REGENERON PHARMACEUTICALS INC
Form 10-Q
May 03, 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 March 31, 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 April 12, 2018:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,911,354
Common Stock, $.001 par value	105,949,824

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"ARCALYST®", "EYLEA®", "ZALTRAP®", "VelocImmune®", "VelociGene®", "VelociMouse®", "VelociMab®", "VelociSuite®", and "Regeneron Genetics Center®" 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)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$1,019,491	$812,733
Marketable securities	605,461	596,847
Accounts receivable - trade, net	1,531,936	1,538,642
Accounts receivable from Sanofi	168,855	193,684
Accounts receivable from Bayer	243,141	242,014
Inventories	820,397	726,138
Prepaid expenses and other current assets	155,451	224,972
Total current assets	4,544,732	4,335,030
Marketable securities	1,821,985	1,486,494
Property, plant, and equipment, net	2,394,727	2,358,605
Deferred tax assets	532,268	506,291
Other noncurrent assets	78,984	77,866
Total assets	$9,372,696	$8,764,286
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$207,611	$178,183
Accrued expenses and other current liabilities	666,216	637,162
Deferred revenue from Sanofi	231,447	177,746
Deferred revenue - other	160,466	142,392
Total current liabilities	1,265,740	1,135,483
Capital and facility lease obligations	704,645	703,453
Deferred revenue from Sanofi	406,778	379,936
Deferred revenue - other	257,967	249,263
Other noncurrent liabilities	169,922	152,073
Total liabilities	2,805,052	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 - 109,703,771 in 2018 and 109,477,222 in 2017	110	110
Additional paid-in capital	3,611,599	3,512,833

Retained earnings	3,287,767	2,946,733
Accumulated other comprehensive (loss) income	(15,594)	640
Treasury Stock, at cost; 3,763,868 shares in 2018 and 2017	(316,240)	(316,240)
Total stockholders' equity	6,567,644	6,144,078
Total liabilities and stockholders' equity	$9,372,696	$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 March 31,	
	2018	2017
Statements of Operations		
Revenues:		
Net product sales	$987,909	$858,245
Sanofi collaboration revenue	189,490	210,367
Bayer collaboration revenue	247,928	193,939
Other revenue	86,158	56,440
	1,511,485	1,318,991
Expenses:		
Research and development	498,586	507,435
Selling, general, and administrative	330,770	296,846
Cost of goods sold	69,243	61,253
Cost of collaboration and contract manufacturing	45,655	22,915
	944,254	888,449
Income from operations	567,231	430,542
Other income (expense):		
Other income, net	24,606	9,248
Interest expense	(6,439)	(7,501)
	18,167	1,747
Income before income taxes	585,398	432,289
Income tax expense	(107,418)	(183,358)
Net income	$477,980	$248,931
Net income per share - basic	$4.44	$2.36
Net income per share - diluted	$4.16	$2.16
Weighted average shares outstanding - basic	107,648	105,572
Weighted average shares outstanding - diluted	114,906	115,106
Statements of Comprehensive Income		
Net income	$477,980	$248,931
Other comprehensive income (loss), net of tax:		
Unrealized (loss) gain on marketable securities	(11,080)	6,956
Unrealized gain on cash flow hedges	1,439	—
Comprehensive income	$468,339	$255,887

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)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net income	$477,980	$248,931
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	36,358	38,115
Non-cash compensation expense	82,422	133,789
Other non-cash items, net	(4,193)	3,956
Deferred taxes	(6,366)	(40,988)
Changes in assets and liabilities:		
Decrease (increase) in Sanofi, Bayer, and trade accounts receivable	30,408	(137,928)
Increase in inventories	(88,760)	(69,744)
Decrease (increase) in prepaid expenses and other assets	68,836	(20,325)
(Decrease) increase in deferred revenue	(54,596)	12,400
Increase in accounts payable, accrued expenses, and other liabilities	76,654	187,695
Total adjustments	140,763	106,970
Net cash provided by operating activities	618,743	355,901
Cash flows from investing activities:		
Purchases of marketable and other securities	(601,313)	(208,694)
Sales or maturities of marketable securities	255,276	119,012
Capital expenditures	(79,375)	(50,461)
Net cash used in investing activities	(425,412)	(140,143)
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	—	(12,861)
Proceeds from issuance of Common Stock	13,427	16,673
Net cash provided by financing activities	13,427	60,812
Net increase in cash, cash equivalents, and restricted cash	206,758	276,570
Cash, cash equivalents, and restricted cash at beginning of period	825,233	547,703
Cash, cash equivalents, and restricted cash at end of period	$1,031,991	$824,273

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 for the three months ended March 31, 2018 as compared with the guidance that was in effect before the change.

	March 31, 2018		
Balance Sheet Data	As Reported	Adjustments	Balance Without Adoption of ASC 606
Deferred tax assets	$532,268	$(18,206)	$514,062
Total assets	$9,372,696	$(18,206)	$9,354,490
Accrued expenses and other current liabilities	$666,216	$(1,513)	$664,703
Deferred revenue from Sanofi (current)	$231,447	$(33,632)	$197,815
Deferred revenue - other (current)	$160,466	$(69,241)	$91,225
Total current liabilities	$1,265,740	$(104,386)	$1,161,354
Deferred revenue from Sanofi (noncurrent)	$406,778	$(51,604)	$355,174
Deferred revenue - other (noncurrent)	$257,967	$18,277	$276,244
Total liabilities	$2,805,052	$(137,713)	$2,667,339
Retained earnings	$3,287,767	$119,507	$3,407,274

Total stockholders' equity	$6,567,644	$119,507	$6,687,151
Total liabilities and stockholders' equity	$9,372,696	$(18,206)	$9,354,490

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

	Three Months Ended March 31, 2018		
Consolidated Statement of Operations Data	As Reported	Adjustments	Balance Without Adoption of ASC 606
Sanofi collaboration revenue	$189,490	$ (8,407)	$181,083
Other revenue	$86,158	$ (17,310)	$68,848
Total revenues	$1,511,485	$ (25,717)	$1,485,768
Income from operations	$567,231	$ (25,717)	$541,514
Income before income taxes	$585,398	$ (25,717)	$559,681
Income tax expense	$(107,418)	$ 1,789	$(105,629)
Net income	$477,980	$ (23,928)	$454,052

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 March 31,	
Net Product Sales in the United States	2018	2017
EYLEA®	$984,049	$854,387
ARCALYST®	3,860	3,858
	$987,909	$858,245

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for the three months ended March 31, 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 March 31,	
	2018	2017
Besse Medical, a subsidiary of AmerisourceBergen Corporation	55%	53%
McKesson Corporation	40%	27%
Curascript SD Specialty Distribution, a subsidiary of Express Scripts	**	19%

** For the three months ended March 31, 2018, sales to Curascript SD Specialty Distribution represented less than 10% of total gross product revenue.

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 and chargebacks 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 three months ended March 31, 2018 and 2017.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2017	$ 29,840	$ 34,142	$ 21,320	$85,302
Provisions	48,495	51,716	11,170	111,381
Credits/payments	(30,674)	(42,025)	(14,665)	(87,364)
Balance as of March 31, 2018	$ 47,661	$ 43,833	$ 17,825	$109,319
Balance as of December 31, 2016	$ 12,712	$ 29,465	$ 3,674	$45,851
Provisions	38,908	41,175	9,520	89,603
Credits/payments	(28,502)	(42,287)	(8,632)	(79,421)
Balance as of March 31, 2017	$ 23,118	$ 28,353	$ 4,562	$56,033

Accruals for chargebacks are recorded as a direct reduction to accounts receivable and accruals for rebates and distribution-related fees 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 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 March 31,	
Sanofi Collaboration Revenue	2018	2017
Antibody:		
Reimbursement of Regeneron research and development expenses	$60,394	$155,245
Reimbursement of Regeneron commercialization-related expenses	85,424	73,559
Regeneron's share of losses in connection with commercialization of antibodies	(74,874)	(108,402)
Other	17,330	11,286
Total Antibody	88,274	131,688
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	73,824	58,679
Reimbursement of Regeneron commercialization-related expenses	1,210	—
Other	26,182	20,000
Total Immuno-oncology	101,216	78,679
	$189,490	$210,367

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 March 31, 2018 and 2017, the Company recognized as research and development expense $13.9 million and $25.0 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 the development of dupilumab and REGN3500 and non-approval trials of dupilumab (collectively, the

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

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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 March 31, 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:

	March 31, 2018	December 31, 2017
Accounts receivable, net	$94,022	$121,001
Deferred revenue	$132,991	$117,682

Significant changes in deferred revenue balances are as follows:

	Three Months Ended March 31, 2018
Increase due to shipments of commercial supplies to Sanofi	$37,036
Revenue recognized that was included in deferred revenue at the beginning of the period	$(21,727)

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 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. The cemiplimab development budget

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has been increased pursuant to the Letter Agreement. Pursuant to the Letter Agreement, 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 the Company's Common Stock directly or indirectly owned by Sanofi through September 30, 2020. If Sanofi desires to sell shares of the Company's 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, the Company may elect to purchase, in whole or in part, such shares from Sanofi. If the Company does 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.

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 March 31, 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 $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 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:

	March 31, 2018	December 31, 2017
Accounts receivable, net	$70,887	$59,274
Deferred revenue	$505,235	$440,000

Significant changes in deferred revenue balances are as follows:

	Three Months Ended March 31,

	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	$(28,408)

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 March 31, 2018 was $1,656.0 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.

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b. Bayer
EYLEA outside the United States
Revenue earned in connection with our EYLEA collaboration with Bayer is detailed below:

	Three Months Ended March 31,	
Bayer EYLEA Collaboration Revenue	2018	2017
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$232,068	$174,876
Reimbursement of Regeneron EYLEA development expenses	3,457	2,451
Other	11,863	10,603
Total EYLEA	$247,388	$187,930

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:

	March 31, 2018	December 31, 2017
Accounts receivable, net	$243,141	$241,153
Deferred revenue	$70,378	$68,734

Significant changes in deferred revenue balances are as follows:

	Three Months Ended March 31, 2018
Increase due to shipments of commercial supplies to Bayer	$11,436
Revenue recognized that was included in deferred revenue at the beginning of the period	$(9,792)

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.

