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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

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, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

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. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ 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 ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of shares outstanding of each of the registrant's classes of common stock as of October 24, 2019:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,848,970
Common Stock, $.001 par value	107,946,794

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
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"ARCALYST®", "EYLEA®", "Libtayo®" (in the United States), "Regeneron®", "Regeneron Genetics Center®", "Veloci-Bi™", "VelociGene®", "VelociMab®", "VelocImmune®", "VelociMouse®", "VelociSuite®", and "ZALTRAP®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,384.8	$ 1,467.7
Marketable securities	1,493.1	1,342.2
Accounts receivable - trade, net	2,027.7	1,723.7
Accounts receivable from Sanofi	345.4	226.4
Accounts receivable from Bayer	286.9	293.1
Inventories	1,344.3	1,151.2
Prepaid expenses and other current assets	226.9	243.3
Total current assets	7,109.1	6,447.6
Marketable securities	3,112.6	1,755.0
Property, plant, and equipment, net	2,771.4	2,575.8
Deferred tax assets	808.3	828.7
Other noncurrent assets	137.9	127.4
Total assets	$ 13,939.3	$ 11,734.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 335.6	$ 218.2
Accrued expenses and other current liabilities	821.1	772.1
Deferred revenue from Sanofi	427.1	246.7
Deferred revenue - other	181.6	205.8
Total current liabilities	1,765.4	1,442.8
Finance lease liabilities	712.7	708.5
Deferred revenue from Sanofi	551.9	279.3
Deferred revenue - other	131.9	184.9
Other noncurrent liabilities	273.0	361.7
Total liabilities	3,434.9	2,977.2
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 - 1,848,970 in 2019 and 1,911,354 in 2018	—	—
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 112,039,746 in 2019 and 111,084,951 in 2018	0.1	0.1
Additional paid-in capital	4,388.4	3,911.6
Retained earnings	6,587.8	5,254.3
Accumulated other comprehensive income (loss)	16.5	(12.3)
Treasury Stock, at cost; 4,167,018 shares in 2019 and 3,990,021 shares in 2018	(488.4)	(396.4)
Total stockholders' equity	10,504.4	8,757.3
Total liabilities and stockholders' equity	$ 13,939.3	$ 11,734.5

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Statements of Operations				
Revenues:				
Net product sales	$ 1,238.3	$ 1,025.5	$ 3,548.0	$ 3,009.8
Sanofi collaboration revenue	404.2	256.3	999.7	683.5
Bayer collaboration revenue	302.8	264.4	868.0	775.2
Other revenue	103.1	117.3	278.2	314.5
	2,048.4	1,663.5	5,693.9	4,783.0
Expenses:				
Research and development	663.4	557.0	2,353.5	1,584.8
Selling, general, and administrative	419.9	369.2	1,248.0	1,064.9
Cost of goods sold	115.9	30.8	253.8	136.1
Cost of collaboration and contract manufacturing	110.7	79.6	304.5	180.9
	1,309.9	1,036.6	4,159.8	2,966.7
Income from operations	738.5	626.9	1,534.1	1,816.3
Other income (expense):				
Other income (expense), net	37.8	16.4	28.7	81.8
Interest expense	(7.8)	(7.4)	(23.5)	(20.8)
	30.0	9.0	5.2	61.0
Income before income taxes	768.5	635.9	1,539.3	1,877.3
Income tax expense	(98.9)	(41.2)	(215.5)	(253.3)
Net income	$ 669.6	$ 594.7	$ 1,323.8	$ 1,624.0
Net income per share - basic	$ 6.12	$ 5.50	$ 12.12	$ 15.06
Net income per share - diluted	$ 5.86	$ 5.17	$ 11.54	$ 14.14
Weighted average shares outstanding - basic	109.4	108.0	109.2	107.8
Weighted average shares outstanding - diluted	114.2	115.1	114.7	114.8
Statements of Comprehensive Income				
Net income	$ 669.6	$ 594.7	$ 1,323.8	$ 1,624.0
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on debt securities	1.0	0.7	31.5	(6.9)
Unrealized (loss) gain on cash flow hedges	(0.3)	0.3	(2.7)	2.4
Comprehensive income	$ 670.3	$ 595.7	$ 1,352.6	$ 1,619.5

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
(In millions)

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2018	1.9	—	111.1	$ 0.1	$ 3,911.6	$5,254.3	$ (12.3)	(4.0)	$ (396.4)	$ 8,757.3
Issuance of Common Stock in connection with exercise of stock options	—	—	0.6	—	140.9	—	—	—	—	140.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(10.7)	—	—	—	—	(10.7)
Issuance/distribution of Common Stock in connection with 401(k) Savings Plan	—	—	—	—	4.3	—	—	0.1	6.2	10.5
Repurchases of Common Stock from Sanofi	—	—	—	—	—	—	—	(0.1)	(54.0)	(54.0)
Stock-based compensation charges	—	—	—	—	114.8	—	—	—	—	114.8
Adjustment upon adoption of new accounting standard	—	—	—	—	—	9.7	—	—	—	9.7
Net income	—	—	—	—	—	461.1	—	—	—	461.1
Other comprehensive gain, net of tax	—	—	—	—	—	—	15.1	—	—	15.1
Balance, March 31, 2019	1.9	—	111.7	0.1	4,160.9	5,725.1	2.8	(4.0)	(444.2)	9,444.7
Issuance of Common Stock in connection with exercise of stock options	—	—	0.3	—	13.9	—	—	—	—	13.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(29.7)	—	—	—	—	(29.7)
Issuance/distribution of Common Stock in connection with 401(k) Savings Plan	—	—	—	—	9.3	—	—	—	2.4	11.7
Stock-based compensation charges	—	—	—	—	109.2	—	—	—	—	109.2
Net income	—	—	—	—	—	193.1	—	—	—	193.1
Other comprehensive gain, net of tax	—	—	—	—	—	—	13.0	—	—	13.0
Balance, June 30, 2019	1.9	—	111.9	0.1	4,263.6	5,918.2	15.8	(4.0)	(441.8)	9,755.9
Issuance of Common Stock in connection with exercise of stock options	—	—	0.1	—	8.3	—	—	—	—	8.3
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(0.1)	—	—	—	—	(0.1)
Issuance/distribution of Common Stock in connection with 401(k) Savings Plan	—	—	—	—	3.9	—	—	—	2.1	6.0
Repurchases of Common Stock from Sanofi	—	—	—	—	—	—	—	(0.2)	(48.7)	(48.7)
Conversion of Class A Stock to Common Stock	(0.1)	—	0.1	—	—	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	112.7	—	—	—	—	112.7
Net income	—	—	—	—	—	669.6	—	—	—	669.6
Other comprehensive gain, net of tax	—	—	—	—	—	—	0.7	—	—	0.7
Balance, September 30, 2019	1.8	—	112.1	$ 0.1	$ 4,388.4	$6,587.8	$ 16.5	(4.2)	$ (488.4)	$ 10,504.4

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited) (*continued*)

