of Investigational New Drug Applications (INDs), and clinical development through proof-of-concept. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized IO Collaboration products to the extent they are sufficient for this purpose. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below).

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future IO Collaboration profits to the extent they are sufficient for this purpose. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (cemiplimab). We have principal control over the development of cemiplimab, and the parties share equally, on an ongoing basis, development expenses for cemiplimab. Pursuant to the January 7, 2018 Letter Agreement with Sanofi, the cemiplimab development budget has been increased to a total of $1.640 billion, $990.0 million over the budget originally set forth in the IO License and Collaboration Agreement. Under the Letter Agreement, we have also agreed to allow Sanofi to satisfy in whole or in part its funding obligation with respect to cemiplimab development costs for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to an aggregate of 800,000 shares (of which 678,399 currently remains available) of our Common Stock directly or indirectly owned by Sanofi.

If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the cemiplimab development and/or, as noted above, Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions.

With regard to cemiplimab, we will lead commercialization activities in the United States, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. Sanofi has exercised its option to co-promote cemiplimab in the United States. We will be entitled to a milestone payment of $375.0 million in the event that global sales of certain licensed products targeting PD-1 (including cemiplimab), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with any of such licensed products targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

Collaborations with Bayer

EYLEA outside the United States. Since October 2006, we and Bayer have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer collaborate on, and share the costs of, the development of EYLEA. Bayer markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits (including payments to us based on sales in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer at a faster rate. As a result, we expect that a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer for this repayment obligation.

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Within the United States, we retain exclusive commercialization rights to EYLEA and are entitled to all profits from any such sales.

Collaboration with Mitsubishi Tanabe Pharma

Fasinumab. In September 2015, we entered into a collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) providing MTPC with development and commercial rights to fasinumab in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the MTPC Territories). In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment in 2015. We had earned an aggregate of $115.0 million in development milestones and additional payments from MTPC through June 30, 2018, and are entitled to receive up to an aggregate of $100.0 million in additional development milestone and other contingent payments.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200.0 million.

Collaboration with Teva

Fasinumab. In September 2016, we entered into a collaboration agreement with Teva to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with MTPC (as described above). In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment in 2016. We lead global development activities, and the parties will share equally, on an ongoing basis, development costs under a global development plan. We had earned an aggregate of $60.0 million of development milestones from Teva through June 30, 2018, and we are entitled to receive up to an aggregate of $400.0 million in additional development milestones and up to an aggregate of $1,890.0 million in contingent payments upon achievement of specified annual net sales amounts. We are responsible for the manufacture and supply of fasinumab globally.

Within the United States, we will lead commercialization activities, and the parties will share equally in any profits or losses in connection with commercialization of fasinumab. In the territory outside of the United States, Teva will lead commercialization activities and we will supply product to Teva at a tiered purchase price, which is calculated as a percentage of net sales of the product (subject to adjustment in certain circumstances).

Corporate Information

We were incorporated in the State of New York in 1988 and publicly listed in 1991. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number at that address is (914) 847-7000.

We make available free of charge on or through our Internet website (http://www.regeneron.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Investors and other interested parties should note that we use our media and investor relations website (http://newsroom.regeneron.com) and our social media channels to publish important information about Regeneron, including information that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our media and investor relations website and the social media channels listed on our media and investor relations website, in addition to our SEC filings, press releases, conference calls, and webcasts.

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Results of Operations
Three and Six Months Ended June 30, 2018 and 2017
Net Income

Net Income	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
(In millions)	2018	2017	(Decrease)	2018	2017	(Decrease)
Revenues	$1,608.0	$1,470.1	$ 137.9	$3,119.5	$2,789.1	$ 330.4
Operating expenses	(985.8)	(919.8)	(66.0)	(1,930.1)	(1,808.3)	(121.8)
Other income (expense), net	33.9	(24.5)	58.4	52.1	(22.7)	74.8
Income before income taxes	656.1	525.8	130.3	1,241.5	958.1	283.4
Income tax expense	(104.7)	(138.1)	33.4	(212.1)	(321.4)	109.3
Net income	$551.4	$387.7	$ 163.7	$1,029.4	$636.7	$ 392.7
Net income per share - diluted	$4.82	$3.34	$ 1.48	$8.97	$5.51	$ 3.46