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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.

In 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 March 31, 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 $58.6 million and $33.1 million of revenue for the three months ended March 31, 2018 and 2017, respectively, in connection with the Teva Collaboration Agreement.

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

	March 31, 2018	December 31, 2017
Accounts receivable, net (recorded within Prepaid expenses and other current assets)	$40,625	$71,297
Deferred revenue	$227,714	$197,357

Significant changes in deferred revenue balances are as follows:

	Three Months Ended March 31,

	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	$(18,917)

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 March 31, 2018 was $686.0 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.

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In April 2018, an independent Data Monitoring Committee monitoring the ongoing safety and efficacy of our fasinumab clinical trials recommended that the higher dose-regimens be discontinued based on the risk benefit assessment and that the program may continue with the lower dose-regimens of fasinumab. The trials are being modified accordingly, which may ultimately impact the transaction price allocated to the remaining performance obligation.

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 March 31,	
	2018	2017
Net income - basic and diluted	$477,980	$248,931
(Shares in thousands)		
Weighted average shares - basic	107,648	105,572
Effect of dilutive securities:		
Stock options	7,244	9,050
Restricted stock	14	484
Dilutive potential shares	7,258	9,534
Weighted average shares - diluted	114,906	115,106
Net income per share - basic	$4.44	$2.36
Net income per share - diluted	$4.16	$2.16

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

	Three Months Ended March 31,	
(Shares in thousands)	2018	2017
Stock options	14,878	11,535
Restricted stock	57	18

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5. Marketable Securities

Marketable securities as of March 31, 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 March 31, 2018	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale debt securities:				
Corporate bonds	$2,126,820	$1,948	$(18,159)	$2,110,609
U.S. government and government agency obligations	156,281	30	(1,611)	154,700
Municipal bonds	2,591	—	(11)	2,580
Commercial paper	70,385	—	—	70,385
Certificates of deposit	20,097	—	—	20,097
	$2,376,174	$1,978	$(19,781)	$2,358,371

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 debt securities based on their contractual maturity dates. The debt securities listed as of March 31, 2018 mature at various dates through March 2023. The fair values of debt security investments by contractual maturity consist of the following:

	March 31, 2018	December 31, 2017
Maturities within one year	$605,461	$593,783
Maturities after one year through five years	1,752,910	1,426,773
	$2,358,371	$2,020,556

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The following table shows the fair value of the Company's 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 March 31, 2018	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$1,343,778	$(13,950)	$234,258	$(4,209)	$1,578,036	$(18,159)
U.S. government and government agency obligations	70,872	(623)	76,793	(988)	147,665	(1,611)
Municipal bonds	2,579	(11)	—	—	2,579	(11)
	$1,417,229	$(14,584)	$311,051	$(5,197)	$1,728,280	$(19,781)
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 months ended March 31, 2018 and 2017.

With respect to marketable securities, for the three months ended March 31, 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 was $9.4 million of unrealized gains on equity securities recognized during the three months ended March 31, 2018 that was recorded in Other income, net. For the three months ended March 31, 2017, there was $5.4 million of unrealized gains and losses on equity securities that was 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 March 31, 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	$2,110,609	—	$2,110,609
U.S. government and government agency obligations	154,700	—	154,700
Municipal bonds	2,580	—	2,580
Commercial paper	70,385	—	70,385
Certificates of deposit	20,097	—	20,097
Equity securities	69,075	$69,075	—
	$2,427,446	$69,075	$2,358,371
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 months ended March 31, 2018 and 2017. There were no transfers of marketable securities between Levels 1 or 2 classifications during the three months ended March 31, 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 March 31, 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 March 31, 2018, the Company had $37.5 million 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:

	March 31, 2018	December 31, 2017
Raw materials	$201,429	$190,045
Work-in-process	374,505	302,042
Finished goods	22,848	21,791
Deferred costs	221,615	212,260
	$820,397	$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 first quarter of 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 is discontinued.

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

	March 31, 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 months ended March 31, 2018, 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 March 31, 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 months ended March 31, 2018, 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 $107.4 million and $183.4 million for the three months ended March 31, 2018 and 2017, respectively. The Company's effective tax rate was 18.3% and 42.4% for the three months ended March 31, 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 in the first quarter of 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 months ended March 31, 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the foreign-derived intangible income deduction and the federal tax credit for research activities. The Company's effective tax rate for the three months ended March 31, 2017 was negatively impacted, compared to the U.S. federal statutory rate, 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, partly offset by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for research activities.

The income tax provision recorded in the Statement of Comprehensive Income for the three months ended March 31, 2018 was not material, and there was no such income tax benefit or provision recorded for the three months ended March 31, 2017.

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:

	March 31, 2018	March 31, 2017
Cash and cash equivalents	$1,019,491	$811,773
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	$1,031,991	$824,273

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

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable, accrued expenses, and other liabilities as of March 31, 2018 and December 31, 2017 were $40.2 million and $41.8 million, respectively, of accrued capital expenditures. Included in accounts payable, accrued expenses, and other liabilities as of March 31, 2017 and December 31, 2016 were $32.3 million and $28.2 million, respectively, of accrued capital expenditures.

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 three months ended March 31, 2017. No such amount was recognized during the three months ended March 31, 2018.

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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. Pending issuance of the final order, the Court of Appeal has granted a pro tem injunction against Kymab, which prevents Kymab from disposing of or removing from England and Wales any infringing mice, cells, antibodies, or antibody-producing cells without the Company's consent (subject to certain exceptions).

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. On September 12, 2017, the Company filed a petition for panel rehearing and/or rehearing en banc in the Federal Circuit. On December 26, 2017, the Federal Circuit issued an order denying the Company's petition for panel rehearing and rehearing en banc.

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 filed a notice of appeal of the Opposition Division's decision on February 9, 2018.

With respect to the '018 Patent infringement litigation against Merus N.V., on March 26, 2018, the United States District Court for the Southern District of New York granted Merus's motion for attorneys' fees and costs; if the Company is ultimately required to pay such fees and costs (the amount of which has not yet been determined by the court), such payment is not expected to have a material impact on the Company's financial statements.

Other than as noted in the preceding sentence, 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.

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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. A new jury trial has been 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, 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 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

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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 June 29, 2018.

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 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.

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 scheduled for April 27, 2018, but was later cancelled by the court. 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 March 19, 2019.

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 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.

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. 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.

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

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;

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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 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 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 $1,511.5 million in the first quarter of 2018, compared to $1,319.0 million in the first quarter of 2017. Our net income was $478.0 million, or $4.16 per diluted share, in the first quarter of 2018, compared to net income of $248.9 million, or $2.16 per diluted share, in the first quarter 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
EYLEA (aflibercept) Injection[2]	Neovascular age-related macular degeneration (wet AMD)	United States, European Union (EU), Japan, and certain other countries outside the United States
	Diabetic macular edema (DME)	United States, EU, Japan, China, and certain other countries outside the United States
	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)	United States, EU, Japan, and certain other countries outside the United States
	Myopic choroidal neovascularization (mCNV)	EU, Japan, and certain other countries outside the United States
	Diabetic retinopathy in patients with DME	United States
Dupixent (dupilumab) Injection[3]	Atopic dermatitis (in adults)	United States, EU, Japan, and certain other countries outside the United States
Praluent (alirocumab) Injection[3]	Heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) (in adults)[4]	United States, EU, Japan, and certain other countries outside the United States
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	Rheumatoid arthritis (RA) (in adults)	United States, EU, Japan, and certain other countries outside the United States
ARCALYST® (rilonacept) Injection for Subcutaneous Use	Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	United States
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[5]	Metastatic colorectal cancer (mCRC)	United States, EU, and certain other countries outside the United States

[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] In 2017, the U.S. Food and Drug Administration (FDA) also approved the supplemental Biologics License Application (sBLA) for a once-monthly (every four weeks), 300 mg dose of Praluent.
[5] 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[1]	Three Months Ended March 31,	
(In millions)	2018	2017
EYLEA in the United States	$984.0	$854.4
ARCALYST	3.9	3.8
Net product sales recorded by Regeneron	$987.9	$858.2
EYLEA outside of the United States[1]	$624.0	$483.9
EYLEA global	$1,608.0	$1,338.3
Global net product sales recorded by Sanofi[1]:		
Praluent	$59.9	$35.9
Dupixent	131.4	—
Kevzara	12.4	—
ZALTRAP	26.3	17.4
Net product sales recorded by Sanofi	$230.0	$53.3

[1] Bayer records net product sales of EYLEA outside the United States and Sanofi records global net product sales of Praluent, Dupixent, Kevzara, and ZALTRAP. Refer to "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 will become the exclusive PCSK9 inhibitor therapy on the Express Scripts national formulary. The agreement takes effect on July 1, 2018 for commercial patients covered by the Express Scripts National Preferred Formulary.

Programs in Clinical Development

All 17 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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Phase 1

Cemiplimab (REGN2810)[a]

Antibody to programmed cell death protein 1 (PD-1)[h]

Solid tumors and advanced hematologic malignancies

REGN3767[a]

Antibody to Lymphocyte Activation Gene 3 (LAG-3) protein

Advanced malignancies (administered alone or in combination with cemiplimab)

REGN1979

Bispecific antibody against CD20 and CD3

Certain B-cell malignancies (monotherapy and in combination cemiplimab)[c]

REGN3470-3471-3479[g]

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

REGN1908-1909[f]

Multi-antibody therapy to Feld1

Allergic disease

Trevogrumab (REGN1033)[f]

Antibody to myostatin (GDF8)

Muscle wasting diseases (in combination with REGN2477)

REGN2477[f]

Antibody to Activin A

Muscle-wasting diseases (in combination with trevogrumab)

REGN3918[f]

Antibody to complement 5 (C5)

Phase 2

Dupilumab[a]

Antibody to the interleukin-4 receptor (IL-4R) alpha subunit

Eosinophilic esophagitis (EoE)[c]

REGN3500[a]

Antibody to interleukin-33 (IL-33). Studied as monotherapy and in combination with dupilumab.