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2017	1.9	—	109.5	$ 0.1	$ 3,512.9	$2,946.7	$ 0.6	(3.8)	$ (316.2)	$ 6,144.1
Issuance of Common Stock in connection with exercise of stock options	—	—	0.1	—	13.6	—	—	—	—	13.6
Issuance of Common Stock in connection with 401(k) Savings Plan	—	—	0.1	—	(0.7)	—	—	—	—	(0.7)
Stock-based compensation charges	—	—	—	—	85.8	—	—	—	—	85.8
Cumulative-effect adjustment upon adoption of new accounting standards	—	—	—	—	—	(136.9)	(6.6)	—	—	(143.5)
Net income	—	—	—	—	—	477.9	—	—	—	477.9
Other comprehensive loss, net of tax	—	—	—	—	—	—	(9.7)	—	—	(9.7)
Balance, March 31, 2018	1.9	—	109.7	0.1	3,611.6	3,287.7	(15.7)	(3.8)	(316.2)	6,567.5
Issuance of Common Stock in connection with exercise of stock options	—	—	0.4	—	19.8	—	—	—	—	19.8
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.2)	—	(31.9)	—	—	—	—	(31.9)
Repurchases of Common Stock from Sanofi	—	—	—	—	—	—	—	(0.1)	(37.6)	(37.6)
Stock-based compensation charges	—	—	—	—	113.1	—	—	—	—	113.1
Net income	—	—	—	—	—	551.4	—	—	—	551.4
Other comprehensive gain, net of tax	—	—	—	—	—	—	4.1	—	—	4.1
Balance, June 30, 2018	1.9	—	109.9	0.1	3,712.6	3,839.1	(11.6)	(3.9)	(353.8)	7,186.4
Issuance of Common Stock in connection with exercise of stock options	—	—	0.4	—	57.3	—	—	—	—	57.3
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(45.2)	—	—	—	—	(45.2)
Repurchases of Common Stock from Sanofi	—	—	—	—	—	—	—	(0.1)	(42.6)	(42.6)
Stock-based compensation charges	—	—	—	—	116.5	—	—	—	—	116.5
Net income	—	—	—	—	—	594.7	—	—	—	594.7
Other comprehensive gain, net of tax	—	—	—	—	—	—	1.1	—	—	1.1
Balance, September 30, 2018	1.9	—	110.3	$ 0.1	$ 3,841.2	$4,433.8	$ (10.5)	(4.0)	$ (396.4)	$ 7,868.2

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

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net income	$ 1,323.8	$ 1,624.0
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	156.0	105.4
Non-cash compensation expense	330.8	300.7
Other non-cash items, net	113.2	(82.7)
Deferred taxes	(110.0)	(33.5)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer, and trade accounts receivable	(460.9)	(228.6)
Increase in inventories	(227.2)	(281.6)
Decrease (increase) in prepaid expenses and other assets	21.2	(87.8)
Increase (decrease) in deferred revenue	375.8	(29.5)
Increase in accounts payable, accrued expenses, and other liabilities	119.9	179.9
Total adjustments	318.8	(157.7)
Net cash provided by operating activities	1,642.6	1,466.3
Cash flows from investing activities:		
Purchases of marketable and other securities	(2,834.9)	(1,533.6)
Sales or maturities of marketable securities	1,306.4	644.1
Capital expenditures	(290.6)	(297.6)
Other	—	(10.0)
Net cash used in investing activities	(1,819.1)	(1,197.1)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	163.5	87.4
Payments in connection with Common Stock tendered for employee tax obligations	(40.5)	(77.1)
Repurchases of Common Stock	(29.4)	(4.4)
Net cash provided by financing activities	93.6	5.9
Net (decrease) increase in cash, cash equivalents, and restricted cash	(82.9)	275.1
Cash, cash equivalents, and restricted cash at beginning of period	1,480.2	825.2
Cash, cash equivalents, and restricted cash at end of period	$ 1,397.3	$ 1,100.3

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

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in millions, 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 condensed consolidated financial statements 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, 2018 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, 2018.

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

We adopted Accounting Standards Codification ("ASC") 842, *Leases*, on January 1, 2019 (the "effective date") and used the effective date as our date of initial application. See Note 8. The new standard requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability for future lease payments and a right-of-use asset representing its right to use the underlying asset over the lease term. We elected the practical expedients upon transition, which permitted companies to not reassess lease identification, classification, and initial direct costs under the new standard for leases that commenced prior to the effective date. Upon adoption of the new standard, we recognized right-of-use assets of $33.2 million related to operating leases as of January 1, 2019. The impact of adopting the standard for the facilities that we had historically applied build-to-suit and capital lease accounting was not material to our Condensed Consolidated Financial Statements. Prior period amounts have not been adjusted in connection with the adoption of this standard.

2. Product Sales

Net product sales consist of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net Product Sales in the United States	**2019**	**2018**	**2019**	**2018**
EYLEA®	$ 1,187.7	$ 1,021.8	$ 3,422.1	$ 2,997.8
Libtayo®	47.6	—	115.2	—
ARCALYST®	3.0	3.7	10.7	12.0
	$ 1,238.3	$ 1,025.5	$ 3,548.0	$ 3,009.8

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the three and nine months ended September 30, 2019 and 2018. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	57%	57%	57%	56%
McKesson Corporation	34%	36%	33%	37%

The following table summarizes the provisions, and credits/payments, for sales-related deductions during the nine months ended September 30, 2019 and 2018.

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

	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2018	$ 41.1	$ 42.0	$ 8.3	$ 91.4
Provisions	301.0	177.3	46.0	524.3
Credits/payments	(265.8)	(172.5)	(40.7)	(479.0)
Balance as of September 30, 2019	$ 76.3	$ 46.8	$ 13.6	$ 136.7
Balance as of December 31, 2017	$ 29.9	$ 34.1	$ 21.3	$ 85.3
Provisions	159.1	155.5	29.7	344.3
Credits/payments	(145.9)	(150.9)	(35.7)	(332.5)
Balance as of September 30, 2018	$ 43.1	$ 38.7	$ 15.3	$ 97.1

3. Collaboration Agreements

a. Sanofi

The collaboration revenue we earned from Sanofi is detailed below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Sanofi Collaboration Revenue	2019	2018	2019	2018
Antibody:				
Reimbursement of Regeneron research and development expenses	$ 60.2	$ 76.2	$ 216.5	$ 201.0
Reimbursement of Regeneron commercialization-related expenses	111.6	103.7	349.3	292.8
Reimbursement for Regeneron's manufacturing of commercial supplies	78.5	40.3	133.3	94.4
Regeneron's share of profits (losses) in connection with commercialization of antibodies	94.2	(38.9)	105.2	(182.6)
Other	4.8	(7.2)	(0.6)	(12.3)
Total Antibody	349.3	174.1	803.7	393.3
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses	38.0	74.8	120.9	225.7
Reimbursement of Regeneron commercialization-related expenses	3.0	3.2	7.0	6.5
Amounts recognized in connection with up-front payments received	18.5	7.9	73.8	65.2
Other	(4.6)	(3.7)	(5.7)	(7.2)
Total Immuno-oncology	54.9	82.2	196.0	290.2
	$ 404.2	$ 256.3	$ 999.7	$ 683.5

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

Antibody

The Company is party to a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). Under the companies' Antibody License and Collaboration Agreement, 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. All other agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi. The Company recognized as research and development expense $10.2 million and $13.4 million during the three months ended September 30, 2019 and 2018, respectively, and during the nine months ended September 30, 2019 and 2018, the Company recognized as research and development expense $29.8 million and $37.2 million, respectively, its share of antibody development expenses that Sanofi incurred related to Dupixent® (dupilumab), Praluent® (alirocumab), and Kevzara® (sarilumab).

Effective January 7, 2018, the Company and Sanofi entered into a letter agreement (the "Letter Agreement") in connection with, among other matters, the allocation of additional funds to certain activities relating to dupilumab and REGN3500 (collectively, the "Dupilumab/REGN3500 Eligible Investments"). Refer to the "*Immuno-Oncology*" section below for further details regarding the Letter Agreement. During the three months ended September 30, 2019, Sanofi elected to sell, and we elected to purchase (in cash), 69,143 shares of the Company's Common Stock in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments. Consequently, we recorded the cost of the shares received, or $19.4 million, as Treasury Stock during the three months ended September 30, 2019.