Revenues

Revenues	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
(In millions)	2018	2017	(Decrease)	2018	2017	(Decrease)
Net product sales in the United States:						
EYLEA	$992.0	$919.5	$ 72.5	$1,976.0	$1,773.9	$ 202.1
ARCALYST	4.3	4.6	(0.3)	8.3	8.5	(0.2)
Sanofi and Bayer collaboration revenue:						
Sanofi	237.8	222.1	15.7	427.2	432.5	(5.3)
Bayer	262.9	210.4	52.5	510.8	404.3	106.5
Other revenue	111.0	113.5	(2.5)	197.2	169.9	27.3
Total revenues	$1,608.0	$1,470.1	$ 137.9	$3,119.5	$2,789.1	$ 330.4

Net Product Sales
Net product sales of EYLEA in the United States increased for the three and six months ended June 30, 2018, compared to the same periods in 2017, due to higher sales volume.
Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions and credits/payments for sales-related deductions.

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(In millions)	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2017	$ 29.9	$ 34.1	$ 21.3	$85.3
Provisions	48.5	51.7	11.2	111.4
Credits/payments	(30.7)	(42.0)	(14.7)	(87.4)
Balance as of March 31, 2018	47.7	43.8	17.8	109.3
Provisions	49.2	50.4	8.7	108.3
Credits/payments	(60.4)	(56.5)	(9.7)	(126.6)
Balance as of June 30, 2018	$ 36.5	$ 37.7	$ 16.8	$91.0
Balance as of December 31, 2016	$ 12.7	$ 29.5	$ 3.6	$45.8
Provisions	38.9	41.2	9.5	89.6
Credits/payments	(28.5)	(42.3)	(8.6)	(79.4)
Balance as of March 31, 2017	23.1	28.4	4.5	56.0
Provisions	39.4	48.8	11.1	99.3
Credits/payments	(39.4)	(48.2)	(12.7)	(100.3)
Balance as of June 30, 2017	$ 23.1	$ 29.0	$ 2.9	$55.0

Sanofi Collaboration Revenue

(In millions)	Three Months Ended June 30, 2018	2017	Six Months Ended June 30, 2018	2017
Antibody:				
Reimbursement of Regeneron research and development expenses - Discovery Agreement	—	$44.0	—	$92.1
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	$64.5	93.3	$124.9	200.4
Reimbursement of Regeneron commercialization-related expenses	103.7	87.1	189.1	160.7
Regeneron's share of losses in connection with commercialization of antibodies	(68.8)	(122.3)	(143.7)	(230.7)
Other	31.7	31.2	49.0	42.5
Total Antibody	131.1	133.3	219.3	265.0
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses - Discovery Agreement	38.3	39.0	73.6	77.2
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	38.7	29.1	77.3	49.6
Reimbursement of Regeneron commercialization-related expenses	2.1	0.7	3.2	0.7
Other	27.6	20.0	53.8	40.0
Total Immuno-oncology	106.7	88.8	207.9	167.5
Total Sanofi collaboration revenue	$237.8	$222.1	$427.2	$432.5

The lower reimbursement of antibody research and development costs during the three and six months ended June 30, 2018, compared to the same periods in 2017, was primarily due to (i) the Company's Discovery and Preclinical Development Agreement with Sanofi ending on December 31, 2017 without any extension and, therefore, funding from Sanofi under the Antibody Discovery

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Agreement ceased after 2017, and (ii) decreased reimbursement levels for Dupixent under our License and Collaboration Agreement subsequent to U.S. regulatory approval for atopic dermatitis.

In March 2017, the FDA approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis, and in September 2017, the European Commission granted marketing authorization for Dupixent for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. In May 2017, the FDA approved Kevzara for the treatment of rheumatoid arthritis in adult patients, and in June 2017, the European Commission granted marketing authorization for Kevzara for the treatment of rheumatoid arthritis in adult patients.

Reimbursement of Regeneron antibody commercialization-related expenses represents reimbursement of internal and external costs in connection with commercializing Praluent, Kevzara, and Dupixent.

During the three and six months ended June 30, 2018 and 2017, we and Sanofi shared commercial expenses related to Praluent, Kevzara, and Dupixent in accordance with the companies' License and Collaboration Agreement. As such, during the same periods in which we recorded reimbursements from Sanofi related to our commercialization expenses, we also recorded our share of losses in connection with the companies commercializing Praluent, Kevzara, and Dupixent within Sanofi collaboration revenue. During the three and six months ended June 30, 2018, Sanofi collaboration revenues in connection with commercialization of antibodies were primarily impacted, compared to the same periods in 2017, by our share of higher net sales of Dupixent (as the product was launched at the end of March 2017), partly offset by an increase in the collaborations' Dupixent commercialization expenses in support of the launch of Dupixent in atopic dermatitis and the preparation for launch in asthma. See "Overview" section above for a summary of global net product sales recorded by Sanofi in connection with our Antibody License and Collaboration Agreement. Sanofi provides us with an estimate of our share of the losses from commercialization of antibodies for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. Sanofi records product sales for commercialized products.