Asthma

Sarilumab[a]

Antibody to the interleukin-6 receptor (IL-6R)

Polyarticular-course juvenile idiopathic arthritis (pcJIA)

Cemiplimab[a]

Metastatic or locally advanced and unresectable cutaneous squamous cell carcinoma (CSCC) (pivotal study)[d]

Basal cell carcinoma (BCC) (potentially pivotal study)

Evinacumab (REGN1500)[f]

Antibody to angiopoietin-like protein 3 (ANGPTL3)

Refractory hypercholesterolemia (both HeFH and non-FH)

REGN2477[f]

Fibrodysplasia ossificans progressiva (FOP)[c][e]

Phase 3

EYLEA

Non-proliferative diabetic retinopathy (NPDR) in patients without DME

Dupilumab[a]

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 adults and adolescents

Asthma in pediatrics (6–11 years of age)

Nasal polyps

Alirocumab[a]

Antibody to PCSK9

LDL cholesterol reduction and prevention of cardiovascular events

Homozygous familial hypercholesterolemia (HoFH)[c]

Cemiplimab[a]

First-line treatment for non-small cell lung cancer (NSCLC)

Cervical cancer

Fasinumab (REGN475)[b][f]

Osteoarthritis of knee and hip[e]

Chronic low back pain in patients with concomitant osteoarthritis of the knee and hip

Evinacumab[f]

HoFH[c][d]

	Paroxysmal nocturnal hemoglobinuria (PNH)
REGN4461 Agonist antibody to leptin receptor (LEPR)	Lipodystrophy and obesity

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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

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 dupilumab. 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:

Trap-based Clinical Program:

	2018 Events to Date	2018–2019 Plans (next 12 months)
EYLEA	Chinese State Food and Drug Administration (CFDA) approved EYLEA for DME	FDA decision on sBLA for every 12-week dosing interval in wet AMD (target action date of August 11, 2018)
	Reported positive top-line results from Phase 3 PANORAMA study for the treatment of NPDR in patients without DME (see "Clinical Programs - Recent Developments" below)	Submit sBLA for pre-filled syringe
		Regulatory agency decision on wet AMD in China
	Submitted sBLA for "vial-only" presentation	Submit sBLA for the treatment of NPDR in patients without DME

Antibody-based Clinical Programs:

	2018 Events to Date	2018–2019 Plans (next 12 months)
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 for additional regulatory approvals in atopic dermatitis and asthma outside the United States
	Initiated Phase 2/3 study in pediatric patients (6 months–5 years of age) with severe atopic dermatitis	Report data from Phase 3 study in adolescent patients (12–17 years of age) with atopic dermatitis and submit sBLA and Marketing Authorization Application (MAA) for expanded indication
	sBLA for asthma in adult and adolescent patients (12 years of age and older) filed with FDA	FDA decision on sBLA for asthma in adult and adolescent patients (target action date of October 20, 2018)
	Regulatory application for asthma accepted for review by the European Medicines Agency (EMA) and Pharmaceuticals and Medical Devices Agency (PMDA) in Japan	Regulatory agency decisions on atopic dermatitis and asthma applications outside the United States
		Report data from Phase 3 studies in nasal polyps Initiate Phase 3 study in eosinophilic esophagitis Initiate Phase 2 study in peanut allergy Initiate Phase 2 study as an adjunct to immunotherapy for grass allergy Initiate Phase 3 program in chronic obstructive pulmonary disease (COPD) Initiate clinical program in co-morbid allergic conditions
Praluent (alirocumab; PCSK9 Antibody)	Reported positive results from ODYSSEY OUTCOMES study (see "Clinical Programs - Recent Developments" below)	Submit for regulatory approval for cardiovascular risk reduction in the United States and EU and for first-line treatment of hyperlipidemia in the United States

	FDA decision on sBLA for use with apheresis (target action date of August 24, 2018) Initiate Phase 3 pediatric studies in HoFH and HeFH

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Antibody-based Clinical Programs (continued):

	2018 Events to Date	2018–2019 Plans (next 12 months)
Kevzara (sarilumab; IL-6R Antibody)	FDA approved single-dose pre-filled pen presentation	Submit for additional regulatory approvals outside of the United States 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 Initiate additional studies in non-small cell lung cancer and various other indications Continue patient enrollment in various studies
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	Modify dosing-regimen in clinical trials based on recommendations of the DMC
Evinacumab (ANGPTL3 Antibody)	Initiated Phase 3 study in HoFH	Initiate Phase 2 study in severe hypertriglyceridemia
Trevogrumab (GDF8 Antibody)		Complete Phase 1 combination study with REGN2477 and report results Initiate Phase 2 program
REGN1908-1909 (Feld1 Antibody)		Continue early stage development
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
REGN3470-3471-3479 (Multi-antibody therapy to Ebola virus)		Initiate pivotal healthy volunteer safety study
REGN3048-3051 (Multiple-antibody therapy to MERS)	Initiated Phase 1 study in healthy volunteers	
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 studies in COPD and atopic dermatitis
REGN3767 (LAG-3 Antibody)		

		Open monotherapy expansion cohorts as well as in combination with cemiplimab in multiple indications
REGN3918 (C5 Antibody)		Complete Phase 1 study in healthy volunteers
REGN4461 (LEPR Agonist Antibody)	Initiated Phase 1 study in healthy volunteers	

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Clinical Programs - Recent Developments

EYLEA

In March 2018, we announced that the Phase 3 PANORAMA trial evaluating EYLEA in NPDR met its 24-week primary endpoint. In the trial, 58% of EYLEA-treated patients experienced a two-step or greater improvement from baseline on the Diabetic Retinopathy Severity Scale (DRSS) at week 24, compared to 6% of patients receiving sham injection ($p<0.0001$). There were no new safety signals in the trial. 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.

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.

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. A Phase 3 study in chronic low back pain in patients with concomitant osteoarthritis is also ongoing.

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 trials are being modified accordingly.

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., and Millennium Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Unlimited). 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.

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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 generally 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 the development of dupilumab and REGN3500 and non-approval trials of dupilumab (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 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

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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 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.

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). We 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.

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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. During 2017, we earned $25.0 million and $35.0 million development milestones from Teva, 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 Months Ended March 31, 2018 and 2017
Net Income

Net Income	Three Months Ended March 31,		Increase (Decrease)
(In millions)	2018	2017	
Revenues	$1,511.5	$1,319.0	$ 192.5
Operating expenses	(944.3)	(888.4)	(55.9)
Other income (expense), net	18.2	1.7	16.5
Income before income taxes	585.4	432.3	153.1
Income tax expense	(107.4)	(183.4)	76.0
Net income	$478.0	$248.9	$ 229.1
Net income per share - diluted	$4.16	$2.16	$ 2.00

Revenues

Revenues	Three Months Ended March 31,		Increase (Decrease)
(In millions)	2018	2017	
Net product sales in the United States:			
EYLEA	$984.0	$854.4	$ 129.6
ARCALYST	3.9	3.8	0.1
Sanofi and Bayer collaboration revenue:			
Sanofi	189.5	210.4	(20.9)
Bayer	247.9	193.9	54.0
Other revenue	86.2	56.5	29.7
Total revenues	$1,511.5	$1,319.0	$ 192.5

Net Product Sales
Net product sales of EYLEA in the United States increased for the three months ended March 31, 2018, compared to the same period in 2017, due to higher sales volume.
Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions and credits/payments for sales-related deductions.

(In millions)	Rebates & Chargebacks	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
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

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Sanofi Collaboration Revenue

Sanofi Collaboration Revenue

(In millions)	Three Months Ended March 31, 2018	2017
Antibody:		
Reimbursement of Regeneron research and development expenses - Discovery Agreement	—	$48.1
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	$60.4	107.1
Reimbursement of Regeneron commercialization-related expenses	85.4	73.6
Regeneron's share of losses in connection with commercialization of antibodies	(74.8)	(108.4)
Other	17.3	11.3
Total Antibody	88.3	131.7
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses - Discovery Agreement	35.3	38.2
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	38.5	20.5
Reimbursement of Regeneron commercialization-related expenses	1.2	—
Other	26.2	20.0
Total Immuno-oncology	101.2	78.7
Total Sanofi collaboration revenue	$189.5	$210.4

The lower reimbursement of antibody research and development costs during the three months ended March 31, 2018, compared to the same period 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 Agreement ceased after 2017, and (ii) decreased reimbursement levels for Dupixent (dupilumab) under our License and Collaboration Agreement subsequent to U.S. regulatory approval for atopic dermatitis. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi funded $130.0 million of our antibody discovery activities in 2017.

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 months ended March 31, 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 months ended March 31, 2018, Sanofi collaboration revenues in connection with commercialization of antibodies were positively impacted, compared to the same period 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. 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.

The following table summarizes global net product sales recorded by Sanofi in connection with our Antibody License and Collaboration Agreement:

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(In millions)	Three Months Ended March 31, 2018	2017
Praluent in the United States	$31.7	$25.4
Praluent outside of the United States	28.2	10.5
Praluent global	$59.9	$35.9
Dupixent in the United States	$116.8	—
Dupixent outside of the United States	14.6	—
Dupixent global	$131.4	—
Kevzara in the United States	$9.3	—
Kevzara outside of the United States	3.1	—
Kevzara global	$12.4	—

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.