Sanofi leads commercialization activities for products developed under the Antibody Collaboration, subject to the Company's right to co-commercialize 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 our share of profits and losses, as well as sales milestones, is deemed to be constrained as of September 30, 2019, and therefore has not been included in the transaction price.

The following table summarizes contract balances in connection with the Company's Antibody Collaboration with Sanofi:

	September 30, 2019	December 31, 2018
Accounts receivable	$ 332.5	$ 138.2
Deferred revenue	$ 377.0	$ 236.1

Significant changes in deferred revenue balances are as follows:

	Nine Months Ended September 30, 2019
Increase due to shipments of commercial supplies to Sanofi	$ 294.3
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (159.0)

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. Therefore, we do not disclose the value of the transaction price allocated to our remaining unsatisfied performance obligations.

Immuno-Oncology

In 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 Amended and Restated Immuno-oncology Discovery and Development Agreement ("Amended IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement").

Effective December 31, 2018, the Company and Sanofi entered into an Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company ("IO Development Activities") under the

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

2015 IO Discovery Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 (the "BCMAxCD3 Program") and (ii) MUC16 and CD3 (the "MUC16xCD3 Program") through clinical proof-of-concept. The Amended IO Discovery Agreement provided for Sanofi's payment of $461.9 million to the Company as consideration for (x) the termination of the 2015 IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the 2015 IO Discovery Agreement during the fourth quarter of 2018.

If Sanofi exercises its option to license rights to a BCMAxCD3 Program antibody or MUC16xCD3 Program antibody thereunder, it will co-develop these drug candidates with the Company through product approval. Sanofi will fund development costs up front for a BCMAxCD3 Program antibody and we will reimburse half of the total development costs for such antibody 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 a MUC16xCD3 Program antibody.

Under the terms of the IO License and Collaboration Agreement, the parties are co-developing and co-commercializing Libtayo (cemiplimab), an antibody targeting the receptor known as programmed cell death protein 1 (PD-1). The parties share equally, on an ongoing basis, agreed-upon development and commercialization expenses for Libtayo. Pursuant to the Letter Agreement, the Libtayo development budget was increased and the Company has agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to the Libtayo development and Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares (of which 869,828 currently remains available) 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 Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. During the three months ended September 30, 2019, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 103,761 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded the cost of the shares received, or $29.2 million, as Treasury Stock during the three months ended September 30, 2019. Refer to the "*Antibody*" section above for a description of share transactions related to Dupilumab/REGN3500 Eligible Investments.

The Company has principal control over the development of Libtayo and leads commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States and the parties equally share profits and losses from worldwide sales. As it relates to revenue earned in connection with the IO Collaboration, "Reimbursement of Regeneron commercialization-related expenses" represents reimbursement of costs by Sanofi in connection with the commercialization of Libtayo outside of the United States.

The following table summarizes contract balances in connection with the Company's IO Collaboration with Sanofi:

	September 30, 2019	**December 31, 2018**
Accounts receivable	$ 8.2	$ 77.9
Deferred revenue	$ 602.0	$ 289.9

Significant changes in deferred revenue balances are as follows:

	Nine Months Ended September 30, 2019
Increase as a result of payment received from Sanofi in connection with the Amended IO Discovery Agreement	$ 415.9
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (73.8)
Revenue recognized that was added to deferred revenue during the period	$ (37.9)

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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 September 30, 2019 was $1,196.9 million. This amount is expected to be recognized as revenue over the remaining period in which the Company is obligated to satisfy its performance obligation in connection with performing development activities.

b. Bayer

Revenue earned in connection with our Bayer EYLEA collaboration is as follows (note that the table excludes amounts in connection with our Bayer Ang2 antibody and PDGFR-beta antibody collaboration agreements, which were previously terminated):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Bayer EYLEA Collaboration Revenue	**2019**	**2018**	**2019**	**2018**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 275.0	$ 243.2	$ 793.3	$ 721.5
Reimbursement of Regeneron EYLEA development expenses	5.0	1.7	15.6	8.8
Other	22.8	20.7	59.1	45.4
	$ 302.8	$ 265.6	$ 868.0	$ 775.7

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA outside the United States. 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 currently entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net product sales. In addition, the Company and Bayer share the funding of agreed-upon EYLEA development costs.

c. Teva

In 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 during 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.

The Company recognized $57.4 million and $69.1 million of revenue for the three months ended September 30, 2019 and 2018, respectively, and $172.2 million and $196.6 million for the nine months ended September 30, 2019 and 2018, respectively, in connection with the Teva Collaboration Agreement.

The following table summarizes contract balances in connection with the Teva Collaboration Agreement:

	September 30, 2019	December 31, 2018
Accounts receivable (recorded within Prepaid expenses and other current assets)	$ 36.0	$ 28.8
Deferred revenue	$ 127.8	$ 194.5

Significant changes in deferred revenue balances are as follows:

	Nine Months Ended September 30, 2019
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (68.7)

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 September 30, 2019 was $300.6 million. This amount is expected to be recognized as revenue over the remaining period in which the Company is obligated to satisfy its performance obligation in connection with performing development activities.

d. Alnylam

In April 2019, the Company and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference ("RNAi") therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. The collaboration is governed by a Master Collaboration Agreement (the "Master Agreement") (including the form of a License Agreement and a Co-Commercialization Collaboration Agreement). Under the terms of the Master Agreement, we made an up-front payment of $400.0 million to Alnylam, which was recorded in Research and development expense during the second quarter of 2019. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200.0 million in clinical proof-of-principle milestones for eye or CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Commercialization Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more INDs (or their equivalent in certain other countries) for programs in the eye and CNS.

In connection with the collaboration, we and Alnylam also entered into a Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, we purchased shares of Alnylam common stock for aggregate cash consideration of $400.0 million.

In August 2019, the parties entered into a Co-Commercialization Collaboration Agreement for a silencing RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic and a fully human monoclonal antibody targeting C5 being developed by us, with us as the licensee. The C5 siRNA Co-Commercialization Collaboration Agreement is consistent with the financial terms contained in the form of the existing Co-Commercialization Collaboration Agreement with Alnylam and the parties will share in development expenses equally. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on our potential future net sales of the combination product only subject to customary reductions, as well as up to $325.0 million in commercial milestones.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net income - basic and diluted	$ 669.6	$ 594.7	$ 1,323.8	$ 1,624.0
(Shares in millions)				
Weighted average shares - basic	109.4	108.0	109.2	107.8
Effect of dilutive securities:				
Stock options	4.8	7.1	5.5	7.0
Weighted average shares - diluted	114.2	115.1	114.7	114.8
Net income per share - basic	$ 6.12	$ 5.50	$ 12.12	$ 15.06
Net income per share - diluted	$ 5.86	$ 5.17	$ 11.54	$ 14.14

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(Shares in millions)	2019	2018	2019	2018
Stock options	18.3	14.4	18.2	14.8
Restricted stock	0.4	—	0.4	0.1

Share repurchase program

In November 2019, our board of directors authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. The share repurchase program permits the Company to effect repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. Repurchases may be made from time to time at management's discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The program has no time limit and can be discontinued at any time. No shares have been repurchased under the program to date, and there can be no assurance as to the timing or number of shares of any repurchases in the future.

5. Marketable Securities

Marketable securities as of September 30, 2019 and December 31, 2018 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).