Sanofi's reimbursement of immuno-oncology research and development costs under our IO License and Collaboration Agreement increased in the second quarter and first half of 2018, compared to the same periods in 2017, due to an increase in late-stage clinical development activities for cemiplimab.

Other Sanofi immuno-oncology revenue primarily includes recognition of deferred revenue from $640.0 million of up-front payments received in 2015 in connection with the execution of the IO Collaboration agreements.

Bayer Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	2018	2017	2018	2017
EYLEA:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$246.3	$190.9	$478.4	$365.8
Reimbursement of Regeneron development expenses	3.7	2.3	7.1	4.8
Other	12.7	10.6	24.6	21.2
Total EYLEA	262.7	203.8	510.1	391.8
Ang2 antibody and PDGFR-beta antibody:				
Reimbursement of development expenses	0.2	4.4	0.7	8.3
Other	—	2.2	—	4.2
Total Ang2 antibody and PDGFR-beta antibody	0.2	6.6	0.7	12.5
Total Bayer collaboration revenue	$262.9	$210.4	$510.8	$404.3

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Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	2018	2017	2018	2017
Net product sales outside the United States	$665.9	$542.4	$1,289.9	$1,026.3
Regeneron's share of collaboration profit from sales outside the United States	$259.4	$204.7	$504.5	$393.2
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(13.1)	(13.8)	(26.1)	(27.4)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$246.3	$190.9	$478.4	$365.8

Bayer records revenue from sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profit, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

We discontinued clinical development of REGN2176-3 in the first quarter of 2017. In the fourth quarter of 2017, we reported that two REGN910-3 Phase 2 studies did not provide sufficient differentiation to warrant Phase 3 development.

Other Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	2018	2017	2018	2017
Teva collaboration revenue:				
Reimbursement of Regeneron research and development expenses	$34.3	$31.4	$73.4	$53.5
Other	34.5	36.3	54.0	47.3
Total Teva collaboration revenue	68.8	67.7	127.4	100.8
Other revenue	42.2	45.8	69.8	69.1
Total other revenue	$111.0	$113.5	$197.2	$169.9

In September 2016, we and Teva entered into a collaboration agreement to develop and commercialize fasinumab. The change in other Teva collaboration revenue for both the three and six month periods ended June 30, 2018, compared to the same periods in 2017, was positively impacted by the recognition of a higher amount of deferred revenue from amounts paid by Teva to us, offset by the recognition in the second quarter of 2017 of a development milestone of $25.0 million from Teva.

In addition to Teva collaboration revenue, "Other revenue" in the table above includes:

- Recognition of a portion of deferred revenue from up-front and other payments received from MTPC and, in the second quarter of 2017, recognition of a development milestone of $30.0 million from MTPC, in connection with our fasinumab collaboration.
- Sanofi's reimbursement for manufacturing commercial supplies of ZALTRAP and a percentage of aggregate net sales of ZALTRAP under the terms of the Amended ZALTRAP Agreement.
- Recognition of revenue related to the $165.0 million up-front payment we received in August 2010, which was deferred upon receipt and was being recognized as revenue through mid-2018, in connection with the VelocImmune license agreement with Astellas. In accordance with the terms of the license agreement, in the first quarter of 2018, Astellas provided notice to us that the agreement will terminate effective June 2018.
- Royalties in connection with a June 2009 agreement with Novartis, under which we receive royalties on worldwide sales of Novartis' Ilaris® (canakinumab). The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion, and we are entitled to royalties until Novartis ceases sale of products subject to royalty.

The $111.0 million and $197.2 million in total other revenue for the three and six months ended June 30, 2018, respectively, also includes the impact of adopting Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, as

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of January 1, 2018. Prior period amounts have not been adjusted in connection with the adoption of this standard. See Note 1 to our Condensed Consolidated Financial Statements.

Expenses

	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
(In millions)	2018	2017	(Decrease)	2018	2017	(Decrease)
Research and development	$529.3	$510.0	$ 19.3	$1,027.9	$1,017.4	$ 10.5
Selling, general, and administrative	364.8	306.9	57.9	695.6	603.8	91.8
Cost of goods sold	36.0	42.1	(6.1)	105.2	103.4	1.8
Cost of collaboration and contract manufacturing	55.7					