Sanofi's reimbursement of immuno-oncology research and development costs under our IO License and Collaboration Agreement increased in the first quarter of 2018, compared to the same period 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

Bayer Collaboration Revenue (In millions)	Three Months Ended March 31, 2018	2017
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$232.1	$174.9
Reimbursement of Regeneron EYLEA development expenses	3.5	2.4
Other	11.8	10.6
Total EYLEA	247.4	187.9
Ang2 antibody and PDGFR-beta antibody:		
Reimbursement of development expenses	0.5	3.9
Other	—	2.1
Total Ang2 antibody and PDGFR-beta antibody	0.5	6.0
Total Bayer collaboration revenue	$247.9	$193.9

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

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Regeneron's Net Profit from EYLEA Sales Outside the United States	Three Months Ended March 31,	
(In millions)	2018	2017
Net product sales outside the United States	$624.0	$483.9
Regeneron's share of collaboration profit from sales outside the United States	$245.1	$188.5
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(13.0)	(13.6)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$232.1	$174.9

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

Other Revenue	Three Months Ended March 31,	
(In millions)	2018	2017
Teva collaboration revenue:		
Reimbursement of Regeneron research and development expenses	$39.1	$22.1
Other	19.5	11.0
Total Teva collaboration revenue	58.6	33.1
Other revenue	27.6	23.4
Total other revenue	$86.2	$56.5

In September 2016, we and Teva entered into a collaboration agreement to develop and commercialize fasinumab. Other Teva collaboration revenue in the first quarter of 2018 includes recognition of a portion of deferred revenue from a $250.0 million up-front payment and development milestones paid by Teva to us.

"Other revenue" in the table above includes:

- Recognition of a portion of deferred revenue from up-front and other payments received 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 amortization of the $165.0 million up-front payment we received in August 2010, which was deferred upon receipt and is 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 $86.2 million in total other revenue for the first quarter of 2018 also includes the impact of adopting Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, as 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.

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Expenses

(In millions)	Three Months Ended March 31, 2018	2017	Increase (Decrease)
Research and development	$498.6	$507.4	$ (8.8)
Selling, general, and administrative	330.8	296.8	34.0
Cost of goods sold	69.2	61.3	7.9
Cost of collaboration and contract manufacturing	45.7	22.9	22.8
Total operating expenses	$944.3	$888.4	$ 55.9
Average headcount	6,401	5,505	896

Our average headcount in 2018 increased compared to 2017 principally in connection with expanding our manufacturing activities.

Operating expenses in the first quarter of 2018 and 2017 included a total of $82.4 million and $133.8 million, respectively, of non-cash compensation expense related to employee stock options and restricted stock. The decrease in total non-cash compensation expense in the first quarter of 2018 was primarily attributable to a revision in our estimate of the number of stock options that are expected to be forfeited.

Research and Development Expenses

The following table summarizes our estimates of direct research and development expenses by clinical development program and other significant categories of research and development expenses. Direct research and development expenses are comprised primarily of costs paid to third parties for clinical and product development activities, including costs related to preclinical research activities, clinical trials, drug filling, packaging, and labeling, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse. Indirect research and development expenses have not been allocated directly to each program, and primarily consist of costs to compensate personnel, overhead and infrastructure costs to maintain our facilities, costs to manufacture bulk drug product (including pre-launch commercial supplies which were not capitalized as inventory) at our manufacturing facilities, and other costs related to activities that benefit multiple projects.

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Research and Development Expenses (In millions)	Three Months Ended March 31, 2018	2017	Increase (Decrease)
Direct research and development expenses:			
Dupilumab	$34.6	$49.7	$ (15.1)
Cemiplimab	41.0	15.0	26.0
Fasinumab	62.2	35.9	26.3
Alirocumab	17.9	21.3	(3.4)
Other product candidates in clinical development and other research programs	51.9	68.9	(17.0)
Total direct research and development expenses	207.6	190.8	16.8
Indirect research and development expenses:			
Payroll and benefits	130.1	145.6	(15.5)
Clinical manufacturing costs	78.4	107.4	(29.0)
Research, licensing, and other development costs	23.6	13.6	10.0
Occupancy and other operating costs	58.9	50.0	8.9
Total indirect research and development expenses	291.0	316.6	(25.6)
Total research and development expenses	$498.6	$507.4	$ (8.8)

Direct research and development expenses increased for cemiplimab and fasinumab in the first quarter of 2018, compared to the same period in 2017, primarily due to continued late-stage clinical development activities and the initiation of additional clinical studies, partly offset by a decrease in direct research and development expenses for dupilumab due to the wind-down and/or completion of various atopic dermatitis clinical studies. Clinical manufacturing costs decreased in the first quarter of 2018, compared to the same period in 2017, primarily due to a higher proportion of commercial manufacturing at our facilities. Research and development expenses included non-cash compensation expense of $40.8 million and $73.5 million in the first quarter of 2018 and 2017, respectively.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors." There is also variability in the duration and costs necessary to develop a pharmaceutical product, potential opportunities and/or uncertainties related to future indications to be studied, and the estimated cost and scope of the projects. The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business. We are unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased in the first quarter of 2018, compared to the same period in 2017, primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses to support the launch of Dupixent. Selling, general, and administrative expenses also included non-cash compensation expense of $35.0 million and $53.8 million in the first quarter of 2018 and 2017, respectively.

Cost of Goods Sold

Cost of goods sold increased for the three months ended March 31, 2018, compared to the same periods in 2017, principally due to an increase in period costs for our Limerick manufacturing facility.

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Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased for the three months ended March 31, 2018, compared to the same period in 2017, primarily due to manufacturing costs in connection with higher sales volumes of Sanofi collaboration antibodies.

Other Income and Expense

Other income, net, in the first quarter of 2018 increased primarily due to (i) the recognition of unrealized gains on equity securities and (ii) increased interest income earned on debt securities due to higher average investment balances. In the first quarter of 2018, we adopted Accounting Standards Update (ASU) 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, as of January 1, 2018, which requires us to measure equity investments at fair value with changes in fair value recognized in net income; previously, such changes in fair value were recognized in Other comprehensive income (loss).

Income Taxes

	Three Months Ended March 31,	
(In millions)	2018	2017
Income tax expense	$107.4	$183.4
Effective tax rate	18.3 %	42.4 %

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, includes a number of provisions that impact us, including 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 immediate expensing of the cost for qualified assets, repealing the deduction for domestic manufacturing, and imposing further limitations on the deductibility of executive compensation. Changes in tax rates and tax laws are accounted for in the period of enactment. Therefore, 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 our U.S. net deferred tax assets at the lower enacted corporate tax rates. The provisional charge recorded in the fourth quarter of 2017 is an estimate and subject to further analysis, interpretation, and clarification of the Act, which could result in changes to this estimate during 2018.

The first quarter 2018 effective tax rate was positively impacted, compared to the U.S. federal statutory rate, primarily by the foreign-derived intangible income deduction and the federal tax credit for research activities. The first quarter 2017 effective tax rate was negatively impacted, compared to the U.S. federal statutory rate, 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, partly offset by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for increased research activities.

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Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	March 31, 2018	December 31, 2017	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	$1,019.5	$812.7	$ 206.8
Marketable securities - current	605.5	596.8	8.7
Marketable securities - noncurrent	1,822.0	1,486.5	335.5
	$3,447.0	$2,896.0	$ 551.0
Working capital:			
Current assets	$4,544.7	$4,335.0	$ 209.7
Current liabilities	1,265.7	1,135.5	130.2
	$3,279.0	$3,199.5	$ 79.5

Additionally, as of March 31, 2018, we had borrowing availability of $750.0 million under a revolving credit facility (see further description under "Credit Facility" below).

Sources and Uses of Cash for the Three Months Ended March 31, 2018 and 2017

(In millions)	March 31, 2018	March 31, 2017	Increase (Decrease)
Cash flows provided by operating activities	$618.7	$355.9	$ 262.8
Cash flows used in investing activities	$(425.4)	$(140.1)	$ (285.3)
Cash flows provided by financing activities	$13.4	$60.8	$ (47.4)

Cash Flows from Operating Activities

Our net income of $478.0 million in the first quarter of 2018 included Non-cash Compensation Expense of $82.4 million. Cash flows from operating activities in the first quarter of 2018 were positively impacted by $32.5 million in connection with changes in other assets and liabilities.

Our net income of $248.9 million in the first quarter of 2017 included Non-cash Compensation Expense of $133.8 million. Deferred tax assets as of March 31, 2017 increased by $41.0 million, compared to December 31, 2016, primarily due to Non-cash Compensation Expense. Accounts payable, accrued expenses, and other liabilities increased by $187.7 million as of March 31, 2017, compared to December 31, 2016, primarily due to higher tax-related liabilities partly offset by lower payroll-related liabilities as our year-end 2016 employee cash bonuses were paid in the first quarter of 2017.

Cash Flows from Investing Activities

Capital expenditures were $79.4 million and $50.5 million in the first quarter of 2018 and 2017, respectively. Capital expenditures increased primarily due to higher capital expenditures in connection with renovations and additions at our Limerick, Ireland and Rensselaer, New York manufacturing facilities. We expect to incur capital expenditures of approximately $340 million to $400 million during the last three quarters of 2018 primarily in connection with expanding a portion of our manufacturing facilities at our Rensselaer, New York facility, continued renovations and expansion of our Limerick, Ireland facility, and laboratory expansion and renovations at our Tarrytown, New York facilities.

Cash Flows from Financing Activities

In the first quarter of 2017, proceeds in connection with capital and facility lease obligations relate to our receipt of $57.0 million in connection with the March 2017 lease transaction as described below under "Tarrytown, New York Leases".

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Credit Facility

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a $750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of March 31, 2018.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Credit Facility as of March 31, 2018.