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

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

	Amortized	Unrealized		Fair
As of September 30, 2019	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 3,880.6	$ 27.0	$ (0.6)	$ 3,907.0
U.S. government and government agency obligations	65.9	0.2	(0.1)	66.0
Sovereign bonds	26.9	0.5	—	27.4
Commercial paper	108.8	—	—	108.8
Certificates of deposit	66.7	0.1	—	66.8
	$ 4,148.9	$ 27.8	$ (0.7)	$ 4,176.0
As of December 31, 2018				
Corporate bonds	$ 2,734.8	$ 1.0	$ (17.4)	$ 2,718.4
U.S. government and government agency obligations	110.4	—	(1.0)	109.4
Sovereign bonds	7.6	—	—	7.6
Commercial paper	113.8	—	—	113.8
Certificates of deposit	60.0	—	—	60.0
	$ 3,026.6	$ 1.0	$ (18.4)	$ 3,009.2

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of September 30, 2019 mature at various dates through September 2024. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	September 30, 2019	December 31, 2018
Maturities within one year	$ 1,493.1	$ 1,342.2
Maturities after one year through five years	2,682.9	1,667.0
	$ 4,176.0	$ 3,009.2

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

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

	Less than 12 Months		12 Months or Greater		Total	
As of September 30, 2019	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 294.8	$ (0.3)	$ 216.3	$ (0.3)	$ 511.1	$ (0.6)
U.S. government and government agency obligations	18.5	(0.1)	19.5	—	38.0	(0.1)
	$ 313.3	$ (0.4)	$ 235.8	$ (0.3)	$ 549.1	$ (0.7)
As of December 31, 2018						
Corporate bonds	$ 1,482.6	$ (6.1)	$ 801.6	$ (11.3)	$ 2,284.2	$ (17.4)
U.S. government and government agency obligations	—	—	99.1	(1.0)	99.1	(1.0)
	$ 1,482.6	$ (6.1)	$ 900.7	$ (12.3)	$ 2,383.3	$ (18.4)

There were no realized losses on sales of marketable securities, and realized gains were not material, for the three and nine months ended September 30, 2019. Realized gains and losses on sales of marketable securities were not material for the three and nine months ended September 30, 2018.

With respect to marketable securities, for the three and nine months ended September 30, 2019 and 2018, amounts reclassified from Accumulated other comprehensive income (loss) into Other income (expense), net were related to realized gains and losses on sales of available-for-sale debt securities.

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

6. Fair Value Measurements

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

		Fair Value Measurements at Reporting Date Using	
As of September 30, 2019	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**
Available-for-sale debt securities:			
Corporate bonds	$ 3,907.0	—	$ 3,907.0
U.S. government and government agency obligations	66.0	—	66.0
Sovereign bonds	27.4	—	27.4
Commercial paper	108.8	—	108.8
Certificates of deposit	66.8	—	66.8
Equity securities (unrestricted)	46.9	$ 46.9	—
Equity securities (restricted)	382.8	49.3	333.5
	$ 4,605.7	$ 96.2	$ 4,509.5
As of December 31, 2018			
Available-for-sale debt securities:			
Corporate bonds	$ 2,718.4	—	$ 2,718.4
U.S. government and government agency obligations	109.4	—	109.4
Sovereign bonds	7.6	—	7.6
Commercial paper	113.8	—	113.8
Certificates of deposit	60.0	—	60.0
Equity securities (unrestricted)	43.6	$ 43.6	—
Equity securities (restricted)	44.4	—	44.4
	$ 3,097.2	$ 43.6	$ 3,053.6

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 held certain restricted equity securities as of September 30, 2019, including its investment in Alnylam (see Note 3), which are subject to transfer restrictions that expire at various dates through 2023.

During the three and nine months ended September 30, 2019, we recorded $15.7 million of net unrealized gains and $58.4 million of net unrealized losses, respectively, on equity securities in Other income (expense), net. During the three and nine months ended September 30, 2018, we recorded $4.9 million of net unrealized losses and $21.0 million of net unrealized gains, respectively, on equity securities in Other income (expense), net.

As of September 30, 2019 and December 31, 2018, the Company had $43.1 million and $45.5 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets.

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7. Inventories

Inventories consist of the following:

	September 30, 2019	December 31, 2018
Raw materials	$ 229.0	$ 226.8
Work-in-process	633.5	571.1
Finished goods	49.4	24.4
Deferred costs	432.4	328.9
	$ 1,344.3	$ 1,151.2

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. In these instances, the Company is reimbursed for its manufacturing costs as product is shipped to its collaborators; however, recognition of such cost reimbursements as revenue is deferred until the product is sold by the Company's collaborators to third-party customers.

8. Leases

We conduct certain of our research, development, and administrative activities at leased facilities. We also lease certain warehouses and vehicles. As described in Note 1, during the first quarter of 2019, we adopted ASC 842, *Leases*.

We determine if an arrangement is a lease considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Our lease terms may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. We account for lease components (*e.g.*, rental payments) separately from non-lease components (*e.g.*, common area maintenance costs).

Right-of-use assets and lease liabilities are recognized at lease commencement date based on the present value of lease payments over the lease term, unless there is a transfer of title or purchase option we are reasonably certain to exercise. For leases where an implicit rate is not readily determinable, we use our incremental borrowing rate based on information available at the lease commencement date to determine the present value of future lease payments. Lease expense for operating leases is recognized on a straight-line basis over the expected lease term.

Operating leases

Amounts recognized in our Condensed Consolidated Balance Sheets and Statements of Operations included in this report associated with operating leases were not material. Operating lease right-of-use assets are included within Other noncurrent assets, and lease liabilities are included in Accrued expenses and other current liabilities and Other noncurrent liabilities.

Finance leases

In March 2017, we entered into a Participation Agreement with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively, the "Participants"). In March 2017, we also entered into a Lease and Remedies Agreement with BAL, pursuant to which we have leased laboratory and office facilities in Tarrytown, New York (the "Facility") for a five-year term. The Participation Agreement, the Lease and Remedies Agreement, and certain other related agreements were amended and restated in May 2019, among other things, to revise certain covenants, representations and warranties, and events of default to be substantially similar to those set forth in the agreement governing the Company's revolving credit facility (as so amended and restated, the "Participation Agreement" and the "Lease," respectively). 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 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.

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

Prior to January 1, 2019, for certain of the premises under the Lease we were deemed, in substance, to be the owner of the buildings (collectively, the "Build-to-Suit Buildings"). Upon the adoption of ASC 842, the classification of the Build-to-Suit Buildings, for which the construction period had been completed, was reassessed and, consequently, they were derecognized and recognized as a finance lease. These premises, along with the other premises under the Lease, are classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised.

The agreements governing the Lease financing contain financial and operating covenants. The Company was in compliance with all such covenants as of September 30, 2019.

Amounts recognized in the Condensed Consolidated Balance Sheet related to the Lease are included in the table below. Other than the Lease described above, we had no leases accounted for as finance leases as of September 30, 2019.

	Classification	September 30, 2019
Finance lease right-of-use assets	Property, plant, and equipment, net [1]	$ 663.7
Finance lease liabilities	Finance lease liabilities (noncurrent)	$ 712.7

[1] Finance lease right-of-use assets are recorded net of accumulated amortization of $72.5 million as of September 30, 2019.

As of December 31, 2018, property, plant, and equipment, at cost, included $723.9 million of leased property under the Lease. Accumulated amortization related to these assets amounted to $61.7 million as of December 31, 2018.