Tarrytown, New York Leases

We lease laboratory and office facilities in Tarrytown, New York (the Facility). In 2016, we entered into a Purchase Agreement with the then lessor, pursuant to which we agreed to purchase the Facility for a purchase price of $720.0 million. In March 2017, we entered into a Participation Agreement with Banc of America Leasing & Capital LLC (BAL), as lessor, and a syndicate of lenders (collectively, the Participants), which provided for lease financing in connection with the acquisition by BAL of the Facility and our lease of the Facility from BAL. In March 2017, we assigned our right to take title to the Facility under the Purchase Agreement to BAL, and the Participants advanced $720.0 million, which was used by BAL to finance the purchase price for the Facility.

Concurrent with entering into the Participation Agreement, we also entered into a lease agreement (the Lease) for the Facility with BAL for a five-year term. The Lease requires us to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month London Interbank Offered Rate (LIBOR), plus an applicable margin that varies with our debt rating and total leverage ratio.

The Participation Agreement and the Lease include an option for us to elect to extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. We also have the option prior to the end of the term of the Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Participation Agreement, all accrued and unpaid interest and yield thereon, and all other outstanding amounts under the Participation Agreement, the Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL. The advances under the Participation Agreement mature, and all amounts outstanding thereunder will become due and payable in full at the end of the term of the Lease.

The Participation Agreement and the Lease contain financial and operating covenants, which are substantially similar to the covenants set forth in our Credit Facility. We were in compliance with all covenants of the Participation Agreement and the Lease as of March 31, 2018.

Sanofi Funding of Certain Development Costs

As described above in "Collaborations - Collaborations with Sanofi," effective January 7, 2018, we and Sanofi entered into a Letter Agreement in connection with, among other matters, increasing the development budget amount for cemiplimab and allocating additional funds to certain proposed activities relating to the development of dupilumab and REGN3500 and non-approval trials of dupilumab. Pursuant to the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to cemiplimab development and/or 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.

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Critical Accounting Policies and Use of Estimates

A summary of our critical accounting policies and use of estimates are presented in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (filed February 8, 2018). Except as described in Note 1 and Note 3 to our Condensed Consolidated Financial Statements included in this report related to the adoption of ASC 606, Revenue from Contracts with Customers, there were no material changes to our critical accounting policies and use of estimates during the three months ended March 31, 2018.

Future Impact of Recently Issued Accounting Standards

See Note 12 to our Condensed Consolidated Financial Statements for a summary of recently issued accounting standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (filed February 8, 2018). There have been no material changes to our market risks or to our management of such risks as of March 31, 2018.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 11 to our Condensed Consolidated Financial Statements included in this report.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products

We are substantially dependent on the success of EYLEA.

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For each of the three months ended March 31, 2018 and 2017, EYLEA net sales in the United States represented 65% of our total revenues. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer are unable to maintain current marketing

approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

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If we or our collaborators are unable to continue to successfully commercialize our products, our business, prospects, operating results, and financial condition will be materially harmed.

We expect that the continued commercial success of our marketed products (in particular, EYLEA, Dupixent, Praluent, and Kevzara) will depend on many factors, including the following (as applicable):

- effectiveness of the commercial strategy in and outside the United States for the marketing of our products, including pricing strategy;
- sufficient coverage of, and reimbursement for, our marketed products by third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions, as well as payer restrictions on eligible patient populations and the reimbursement process, both in the United States and abroad;
- our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development; and, in the case of EYLEA, the willingness of retinal specialists and patients to switch from Lucentis® (ranibizumab) or off-label use of repackaged Avastin® (bevacizumab) to EYLEA or to start treatment with EYLEA;
- maintaining and successfully monitoring commercial manufacturing arrangements for our marketed products with third parties who perform fill/finish or other steps in the manufacture of such products to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of our marketed products;
- the outcome of the pending patent infringement proceedings relating to Dupixent and Praluent (described further in Note 11 to our Condensed Consolidated Financial Statements included in this report), and other risks relating to our marketed products associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below;
- the results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and studies of other products that could implicate an entire class of products or are perceived to do so; and
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices.

More detailed information about the risks related to the commercialization of our marketed products is provided in the risk factors below.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the marketed products subject to such collaborations. If we or our collaborators fail to maintain regulatory compliance for any of such products, the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the marketed products subject to such collaborations (such as EYLEA, Dupixent, Praluent, and Kevzara) for the products' currently approved indications in the United States, EU, and other countries where such products are approved. If we or our collaborators fail to maintain regulatory compliance for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies, or for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain"), the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we

could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales" below.

Serious complications or side effects in connection with the use of our marketed products could materially harm our business, prospects, operating results, and financial condition.

Serious complications or serious, unexpected side effects in connection with the use of our marketed products (such as EYLEA, Dupixent, Praluent, and Kevzara) could materially harm our business, prospects, operating results, and financial condition. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - Serious

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complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition" below.

Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales of our marketed products (such as EYLEA, Dupixent, Praluent, and Kevzara) in the United States are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of our marketed products in other countries are dependent, in large part, on similar reimbursement mechanisms and programs in those countries.

Our future revenues and profitability will be adversely affected in a material manner if such third-party payers do not adequately defray or reimburse the cost of our marketed products to the patients. If these entities do not provide coverage and reimbursement with respect to our marketed products or provide an insufficient level of coverage and reimbursement, such products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payers more expensive for patients. Third-party payers may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply and regulatory review of such products. Given cost sensitivities in many health care systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our marketed products, we must, among other things, maintain our FDA registration and our National Drug Code, maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and the Centers for Medicare & Medicaid Services (CMS). There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage) of our current and future marketed products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process, including by means of required prior authorizations and utilization management criteria. In March 2010, the federal Patient Protection and Affordable Care Act (PPACA) and a related reconciliation bill were enacted in the United States. This legislation imposes cost-containment and other measures affecting the amount of reimbursement for our current and future products. The full effects of this legislation depend on a number of factors, many of which are beyond our control, including new regulations and guidance issued by CMS and other federal and state agencies. Some states are also considering legislation that would control the prices and reimbursement of prescription drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform measures in the future that will impose additional constraints on prices and reimbursements for our marketed products.

In addition, pharmacy benefit management companies often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one pharmacy benefit management

company to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our marketed products. If our marketed products are not included within an adequate number of formularies, adequate reimbursement levels are not provided, the eligible insured patient population for our products is limited, or a key payer refuses to provide reimbursement for our products in a particular jurisdiction altogether, this could have a material adverse effect on our and our collaborators' ability to commercialize the applicable product.

In the United States, there also is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. For example, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-label, repackaged Avastin rather than Lucentis for the treatment of wet AMD. A reduction in the availability or extent of reimbursement from U.S.

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government programs could have a material adverse effect on the sales of EYLEA or our other marketed products. Economic pressure on state budgets may also have a similar impact. Since our marketed products are too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers in the United States and other countries, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize our products will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our marketed products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our marketed products in foreign countries is limited or delayed.

The commercial success of our products and product candidates is subject to strong competition.

Marketed Products

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. There is significant actual and potential future competition for each of our marketed products.

EYLEA. The market for eye disease products is very competitive. For example, Novartis AG and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of various eye indications. Lucentis is approved in one or more jurisdictions for the treatment of wet AMD, macular edema following RVO (including CRVO and BRVO), DME, diabetic retinopathy, and mCNV. In addition, we are aware of several companies developing biosimilar versions of EYLEA. For example, Momenta Pharmaceuticals, Inc. (in partnership with Mylan N.V.) is developing M710 (currently in a pivotal trial in patients with DME). Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Pfenex Inc. is developing PF582 (a Phase 1b/2a trial in patients with wet AMD has been completed), Formycon AG (in collaboration with Bioeq GmbH) is developing FYB201 (currently in a Phase 3 trial in patients with wet AMD), and Samsung Bioepis Co., Ltd. is developing SB11 (currently in a Phase 3 trial in patients with wet AMD).

Other competitive or potentially competitive products include Allergan plc's Ozurdex® (dexamethasone intravitreal implant) (approved by the FDA for the treatment of macular edema following RVO and for the treatment of DME) and Alimera Sciences, Inc.'s Iluvien® (fluocinolone acetonide intravitreal implant) (approved by the FDA for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids. Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, and RVO, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, Genentech/Roche is developing a Lucentis port delivery system implant (currently in a Phase 2 study in patients with wet AMD). Novartis is developing RTH258 (brolucizumab), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and announced in June 2017 that two Phase 3 studies of RTH258 met their primary endpoint

of non-inferiority to EYLEA. Allergan is developing abicipar pegol for wet AMD and related conditions (currently studied in Phase 3 trials against Lucentis as a comparator drug). Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, Ang2). Genentech/Roche is developing a bi-specific antibody (RG7716) targeting both VEGF and Ang2 for wet AMD and DME (currently in Phase 2 trials for both indications). Products that are being developed for use in combination with EYLEA and/or Lucentis may also pose a competitive threat. Opthea Limited is developing OPT-302, a VEGFR-3 large molecule trap in combination with Lucentis in a Phase 2 trial for wet AMD. Santen Pharmaceuticals Co. Ltd. (in partnership with TRACON Pharmaceuticals, Inc.) is developing DE-122, an anti-endoglin antibody in combination with Lucentis in a Phase 2 trial for wet AMD. Small-molecule tyrosine kinase inhibitors that have activity against VEGF may also compete against EYLEA, if approved for wet AMD and/or related conditions. Graybug Vision, Inc. is developing GB-102, an intravitreally administered depot formulation of the small molecule tyrosine kinase inhibitor, sunitinib, in a Phase 1/2 trial for wet AMD. Tyrogenex, Inc. is developing X-82, an orally administered small-molecule

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tyrosine kinase inhibitor, in a Phase 2 trial in combination with an anti-VEGF. Competitors are also developing other eye-drop formulations, devices, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

In addition, ophthalmologists are using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, Avastin, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged Avastin presents a significant competitive challenge in these indications. Avastin is also being evaluated in eye diseases in clinical trials in certain countries. Furthermore, Lucentis and off-label use of repackaged Avastin present significant competitive challenges as doctors and patients have had significant experience using these medicines. The relatively low cost of repackaged Avastin in treating patients may exacerbate the competitive challenge which EYLEA faces in the eye indications for which it is approved. Amgen Inc. (in collaboration with Allergan) has obtained regulatory approval of a biosimilar version of Avastin in the United States and the EU, and other competitors are also developing a biosimilar version of Avastin. Off-label use of any such biosimilar in one or more of the eye indications for which EYLEA is approved may put further pressure on the commercialization of EYLEA.

Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, and there is a risk that third parties may attempt to repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye.

Dupixent. A number of companies are developing antibodies that, if approved, may compete with Dupixent in its current or potential future indications, including Roche (in collaboration with Dermira, Inc.) (an antibody against IL-13); LEO Pharma A/S (in collaboration with AstraZeneca PLC) (IL-13 antibody tralokinumab being developed in the atopic dermatitis indication); AstraZeneca (antibodies against IL-4R and IL-5R); Galderma S.A. (an antibody against IL-31R); AnaptysBio, Inc. (an antibody against IL-33); and Amgen (in collaboration with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). GlaxoSmithKline plc's Nucala® (mepolizumab) and Teva Pharmaceutical Industries Ltd.'s Cinqair® (reslizumab), both of which are antibodies against IL-5, may also compete with Dupixent in its current or potential future indications. We are also aware of companies developing or marketing small molecules that may compete with Dupixent in its current or potential future indications. These include Pfizer Inc.'s Eucrisa® (crisaborole), a topical ointment that competes with Dupixent in the atopic dermatitis indication; and JAK inhibitors, such as AbbVie Inc.'s upadacitinib, Pfizer's PF-04965842, and Eli Lilly and Company's Olumiant® (baricitinib).

Praluent. Amgen's Repatha® (evolocumab) has already received regulatory approvals in jurisdictions including the U.S., the EU, and Japan. Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Repatha has also received regulatory approval for cardiovascular risk reduction. Other companies with development programs for injectables against PCSK9 include Alnylam Pharmaceuticals, Inc. (in collaboration with The Medicines Company), which has a clinical program underway with inclisiran, an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including oral products and vaccines. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including Praluent. These include bempedoic acid, which is being developed by Esperion Therapeutics, Inc., and gemcabene, which is being developed by Gemphire Therapeutics Inc.

Kevzara. Genentech/Roche and Chugai Pharmaceutical Co., Ltd. are marketing an antibody against IL-6R (Actemra® (tocilizumab)) for the treatment of rheumatoid arthritis that competes with Kevzara. In addition, several other companies, including Alder Biopharmaceuticals, Inc. (in collaboration with Vitaeris Inc. and CSL Limited), Ablynx NV, R-Pharm JSC, BIOCAD, Mycenax Biotech Inc., MICROBIO Group, and Bird Rock Bio, Inc. have antibodies against IL-6 or IL-6R in clinical development. Further, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz® (tofacitinib), Eli Lilly's Olumiant, Gilead Sciences, Inc.'s filgotinib, and AbbVie's upadacitinib may pose a competitive threat for Kevzara.

Product Candidates

Our other late-stage and earlier-stage clinical candidates in development are all fully human antibodies, which were generated using our VelocImmune technology. Our antibody generation technologies and other late-stage and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody-based products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody-based product candidate against NGF. For cemiplimab, there are several competitors that are marketing or developing antibodies against PD-1 and/or PDL-1, including Bristol-Myers Squibb Company's Opdivo® (nivolumab), Merck & Co., Inc.'s Keytruda® (pembrolizumab), Roche's Tecentriq® (atezolizumab), AstraZeneca's Imfinzi® (durvalumab), Pfizer's Bavencio® (avelumab), Novartis's PDR001, and Celgene Corporation/BeiGene Ltd.'s BGB-A317. Competitors to evinacumab include Ionis Pharmaceuticals, Inc./Akcea Therapeutics, Inc.’s AKCEA-ANGPTL3-LRx, a ligand conjugated antisense drug against ANGPTL3. We are also aware of several companies developing or marketing small molecules

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that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

We rely on our collaborations with Bayer and Sanofi for commercializing EYLEA and Dupixent, Praluent, and Kevzara, respectively.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA outside the United States. Under the terms of our license and collaboration agreement with Bayer (which is terminable by Bayer at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination), we rely on Bayer for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, while we have elected to co-promote Dupixent, Praluent, and Kevzara with Sanofi in the United States in accordance with the terms of our Antibody Collaboration, we continue to rely in part on Sanofi's sales and marketing organization in the United States. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of Dupixent, Praluent, or Kevzara (as applicable) may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent, Praluent, and Kevzara in the United States. For example, Sanofi records product sales for Dupixent, Praluent, and Kevzara in the United States, serves as the lead regulatory party for certain products and product candidates included in the Antibody Collaboration (e.g., is responsible for regulatory filings and negotiations relating to such products and product candidates) in the United States, and may lead negotiations with payors relating to such products and product candidates. We also rely on Sanofi for sales, marketing, and distribution of Dupixent, Praluent, and Kevzara in countries outside the United States.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see "Risks Related to Our Reliance on Third Parties - If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed" below and "Risks Related to Our Reliance on Third Parties - If any of our collaborations with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed" below.

Sales of our marketed products recorded by us and our collaborators could be reduced by imports from countries where such products may be available at lower prices.

Our sales of EYLEA in the United States, Bayer's sales of EYLEA in other countries, and sales of Dupixent, Praluent, and Kevzara recorded by Sanofi in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under our Antibody Collaboration with Sanofi and, therefore, our results of operations) may be reduced if the applicable product is imported into those countries from lower priced

markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or otherwise alter the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. Similarly, under our Antibody Collaboration with Sanofi, pricing and reimbursement for Dupixent, Praluent, and Kevzara outside the United States is the responsibility of Sanofi. Prices for our marketed products in jurisdictions outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United

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States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced.

We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture, market, and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payers, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the three months ended March 31, 2018, product sales to two customers accounted on a combined basis for 95% of our total gross product revenue. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and do not currently have an organization for the sales, marketing, and distribution of marketed products outside the United States. There may be circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to exercise our option to co-promote a product outside the United States or commercialize a particular product independently; we are unable to find an appropriate collaborator; or our existing collaborator decides not to opt in, decides to opt out, or breaches its obligations to us with respect to a particular product.

In order to commercialize any products outside the United States, we must build our sales, marketing, distribution, managerial, and other non-technical capabilities in the relevant markets or make arrangements with third parties to perform these services, which would likely be expensive and time consuming and could delay product launch in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop commercial capabilities outside the United States within an acceptable time frame or at all. These and other difficulties relating to commercializing our products outside the United States may severely harm our business, prospects, operating results, and financial condition.

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Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products

If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.

We cannot sell or market products without regulatory approval. If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products, the value of our Company and our business, prospects, operating results, and financial condition will be materially harmed. If we are unable to obtain regulatory approval for our product candidates, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition may be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

In certain instances (such as when we use a biomarker-based test to identify and enroll specific patients in a clinical trial), regulatory approval of a companion diagnostic to our therapeutic product candidate may be required as a condition to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. Its ability to do so has been enhanced by the Food and Drug Administration Amendments Act of 2007, pursuant to which the FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. Standard review can be accomplished in a 10-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug

application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within six months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. Even if any of our applications receives a priority review designation, we may not ultimately be able to obtain approval of our application within a time frame consistent with the FDA's stated review goals or at all, and such designation may not actually lead to a faster development or regulatory review or approval process.

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The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional inspections or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for Kevzara, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi facility in Le Trait, France where Kevzara is filled and finished; while the BLA for Kevzara has since been approved by the FDA, this delayed the FDA approval of Kevzara. For additional information, see "Risks Related to Manufacturing and Supply - If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales." Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to

other products or product candidates), difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to the FDA's Good Laboratory Practices (GLPs) or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates

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for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.
Furthermore, some of our product candidates (such as cemiplimab) are studied in combination with agents and treatments developed by us or our collaborators. There may be additional risks and unforeseen safety issues resulting from such combined administration, any of which may materially adversely impact clinical development of these product candidates and our ability to obtain regulatory approval.
Successful development of our current and future product candidates is uncertain.
Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our Company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness, and clinical trials evaluating our product candidates failed to meet the relevant endpoints. For example, in August 2017, we reported that the Phase 3 study evaluating suptavumab, an antibody to RSV, did not meet its primary endpoint of preventing medically-attended RSV infections in infants; as a result, we have discontinued further clinical development of this antibody.
Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response Letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.
Many of our clinical trials are conducted under the oversight of independent Data Monitoring Committees (DMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible DMCs based on their review of such interim trial results. For example, in April 2018, the DMC monitoring the ongoing safety and efficacy of our Phase 3 clinical trials of fasinumab recommended that the higher dose-regimens be discontinued based on the risk-benefit assessment and that the program may continue with lower dose-regimens of fasinumab. The recommended termination or material modification of any of our ongoing late-stage clinical trials by a DMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.
We are studying our antibody-based product candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our Company.

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Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

With respect to EYLEA, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize EYLEA. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like aflibercept (such as intraocular inflammation (IOI), sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), which can cause injury to the eye and other complications. The side effects previously reported for EYLEA include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. In addition, commercialization of EYLEA or our other products may be impacted by actions of third parties on which we rely, such as manufacturers of syringes or other devices used in the administration of our products. For example, in February 2018, we issued a letter to healthcare professionals providing updated guidance relating to reports of IOI following EYLEA injections. In this letter, we noted that while our review did not identify any association of IOI rates with the EYLEA drug itself, an association was seen with certain batches of the syringe that were included in specific lots of final packaged EYLEA kits. These and other complications or issues or side effects could harm further development and/or commercialization of EYLEA.