Finance lease costs consist of the following:

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Amortization of right-of-use assets	$ 3.6	$ 10.8
Interest on lease liabilities	6.9	21.4
	$ 10.5	$ 32.2

Other information related to our finance lease includes the following:

	September 30, 2019
Remaining lease term (in years)	2.42
Discount rate	2.89%

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

Supplemental information

The following is an analysis of lease liability maturities as of September 30, 2019:

	Operating Leases	Finance Leases
2019	$ 1.9	$ 5.7
2020	8.0	21.2
2021	6.6	20.1
2022	3.3	725.0
2023	2.0	—
2024	2.3	—
Thereafter	4.3	—
Total undiscounted lease payments	28.4	772.0
Imputed interest	(3.1)	(53.2)
Debt financing costs	—	(6.1)
Total lease liabilities	$ 25.3	$ 712.7

As of December 31, 2018, the estimated future minimum noncancelable lease commitments, excluding the purchase price we would be obligated to pay if we were to exercise our option to purchase the Facility, were as follows:

	Operating Leases	Capital and Facility Lease Obligations
2019	$ 10.4	$ 26.4
2020	3.8	28.4
2021	3.4	27.9
2022	2.2	7.0
2023	1.5	—
Thereafter	4.1	—
	$ 25.4	$ 89.7

9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 12.9% and 6.5% for the three months ended September 30, 2019 and 2018, respectively, and 14.0% and 13.5% for the nine months ended September 30, 2019 and 2018, respectively. The Company's effective tax rate for the three and nine months ended September 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by federal tax credits for research activities, the foreign-derived intangible income deduction, and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee.

The Company's effective tax rate for the three and nine months ended September 30, 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with tax planning in connection with the "Tax Cuts and Jobs Act," the federal tax credit for research activities, and, to a lesser extent, stock-based compensation and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate.

10. Statement of Cash Flows

As described in Note 6, included in our purchases of marketable securities during the nine months ended September 30, 2019 is our purchase of Alnylam common stock.

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

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:

	September 30, 2019	September 30, 2018
Cash and cash equivalents	$ 1,384.8	$ 1,087.8
Restricted cash included in Other noncurrent assets	12.5	12.5
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$ 1,397.3	$ 1,100.3

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 September 30, 2019 and December 31, 2018 were $100.5 million and $54.5 million, respectively, of accrued capital expenditures. Included in accounts payable, accrued expenses, and other liabilities as of September 30, 2018 and December 31, 2017 were $40.5 million and $41.8 million, respectively, of accrued capital expenditures.

As described in Note 3, during the nine months ended September 30, 2019, we purchased (by issuing a credit towards the amount owed by Sanofi) 210,733 shares of our Common Stock from Sanofi to satisfy Sanofi's funding obligation related to Libtayo development costs, and recorded the cost of the shares received, or $73.3 million, as Treasury Stock. During the nine months ended September 30, 2018, we purchased (by issuing a credit towards the amount owed by Sanofi) 215,387 shares of our Common Stock from Sanofi, and recorded the cost of the shares received, or $75.8 million, as Treasury Stock.

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. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Unless otherwise noted below, the Company is unable to predict the outcome, or estimate a range of possible loss or possible gain, of the respective proceedings. 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 and '163 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") and its European Patent No. 2,264,163 (the "'163 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 and the '163 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 and the '163 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. Following a trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent, the court issued a final judgment on February 1, 2016, 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. On appeal, 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 and subsequently issued a final order, which enjoins Kymab from infringing the '287 Patent and '163 Patent (subject to certain exceptions) and requires Kymab to destroy or deliver to a third party all products and antibodies and cells engineered to produce antibodies which infringe the '287 Patent and '163 Patent (subject to certain exceptions). Thereafter, the Supreme Court of the United Kingdom granted Kymab's application for permission to appeal the order made by the Court of Appeal with respect to an issue of validity of the '287 Patent and the '163 Patent and scheduled an oral hearing for February 11–12, 2020. The provisions of the final order of the Court of Appeal are stayed pending final determination of Kymab's appeal to the Supreme Court of the United Kingdom. The Company has also been awarded a portion of the legal fees incurred by it in connection with the proceedings in the English High Court and the Court of Appeal described above. On July 31, 2019, the Company filed an action in the English High Court for a calculation of damages relating to Kymab's infringement of the '287 Patent and the '163 Patent.

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. Following an oral hearing before the Opposition Division of the EPO on February 5–7, 2018, the Opposition Division upheld the '163 Patent without amendments. Kymab, Merus, and Novo Nordisk each filed a notice of appeal of the Opposition Division's decision on February 9, 2018, May 25, 2018, and June 26, 2018, respectively. On January 7, 2019, Merus withdrew its appeal of the '163 Patent in the EPO in connection with the previously reported global settlement.

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 claims of 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. The first jury trial in this litigation (the "First Trial") 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 First 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 in the First Trial, 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 October 5, 2017, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") reversed in part the District Court's decision and remanded for a new trial on the issues of written description and enablement. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious.

On January 3, 2019, the District Court held oral argument in the remanded proceedings on the Company and the Sanofi defendants' motion for judgment on the pleadings regarding Amgen's willful infringement claim. On January 18, 2019, the District Court entered an order (i) denying the Company and the Sanofi defendants' motion for summary judgment on validity, (ii) denying Amgen's motion for partial summary judgment on estoppel, and (iii) granting the Company and the Sanofi defendants' cross-motion for summary judgment on estoppel. On February 8, 2019, the District Court granted the Company and the Sanofi defendants' motion for judgment on the pleadings, thereby dismissing Amgen's claim of willful infringement. The second jury trial in this litigation (the "Second Trial") was held before the District Court in February 2019 to determine the validity of Amgen's asserted patent claims. On February 25, 2019, the jury returned a verdict in the Second Trial generally in favor of Amgen, finding that two claims of the '165 Patent and one claim of the '741 Patent were not invalid. The jury also found that two claims of the '165 Patent were invalid for lack of adequate written description while rejecting the lack of enablement challenges to those two claims. On August 28, 2019, the District Court ruled as a matter of law that Amgen's asserted patent claims are invalid based on lack of enablement. The District Court also conditionally denied the Company and the Sanofi defendants' motion for a new trial. On October 23, 2019, Amgen filed a notice of appeal of the District Court's decision with the Federal Circuit.

On March 18, 2019, Amgen filed a renewed motion for a permanent injunction to prohibit the Company and the Sanofi defendants from Commercializing Praluent in the United States (a "Permanent Injunction"), and an oral hearing on this motion was held in June 2019. Previously, the Federal Circuit stayed and then vacated a Permanent Injunction granted by the District Court in connection with the First Trial. On August 28, 2019, the District Court dismissed as moot Amgen's renewed motion for a Permanent Injunction.

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 held an oral hearing on September 11, 2018 and ruled on December 10, 2018 that the infringement proceedings would be reopened. On July 11, 2019, the Düsseldorf Regional Court found that Praluent infringes the '124 Patent and granted an injunction prohibiting the Company and Sanofi's manufacture, sale, and marketing of Praluent in Germany (the "July 11 Decision"). On July 12, 2019, the Company and Sanofi appealed the July 11 Decision to the Higher Regional Court of Düsseldorf (the "Higher Regional Court"). An oral hearing on the merits of the appeal to the Higher Regional Court has been scheduled for April 2, 2020. On August 5, 2019 and October 31, 2019, the Higher Regional Court denied the Company and Sanofi's requests for a stay of preliminary enforcement of the July 11 Decision pending the appeal on the merits.