Dupilumab is being studied in additional indications, including atopic dermatitis in adolescent and pediatric patients, asthma, nasal polyps, and eosinophilic esophagitis. There is no guarantee that marketing approval of dupilumab in any of these indications will be successfully obtained. The side effects previously reported for dupilumab include hypersensitivity reactions, conjunctivitis and keratitis, injection-site reactions, eye and eyelid inflammation, and cold sores. These and other complications or side effects could harm further development and/or commercialization of dupilumab.

There also are risks inherent in subcutaneous injections (which are used for administering our antibody-based products and product candidates, including Dupixent, Praluent, and Kevzara), such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. These and other complications or side effects could harm further development and/or commercialization of our antibody-based products and product candidates, including Dupixent, Praluent, or Kevzara.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies

against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross-react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so neutralizing antibodies may be detected at a later date, in some cases even after pivotal clinical trials have been completed.

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We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody-based product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Many of our products are intended to be used and, if approved, our product candidates may be used in combination with drug-delivery devices, which may result in additional regulatory and other risks.

Many of our products (including Dupixent, Praluent, and Kevzara) are used and, if approved, some of our product candidates may be used in combination with a drug-delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. The success of our product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application and the additional risks resulting from a product candidate's designation as a combination product discussed below, our product candidates used with such drug-delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. The FDA review process and criteria for such applications is not a well-established area, which could also lead to delays in the approval process. In addition, some of these drug-delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply the devices; to conduct the studies required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our Company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic, or device. The determination whether a product is a combination product or two separately regulated products is made by the FDA on a case-by-case basis. Although a single marketing application is generally sufficient for the approval, clearance, or licensure of a combination product, the FDA may determine that separate marketing applications are necessary. In addition, submitting separate marketing applications may be necessary to receive some benefit that accrues only from approval under a particular type of application. This could significantly increase the resources and time required to bring a particular combination product to market.

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Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our Company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 2,264,163 is the subject of opposition proceedings in the EPO, as described in Note 11 to our Condensed Consolidated Financial Statements included in this report. We have pending patent applications in the USPTO, the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review or inter partes review under the America Invents Act of 2011 or ex parte reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody-based products made using our VelocImmune technology, or any other of our technologies, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we are currently party to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent and patent infringement proceedings relating to Dupixent, as described in Note 11 to our Condensed Consolidated Financial Statements. In addition, we are currently party to patent infringement proceedings initiated by us relating to our European Patent No. 1,360,287, our European Patent No. 2,264,163, and our U.S. Patent No. 8,502,018, all of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Note 11 to our Condensed Consolidated Financial Statements.

We are aware of patents and pending patent applications owned by others that respectively claim antibodies to IL-4R and methods of treating conditions including atopic dermatitis and asthma with such antibodies; antibodies to IL-6R and methods of treating conditions including rheumatoid arthritis with such antibodies; antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies; and antibodies to PD-1 and methods of treating cancer with such antibodies. In addition to Dupixent (dupilumab), Praluent (alirocumab), and Kevzara (sarilumab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF; cemiplimab, an antibody to PD-1, intended for the treatment of certain cancer indications including advanced CSCC; and evinacumab, an antibody to ANGPTL3. With respect to Dupixent, we are aware of certain patents owned by Immunex Corporation, a wholly

owned subsidiary of Amgen. These patents include U.S. Patent No. 8,679,487 (currently subject to the patent infringement proceedings described in Note 11 to our Condensed Consolidated Financial Statements) and European Patent No. 2,292,665 (the '665 Patent) and are generally directed to antibodies that bind to IL-4R. On September 30, 2016, Sanofi initiated a revocation proceeding to invalidate the U.K. counterpart of the '665 Patent in the United Kingdom. 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 us 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, we 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,

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disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). The original patent term of the Immunex patents is set to expire in 2021.

Although we do not believe that any of our late-stage antibody-based product candidates infringes any valid claim in these patents or patent applications, these other parties could initiate lawsuits for patent infringement and assert that their patents are valid and cover our late-stage antibody-based product candidates, similar to the patent infringement proceedings referred to above. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our products or product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our products or product candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our products or product candidates infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business.

Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed," the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic, biosimilar, and/or interchangeable versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the PPACA, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened.

A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

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Risks Related to Manufacturing and Supply

We rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to continue to successfully commercialize EYLEA, to successfully commercialize Dupixent, Praluent, and Kevzara and, if approved, our product candidates or other indications for our marketed products, and to advance our clinical pipeline.

Our manufacturing facilities would be inadequate to produce the active pharmaceutical ingredients of (a) our current marketed products, including EYLEA, Dupixent, Praluent, and Kevzara, and (b) our antibody-based product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody-based product candidates, our current manufacturing capacity will likely not be sufficient, and we may depend on our collaborators or contract manufacturers, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and late-stage product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

We own an approximately 445,000-square-foot facility in Limerick, Ireland, which we purchased and subsequently renovated to expand our manufacturing capacity and support our global supply chain. In the future, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing activities. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. In addition, while the Limerick, Ireland facility has received certain manufacturing approvals by regulatory agencies, including the FDA, the facility remains subject to securing certain other governmental permits, and there is no guarantee that we will be able to obtain the remaining required permits in the contemplated timeframe, or at all. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product

candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, including EYLEA, Dupixent, Praluent, and Kevzara, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future, or to utilize third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. A judicial or regulatory decision in favor of one or more parties

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making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of EYLEA, Dupixent, Praluent, or Kevzara do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.

We have large-scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we or our collaborators experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

Third-party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York and Limerick, Ireland or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

We currently manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland. We would be unable to manufacture these materials if our Rensselaer and Limerick facilities were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, acts of war or terrorism, or other problems.

Many of our products and product candidates are very difficult to manufacture. As our products and product candidates are biologics, they require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us in a timely manner), could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time-consuming, and expensive to transfer our technology to our collaborators or contract manufacturers.

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties or our collaborators to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contaminations, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development or commercial activities may be

delayed or interrupted.

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If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facility in Rensselaer, New York, including EYLEA, Dupixent, Praluent, Kevzara, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for Kevzara, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi fill-and-finish facility in Le Trait, France. While the BLA for Kevzara has since been approved by the FDA, this delayed the FDA approval of Kevzara. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Regulatory and Litigation Risks

If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell approved products in a way that violates federal or state healthcare laws, we may be subject to civil or criminal penalties.

The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA's review of promotional activities includes healthcare provider-directed and direct-to-consumer advertising as well as sales representatives' communications. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.
Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting

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to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any "transfers of value" made to U.S. prescribers and certain other healthcare providers and teaching hospitals. Information provided by companies is aggregated and posted annually on an "Open Payments" website, which is managed by CMS, the agency responsible for implementing these disclosure requirements. We will need to continue to dedicate significant resources to comply with these requirements and to be prepared to comply with additional reporting obligations outside of the United States that may apply in the future. The PPACA also includes various provisions designed to strengthen fraud-and-abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, several states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that

all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, a number of which have yet to be fully implemented. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

The current U.S. administration and Congress could carry out significant changes in legislation, regulation, and government policy (including with respect to the possible repeal of all or portions of the PPACA, possible government reimbursement changes, and possible changes in the existing treaty and trade relationships with other countries), as evidenced by statements and recent actions of the current president and certain members of Congress. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our products could adversely affect our business. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA.

Risks associated with our operations outside of the United States could adversely affect our business.

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "Risks from the improper conduct of employees, agents,

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contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition");

- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- our ability to deploy overseas funds in an efficient manner;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

For example, on June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, the British government has begun negotiating the terms of the United Kingdom's future relationship with the EU. We do not know to what extent Brexit will impact the business and regulatory environment in the United Kingdom, the rest of the EU, or other countries. We have large-scale manufacturing operations in Limerick, Ireland and have also established an office in London. Changes impacting our ability to conduct business in the United Kingdom or other EU countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities that involve significant management judgment for uncertain tax positions. The Internal Revenue Service or other domestic or foreign taxing authorities may disagree with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country and changes in tax laws and regulations. Changes in tax laws of various jurisdictions in which we do business could also result from the base erosion and profits shifting, or BEPS, recommendations by the Organization for Economic Co-operation and Development. If these recommendations (or other changes in law) were adopted by the countries in which we do business, it could adversely affect our provision for income tax and our current rate.

On December 22, 2017, President Trump signed into law H.R.1., "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018" (also known as the "Tax Cuts and Jobs Act") (the Act). Most of the provisions of the Act went into effect on January 1, 2018. The Act includes a number of provisions that are expected to impact our operating results, cash flows, and financial condition, including reducing the U.S. federal corporate tax rate from 35% to 21%, changing the taxation of foreign earnings (including taxation of certain global intangible low-taxed income), allowing for immediate expensing of qualified assets, repealing the deduction for domestic manufacturing, and imposing further limitations on the deductibility of executive compensation.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with research institutions, including the Geisinger Health System, which

are subject to such regulations. Regeneron is not currently classified as a covered entity or business associate under HIPAA and thus is not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs and research collaborations outside the U.S. (such as our consortium with a group of companies

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to fund the generation of genetic exome sequence data from the UK Biobank health resource) may implicate international data protection laws, including the EU Data Protection Directive and the General Data Protection Regulation (GDPR) that is replacing it. Our activities outside the U.S. impose additional compliance requirements and generate additional risks of enforcement for noncompliance, including the new risk of substantial financial penalties for data breach or improper processing of personal data under the GDPR. Failure by our collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business and could create liability for us. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Risks Related to Our Reliance on Third Parties

If any of our collaborations with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from Sanofi to support certain research and development programs, including our immuno-oncology research and development programs. Sanofi has committed to reimburse us for up to $825.0 million of the costs of our efforts to identify and validate potential immuno-oncology targets and develop fully-human therapeutic antibodies against such targets under the IO Discovery and Development Agreement over the term of the IO Discovery and Development Agreement. Sanofi also initially funds almost all of the development expenses incurred in connection with the clinical development of product candidates for which Sanofi is the principal controlling party under our IO Collaboration. In addition, Sanofi initially funds half of the development expenses incurred in connection with the clinical development of product candidates for which we are the principal controlling party under our IO Collaboration. We rely on Sanofi to fund these activities. In addition, with respect to Dupixent, Praluent, Kevzara, and REGN3500, which Sanofi co-develops with us under our Antibody Collaboration, or for

products or product candidates for which Sanofi is the principal controlling party under our IO Collaboration, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we also rely on Sanofi to lead (i) the commercialization efforts of Dupixent, Praluent, Kevzara, and REGN3500 under our Antibody Collaboration and (ii) the commercialization efforts outside the Unites States to support all products that are co-developed by Sanofi and us under our IO Collaboration (as well as the commercialization efforts in the United States to support all products for which Sanofi is the principal controlling party under our IO Collaboration).

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If Sanofi does not elect to co-develop the product candidates discovered under our IO Collaboration or opts out of their development, unless we enter into a collaboration agreement with another party, we would be required to fund and conduct on our own the clinical trials, regulatory activities, and the ensuing commercialization efforts to support those antibody-based products. For example, under our Antibody Collaboration, Sanofi elected not to continue co-development of fasinumab and trevogrumab, and decided not to opt in to the evinacumab and other programs. In addition, as previously reported, we will now be required to fund all of our antibody discovery activities and the research and preclinical development activities of our drug candidates (other than those funded under the IO Discovery and Development Agreement or other collaboration agreements), as Sanofi's funding obligations under the Antibody Discovery Agreement have ceased.

If Sanofi terminates the License and Collaboration Agreement or the IO Collaboration or fails to comply with its payment obligations under any of our collaborations, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. If Sanofi does not perform its obligations with respect to the product candidates that it elects to co-develop, our ability to develop, manufacture, and commercialize these product candidates will be significantly adversely affected. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for products commercialized under our Antibody Collaboration, such as Dupixent, Praluent, and Kevzara, as well as cemiplimab and any other product candidates potentially commercialized under our IO Collaboration (see also "Risks Related to Commercialization of Products - If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected" above). Termination of the License and Collaboration Agreement or the IO License and Collaboration Agreement would create substantial new and additional risks to the successful development and commercialization of (i) Dupixent, Praluent, and Kevzara and (ii) cemiplimab and any other product candidate potentially commercialized under the IO License and Collaboration Agreement, respectively, particularly outside the United States.

If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed.

We rely heavily on Bayer with respect to the commercialization of EYLEA outside the United States. Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to commercialize EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the commercialization of EYLEA outside the United States and result in substantial additional costs to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also "Risks Related to Commercialization of Products - If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA outside the United States.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi, Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third-party manufacturers, fill/finish providers, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of our marketed products and our late-stage product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner (including as a result of its inability to perform due to financial or other relevant constraints) or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators'

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arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer; and Neil Stahl, Ph.D., our Executive Vice President, Research and Development. As we continue to commercialize EYLEA, Dupixent, Praluent, and Kevzara and, assuming the receipt of required regulatory approvals, other products, we are also highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses, which may impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property, result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Such disruptions and breaches of security could result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing

If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.

Beginning in 2012, we reported profitability; prior to that, we generally incurred net losses. If we cannot sustain profitability, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our sales of EYLEA, our share of the profits from Bayer's sales of EYLEA outside the United States, funding we receive under our collaboration agreements, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible

commercialization of our other product candidates and new indications of our marketed products.

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We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the commercialization of our marketed products and the potential commercial launches of our product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody-based product candidates we are developing on our own (without a collaborator), and expenses for which we are responsible in accordance with the terms of our collaboration agreements.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable terms or at all. For example, in March 2017, we completed a $720.0 million lease financing for our existing corporate headquarters and other rentable area consisting of approximately 170 acres of predominately office buildings and laboratory space located in the towns of Mount Pleasant and Greenburgh, NY, which will become due and payable in full on the five-year anniversary of the closing date unless extended with the consent of all the participants and subject to certain other conditions. Our ability to refinance or to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of our marketed products, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

Changes in foreign currency exchange rates could have a material adverse effect on our operating results.

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our Company.

Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.

As of March 31, 2018, we had $1,019.5 million in cash and cash equivalents and $2,427.4 million in marketable securities (including $69.1 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant

volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

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Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- net product sales of our marketed products, in particular EYLEA and Dupixent, as well as our overall operating results;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and the market share for, our marketed products, especially EYLEA and Dupixent;
- whether our net product sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the EPO and in the USPTO;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management companies) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding (i.e., a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient);
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been maintaining its percentage ownership of our Common Stock but has previously publicly disclosed that it may opportunistically increase its percentage ownership of our Common Stock (note, however, that we have agreed to

grant a limited waiver of the requirement that Sanofi maintain the Highest Percentage Threshold (as defined below) as a condition to its director designation right during the term of the letter agreement with Sanofi described below under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management"). As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of

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volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 12, 2018, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 45.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 12, 2018. As of April 12, 2018, Sanofi beneficially owned 23,880,537 shares of our Common Stock, representing approximately 22.5% of the shares of Common Stock then outstanding. Under our January 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time are subject to a "lock-up" and may not be sold until December 20, 2020 (other than with respect to an aggregate of up to 1,400,000 shares, as to which we have agreed to waive the lock-up during the term of the letter agreement with Sanofi described below under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management"). These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our Company. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase (subject to market conditions, including the price and availability of shares of our Common Stock, and legal and regulatory requirements) additional shares of our Common Stock to maintain and opportunistically increase its beneficial ownership on a percentage basis up to the maximum allowed under the "standstill" provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market (including, in the case of Sanofi, as a result of the lock-up waiver referred to above), or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 12, 2018, holders of Class A Stock held 15.3% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 12, 2018:

- our current executive officers and directors beneficially owned 10.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2018, and 21.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2018; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 45.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 12, 2018. In addition, these five shareholders plus our Chief Executive Officer held approximately

51.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 12, 2018. Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our Company, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

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In addition, we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as (other than during the term of the letter agreement described below) Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition of 20% of our outstanding shares of Class A Stock and Common Stock (taken together) (which occurred in April 2014), and (ii) 25% of our outstanding shares of Class A Stock and Common Stock (taken together) (Highest Percentage Threshold). This designee is required to be "independent" of our Company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi. The current Sanofi designee, N. Anthony Coles, M.D., is a Class II director whose current term expires at the 2020 annual shareholder meeting.

Effective January 7, 2018, we and Sanofi and certain of Sanofi's direct and indirect subsidiaries entered into a letter agreement in connection with (a) the increase of the development budget amount for cemiplimab set forth in the IO License and Collaboration Agreement and (b) the allocation of additional funds to certain proposed activities relating to the development of dupilumab and REGN3500 and non-approval trials of dupilumab (the Dupilumab/REGN3500 Eligible Investments). Pursuant to the letter agreement, we have agreed, among other things, to grant a limited waiver of Sanofi's obligation to maintain the Highest Percentage Threshold during the term of the letter agreement in order to allow Sanofi to satisfy in whole or in part (a) its funding obligations with respect to the cemiplimab development costs under the IO License and Collaboration Agreement for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to 800,000 shares of our Common Stock directly or indirectly owned by Sanofi and (b) its funding obligations with respect to the costs incurred by or on behalf of the parties to the Antibody License and Collaboration Agreement 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 600,000 shares 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 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. In addition, we and Sanofi have agreed that, upon termination of the letter agreement, the amended and restated investor agreement will be amended to define "Highest Percentage Threshold" as the lower of (i) 25% of our outstanding shares of Class A Stock and Common Stock (taken together) and (ii) the higher of (a) Sanofi's percentage ownership of Class A Stock and Common Stock (taken together) on such termination date and (b) the highest percentage ownership of our outstanding shares of Class A Stock and Common Stock (taken together) Sanofi attains following such termination date.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements, could deter, delay, or prevent an acquisition or other "change of control" of us and could adversely affect the price of our Common Stock.

Our certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our Company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual shareholder meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our Company and an "interested shareholder," a plan of merger or consolidation of our Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management."

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Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our Company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our License and Collaboration Agreement with Sanofi relating to our Antibody Collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our Company.

Similarly, under our 2016 ANG2 license and collaboration agreement with Bayer, Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of our Company or acquiring more than 20% of our outstanding Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our Company; (iii) the acquisition by a third party or a group of third parties (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer; or (v) other specified events, such as a liquidation or dissolution of our Company.

Further, pursuant to the 2016 collaboration agreement between us and Teva, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of our Company or acquiring more than 5% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the acquisition by a third party or a group of third parties of more than 30% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (v) the date of any issuance of shares of capital stock by us that would result in another party having more than 10% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Teva; or (vi) other specified events, such as a liquidation or dissolution of our Company.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our Company. Also, stock option awards issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, our 2014 Long-Term Incentive Plan, and our Amended and Restated 2014 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our Company, as defined in the plans. Further, under the amended and restated investor agreement between us and Sanofi, we are required to appoint an individual agreed upon by us and Sanofi to our board of directors and to use our reasonable efforts to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains a specified equity interest in us. As described above under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management," a Sanofi designee currently serves on our board of directors. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

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ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1 +	Retirement Agreement, effective as of January 5, 2018, by and between Regeneron Pharmaceuticals, Inc. and Robert J. Terifay.
10.2	Letter Agreement, dated as of January 7, 2018, by and among Regeneron Pharmaceuticals, Inc., Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amérique du Nord, and Sanofi Biotechnology SAS.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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+ Indicates a management contract or compensatory plan or arrangement.

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SIGNATURE

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

REGENERON
PHARMACEUTICALS, INC.

Date: May 3, 2018 By: /s/ Robert E. Landry

Robert E. Landry
Senior Vice President, Finance and
Chief Financial Officer
(Duly Authorized Officer)