On July 12, 2018, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie S.A. filed an action in the Federal Patents Court (the "FPC") in Munich, Germany, seeking a compulsory license from Amgen based on the '124 Patent for the continued commercializing of Praluent in Germany. This compulsory license action included a request for a provisional compulsory license. The FPC held an oral hearing on September 6, 2018 and denied the Sanofi parties' request for the provisional compulsory license. On January 16, 2019, the Sanofi parties appealed the FPC's denial of the provisional compulsory license to the Federal Court of Justice (the "FCJ") of Germany. The FCJ held an oral hearing on June 4, 2019 on the appeal of the provisional compulsory license ruling and dismissed the Sanofi parties' appeal. On September 16, 2019, the Sanofi parties filed a brief to withdraw the compulsory license action with the FPC.

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

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. An oral hearing on the oppositions against the '124 Patent was held on November 28–30, 2018, at which the Opposition Division upheld the validity of the '124 Patent's claims in amended form. The Company and Sanofi filed notices of appeal to the Technical Board of Appeal (the "TBA") of the EPO on November 30, 2018. An oral hearing before the TBA has been scheduled for March 24–25, 2020.

The Company has recorded an accrual for loss contingencies associated with the '124 Patent proceedings discussed above. The ultimate resolution of these proceedings is not expected to have a material impact on the Company’s financial statements.

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 (the "Tokyo District Court") 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. On January 17, 2019, the Tokyo District Court upheld the validity of the '333 Patent and '288 Patent and ordered a permanent injunction against Sanofi K.K. to stop manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) and to dispose of all product. However, the Tokyo District Court stayed the enforcement of such injunction pending appeal to the Intellectual Property High Court of Japan (the "IPHC"). On January 30, 2019, Sanofi K.K. appealed the Tokyo District Court's decision in the infringement proceedings to the IPHC. Following an oral hearing on October 30, 2019, the IPHC affirmed the Tokyo District Court's decision in the infringement proceedings. The injunction will remain stayed pending appeal of the IPHC's decision to the Supreme Court of Japan.

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. Oral hearings on the Additional IPR Petitions before the PTAB were held on November 14, 2018. On February 14, 2019, the PTAB issued final written decisions on the Additional IPR Petitions, invalidating all 17 claims of the '487 Patent as obvious based on one of the Additional IPR Petitions while declining to hold the challenged claims of the '487 Patent invalid based on the other. In April 2019, the parties filed notices of appeal with the Federal Circuit appealing the PTAB's respective adverse final written decisions on the Additional IPR Petitions.

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 the Company and the Sanofi parties' motion for summary judgment on the issue of indefiniteness of the '487 Patent claims was held on July 12, 2018. On August 24, 2018, the court issued an order denying this motion and construed the disputed claim terms as proposed by Amgen. On February 28, 2019, the court granted a joint stipulation by the parties to stay the litigation pending resolution of the appeals of the PTAB's final written decisions on the Additional IPR Petitions discussed above.

On September 30, 2016, Sanofi initiated a revocation proceeding in the United Kingdom to invalidate the U.K. counterpart of European Patent No. 2,292,665 (the "'665 Patent"), another patent owned by Immunex relating to antibodies that bind the human interleukin-4 receptor. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the currently pending EPO opposition proceedings initiated by the Company and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions occurred on November 20, 2017, at which the claims of the '665 Patent were found invalid and the patent was revoked. A final written decision of revocation of the '665 Patent was issued by the EPO on January 4, 2018. Immunex filed a notice of appeal of the EPO's decision on January 31, 2018. On September 20, 2017 and September 21, 2017, respectively, the Company and Sanofi initiated opposition proceedings in the EPO against Immunex's European Patent No. 2,990,420 (the "'420 Patent"), a divisional patent of the '665 Patent (*i.e.*, a patent that shares the same priority date, disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). The oral hearing before the EPO on the oppositions occurred on February 14–15, 2019, at which the '420 Patent was revoked in its entirety. Immunex filed a notice of appeal of the EPO's decision on May 31, 2019. The original patent term of the Immunex patents is set to expire in 2021.

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 (dismissed on October 24, 2018); 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. On March 20, 2019, the court issued its Opinion and Order on Claim Construction (the "Claim Construction Order") in the '688 Patent infringement litigation. Pursuant to the Claim Construction Order, on April 1, 2019, the court approved a joint stipulation and entered a partial judgment of noninfringement of the '688 Patent of nine asserted claims. On August 14, 2019, the court issued a second Opinion and Order on Claim Construction concerning the one remaining asserted claim in this litigation. On September 5, 2019, the court entered a stipulated judgment of noninfringement and dismissed with prejudice all of the Novartis Parties' claims of the '688 Patent, finding that the manufacture, use, offer for sale, sale, or importation into the United States of aflibercept does not infringe the claims of the '688 Patent.

On May 14, 2019, the Company filed an IPR in the USPTO seeking a declaration of invalidity of the '688 Patent. On September 26, 2019, in connection with the dismissal of the '688 Patent infringement litigation discussed above, the Company and the Novartis Parties filed a joint motion to terminate the IPR petition, and the PTAB dismissed the IPR petition on October 1, 2019.

Department of Justice Investigations

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.

In September 2019, the Company and Regeneron Healthcare Solutions, Inc., a wholly-owned subsidiary of the Company, each received a civil investigative demand ("CID") from the U.S. Department of Justice pursuant to the federal False Claims Act relating to remuneration paid to physicians in the form of consulting fees, advisory boards, speaker fees, and payment or reimbursement for travel and entertainment allegedly in violation of the federal Anti-Kickback Statute. The CIDs relate to EYLEA, Praluent, Dupixent, ZALTRAP, ARCALYST, and Kevzara and cover the period from January 2015 to the present. The Company is cooperating with this investigation.

12. Recently Issued Accounting Standards

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the current other-than-temporary impairment model. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We do not expect the adoption of this standard to have a significant impact on our financial statements or internal controls; however, the ultimate impact will depend on the composition of the Company's portfolio of financial instruments as of the adoption date.

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, Libtayo® (cemiplimab) Injection, fasinumab, evinacumab, and REGN-EB3; the likelihood and timing of achieving any of our anticipated clinical development milestones referenced in this report; 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, Libtayo, fasinumab, evinacumab, and REGN-EB3; 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, Kevzara, and Libtayo), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict 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 (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to our products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to Dupixent and Praluent described further in Note 11 to our Condensed Consolidated Financial Statements included in this report), other litigation and other proceedings and governmental investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition. 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 diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, infectious diseases, pain, and rare diseases.

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 biotechnology company that provides patients and medical professionals with important options for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues	$ 2,048.4	$ 1,663.5	$ 5,693.9	$ 4,783.0
Net income	$ 669.6	$ 594.7	$ 1,323.8	$ 1,624.0
Net income per share - diluted	$ 5.86	$ 5.17	$ 11.54	$ 14.14

Marketed Products

We currently have seven products that have received marketing approval:

Product	Disease Area[(1)]	Territory			
		U.S.	EU	Japan	ROW[(6)]
EYLEA (aflibercept) Injection[(2)]	- Neovascular age-related macular degeneration (wet AMD)	✔	✔	✔	✔
	- Diabetic macular edema (DME)	✔	✔	✔	✔
	- 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)	✔	✔	✔	✔
	- Myopic choroidal neovascularization (mCNV)		✔	✔	✔
	- Diabetic retinopathy	✔			
Dupixent (dupilumab) Injection[(3)]	- Atopic dermatitis (in adults)	✔	✔	✔	✔
	- Atopic dermatitis (in adolescents)	✔	✔		✔
	- Asthma (in adults and adolescents)	✔	✔	✔	✔
	- Chronic rhinosinusitis with nasal polyposis (CRSwNP)	✔	✔		
Praluent (alirocumab) Injection[(3)]	- LDL-lowering in heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) (in adults)	✔	✔	✔	✔
	- Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔		✔
Kevzara (sarilumab) Solution for Subcutaneous Injection[(3)]	- Rheumatoid arthritis (RA) (in adults)	✔	✔	✔	✔
Libtayo (cemiplimab) Injection[(3)(4)]	- Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	✔	✔		✔
ARCALYST® (rilonacept) Injection for Subcutaneous Use	- Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	✔			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[(5)]	- Metastatic colorectal cancer (mCRC)	✔	✔	✔	✔

(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) Marketed as Libtayo (cemiplimab-rwlc) Injection in the United States

(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

(6) Rest of world. Checkmark in this column indicates that the product has received marketing approval in at least one country outside of the United States, European Union (EU), or Japan

Net Product Sales of Regeneron-Discovered Products(*)	Three Months Ended September 30,						
(In millions)	2019			2018			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA*	$ 1,187.7	$ 730.2	$ 1,917.9	$ 1,021.8	$ 654.6	$ 1,676.4	14%
Libtayo*	47.6	3.9	51.5	—	—	—	**
ARCALYST	3.0	—	3.0	3.7	—	3.7	(19%)
Net product sales recorded by Regeneron	$ 1,238.3			$ 1,025.5			
Global net product sales recorded by Sanofi:*							
Dupixent	$ 508.3	$ 124.8	$ 633.1	$ 219.6	$ 43.0	$ 262.6	141%
Praluent	$ 33.5	$ 36.2	$ 69.7	$ 48.4	$ 31.8	$ 80.2	(13%)
Kevzara	$ 36.5	$ 18.3	$ 54.8	$ 19.9	$ 5.0	$ 24.9	120%
ZALTRAP	$ 3.1	$ 25.3	$ 28.4	$ 1.5	$ 23.9	$ 25.4	12%

	Nine Months Ended September 30,						
	2019			2018			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA*	$ 3,422.1	$ 2,114.9	$ 5,537.0	$ 2,997.8	$ 1,944.5	$ 4,942.3	12%
Libtayo*	115.2	3.9	119.1	—	—	—	**
ARCALYST	10.7	—	10.7	12.0	—	12.0	(11%)
Net product sales recorded by Regeneron	$ 3,548.0			$ 3,009.8			
Global net product sales recorded by Sanofi:*							
Dupixent	$ 1,266.0	$ 298.1	$ 1,564.1	$ 517.7	$ 85.4	$ 603.1	159%
Praluent	$ 82.9	$ 124.4	$ 207.3	$ 121.5	$ 92.0	$ 213.5	(3%)
Kevzara	$ 91.4	$ 55.6	$ 147.0	$ 48.1	$ 13.3	$ 61.4	139%
ZALTRAP	$ 4.9	$ 74.6	$ 79.5	$ 6.6	$ 73.5	$ 80.1	(1%)

* Bayer records net product sales of EYLEA outside the U.S., and Sanofi records net product sales of Libtayo outside the U.S. and global net product sales of Dupixent, Praluent, Kevzara, and ZALTRAP. Refer to "Marketed Products" section above and "Collaboration Agreements" section below for further details.

** Percentage not meaningful

Programs in Clinical Development

All 24 of our product candidates in clinical development, including the five U.S. Food and Drug Administration (FDA) approved products which we are investigating in additional indications, were discovered in our research laboratories and are summarized in the table below. 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.

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, changes to drug pricing and reimbursement regulations and 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.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
EYLEA		- High-dose formulation in wet AMD	- Retinopathy of prematurity (ROP)[c]	
Dupixent (dupilumab)[a] *Antibody to IL-4R alpha subunit*		- Grass allergy - Peanut allergy	- Atopic dermatitis in pediatrics (6–11 years of age)[d] - Atopic dermatitis in pediatrics (6 months–5 years of age) (Phase 2/3)[d] - Asthma in pediatrics (6–11 years of age) - Eosinophilic esophagitis (EOE)[c] - Chronic obstructive pulmonary disease (COPD)	- Auto-injector for 300 mg dose (U.S., EU, and Japan) - CRSwNP (Japan)
Praluent (alirocumab)[a] *Antibody to PCSK9*			- Homozygous familial hypercholesterolemia (HoFH)[c] in adults and pediatrics - HeFH in pediatrics	
Kevzara (sarilumab)[a] *Antibody to IL-6R*		- Polyarticular-course juvenile idiopathic arthritis (pcJIA) - Systemic juvenile idiopathic arthritis (sJIA)	- Polymyalgia rheumatica (PMR) - Giant cell arteritis (GCA)	
Libtayo (cemiplimab)[a][h] *Antibody to PD-1*	- Solid tumors and advanced hematologic malignancies	- Basal cell carcinoma (BCC) (potentially pivotal study) - Metastatic or locally advanced CSCC[d]	- First-line non-small cell lung cancer (NSCLC) - Second-line cervical cancer[e] - Adjuvant CSCC	
Fasinumab[b][f] (REGN475) *Antibody to NGF*			- Osteoarthritis pain of the knee or hip[e]	
Evinacumab[f] (REGN1500) *Antibody to ANGPTL3*		- Refractory hypercholesterolemia (both HeFH and non-FH) - Severe hypertriglyceridemia	- HoFH[c][d]	
REGN1979 *Bispecific antibody targeting CD20 and CD3*	- Certain B-cell malignancies[c] (on partial clinical hold pending FDA review of protocol amendment)	- Relapsed/refractory follicular lymphoma (FL)		
REGN-EB3[g] (REGN3470-3471-3479) *Multi-antibody therapy to Ebola virus infection (Ebola)*				- Ebola (U.S.)[c][d][j]

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
Garetosmab[f] (REGN2477) *Antibody to Activin A*		- Fibrodysplasia ossificans progressiva (FOP)[c][e] (potentially pivotal study)		
REGN3500[a] *Antibody to IL-33. Studied as monotherapy and in combination with Dupixent.*		- Asthma - COPD - Atopic dermatitis		
REGN1908-1909[f] *Multi-antibody therapy to Feld1*		- Cat allergy		
Pozelimab[f] (REGN3918) *Antibody to C5*		- Paroxysmal nocturnal hemoglobinuria (PNH)[c]		
REGN5069 *Antibody to GFRα3*		- Osteoarthritis pain of the knee		
REGN3048-3051[g] *Multi-antibody therapy to Middle East Respiratory Syndrome (MERS) virus*	- MERS virus infection			
REGN3767[f] *Antibody to LAG-3*	- Solid tumors and advanced hematologic malignancies			
REGN4461 *Agonist antibody to leptin receptor (LEPR)*	- Lipodystrophy and obesity			
REGN4018[a] *Bispecific antibody targeting MUC16 and CD3*	- Platinum-resistant ovarian cancer			
REGN4659[f] *Antibody to CTLA4*	- Advanced NSCLC			
REGN5458[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma			
REGN5459[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma			
REGN5713-5714-5715 *Antibody to Betv1*	- Birch allergy			
REGN5678 *Bispecific antibody targeting PSMA and CD28*	- Prostate cancer			
REGN5093 *Bispecific antibody targeting two distinct MET epitopes*	- MET-altered advanced NSCLC			

Note: For purposes of the table above, a program is classified in Phase 1, 2, or 3 clinical development after recruiting for the corresponding study or studies has commenced

[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 sales of the product candidate.

[g] Sanofi did not opt-in to the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate. We and the Biomedical Advanced Research Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) are parties to agreements whereby HHS provides certain funding to support research, development, and manufacturing of these antibodies.

[h] Studied as monotherapy and in combination with other antibodies and treatments

[i] Information in this column relates to U.S., EU, and Japan regulatory submissions only

[j] Included as part of the Extension Phase of a trial coordinated by World Health Organization

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 2019 to date were, and milestones for the next twelve months are, as follows:

Clinical Program	2019 Events to Date	2019–2020 Milestones (next 12 months)
EYLEA	- Approved by FDA for the treatment of diabetic retinopathy - Approved by FDA for pre-filled syringe - Initiated Phase 3 study in ROP - Initiated Phase 2 study using a high-dose formulation of aflibercept in wet AMD	- Initiate Phase 3 studies of a high-dose formulation of aflibercept in wet AMD and DME
Dupixent (dupilumab; IL-4R Antibody)	- Approved by FDA and European Commission (EC) for expanded atopic dermatitis indication in adolescent patients (12–17 years of age)	- Submit supplemental Biologics License Application (sBLA) and Marketing Authorization Application (MAA) for expanded atopic dermatitis indication in pediatric patients (6–11 years of age)
	- Reported that Phase 3 study in pediatric patients (6–11 years of age) with severe atopic dermatitis met its primary and secondary endpoints	- Japan decision on application for CRSwNP - FDA decision (target action date of March 20, 2020) and final EU decision on applications for 300 mg auto-injector
	- Approved by EC for treatment of asthma in adults and adolescents	- Resubmit sBLA for 200 mg auto-injector
	- Approved by FDA and EC for CRSwNP	- Present results from Phase 2a trial in grass allergy at medical meeting
	- Submitted regulatory application in Japan for CRSwNP	- Initiate Phase 3 study in pediatric patients with EOE
	- EMA's Committee for Medicinal Products for Human Use (CHMP) recommended approval for 300 mg auto-injector	- Initiate Phase 3 studies in bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, and additional type 2 inflammatory diseases
	- Submitted sBLA for 300 mg auto-injector - EU approval for 200 mg auto-injector - FDA issued Complete Response Letter (CRL) regarding the sBLA for 200 mg auto-injector - Initiated Phase 3 study in COPD - Completed Phase 2a trial in grass allergy	

Clinical Program *(continued)*	2019 Events to Date	Select 2019–2020 Milestones (next 12 months)
Praluent (alirocumab; PCSK9 Antibody)	- Approved by EC for a new indication to reduce cardiovascular risk in adults with established ASCVD - Approved by FDA for a new indication to reduce the risk of heart attack, stroke and unstable angina requiring hospitalization in adults with established CV disease - Approved by FDA for the treatment of adults with primary hyperlipidemia (including HeFH) to reduce low-density lipoprotein cholesterol (LDL-C)	- Report results from Phase 3 study in HoFH
Libtayo (cemiplimab; PD-1 Antibody)	- Conditionally approved by EC for treatment of advanced CSCC - Initiated Phase 3 adjuvant study in CSCC - An independent data monitoring committee conducted an interim analysis for overall survival in a Phase 3 NSCLC trial, and recommended the trial continue as planned	- Continue patient enrollment in NSCLC and various other studies - Report results from Phase 2 study in BCC - Initiate Phase 2 neoadjuvant study in CSCC
Fasinumab (NGF Antibody)	- Completed patient enrollment in Phase 3 efficacy studies and Phase 3 long-term safety study in osteoarthritis pain	- Report results from Phase 3 studies
Evinacumab (ANGPTL3 Antibody)	- Reported positive top-line results from Phase 3 trial in HoFH	- Submit BLA and MAA for HoFH
REGN1979 (CD20 and CD3 Antibody)	- Reported updated data from Phase 1 study in patients with relapsed or refractory B-cell non-Hodgkin lymphoma - Began recruiting patients in Phase 2 study in relapsed/refractory FL	- Initiate potentially pivotal Phase 2 program in aggressive non-Hodgkin lymphoma
REGN-EB3 (Multi-antibody therapy to Ebola)	- Included in randomized controlled trial coordinated by World Health Organization in the Democratic Republic of Congo (DRC) - Investigational trial in the DRC was stopped early based on data showing that REGN-EB3 was superior to ZMapp in preventing death - FDA granted Breakthrough Therapy designation for the treatment of Ebola - Commenced rolling BLA submission for Ebola	- Complete rolling BLA submission for Ebola
Garetosmab (Activin A Antibody)		- Report results from Phase 2 study in FOP
REGN3500 (IL-33 Antibody)	- Reported that the Phase 2 study in asthma met its primary and key secondary endpoints	- Initiate Phase 2b study in asthma - Report results from Phase 2 study in COPD - Report results from Phase 2 study in atopic dermatitis
REGN1908-1909 (Feld1 Antibody)	- Initiated Phase 2 study in cat allergic asthmatics	- Report results from Phase 2 study in cat allergic asthmatics
Pozelimab (C5 Antibody)	- Initiated Phase 2 study in PNH	- Report interim results from Phase 2 study in PNH
REGN5069 (GFRα3 Antibody)	- Initiated Phase 2 study in osteoarthritis pain	

Clinical Program *(continued)*	2019 Events to Date	Select 2019–2020 Milestones (next 12 months)
REGN3048-3051 (Multiple-antibody therapy to MERS)		- Complete Phase 1 study in healthy volunteers
REGN4461 (LEPR Agonist Antibody)		- Initiate Phase 2 study in generalized lipodystrophy
REGN5458 (BCMA and CD3 Antibody)	- Initiated Phase 1 study in multiple myeloma	- Report interim results from Phase 1 study in multiple myeloma
REGN5459 (BCMA and CD3 Antibody)	- Initiated Phase 1 study in multiple myeloma	
REGN5713-5714-5715 (Betv1 Antibody)	- Initiated Phase 1 study in birch allergy	
REGN5678 (PSMA and CD28 Antibody)	- Initiated Phase 1 study in prostate cancer	
REGN5093 (MET Antibody)	- Initiated Phase 1 study in MET-altered advanced NSCLC	

General

Our ability to generate profits and to generate positive cash flow from operations over the next several years depends significantly on the continued success in commercializing EYLEA and Dupixent. We expect to continue to incur substantial expenses related to our research and development activities, a 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, Kevzara, and Libtayo. 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.

Collaboration Agreements

Collaborations with Sanofi

Antibody

We are collaborating with Sanofi on the global development and commercialization of various antibodies and antibody product candidates (Dupixent, Praluent, Kevzara, and REGN3500) (the Antibody Collaboration). Under the terms of the Antibody License and Collaboration Agreement (LCA), 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. All other agreed-upon development costs incurred by both companies are funded 100% by Sanofi. We are obligated to reimburse Sanofi for 50% of worldwide development expenses that were fully funded by Sanofi and 30% of shared Phase 3 trial-related costs based on our share of collaboration profits from commercialization of collaboration products. However, we are only required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs.

Effective January 7, 2018, we and Sanofi entered into a letter agreement (Letter Agreement) amending the LCA in connection with, among other matters, the allocation of additional funds to certain proposed activities relating to dupilumab and REGN3500 (collectively, the Dupilumab/REGN3500 Eligible Investments). Pursuant to the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to the Dupilumab/REGN3500 Eligible Investments for the quarterly periods commencing on January 1, 2018 and ending on September 30, 2020 by selling up to an aggregate of 600,000 shares (of which 495,948 currently remains available) 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-commercialize such products on a country-by-country basis. We have exercised our option to co-commercialize Dupixent, Praluent, and Kevzara in the United States. We are not currently co-commercializing these antibodies outside the United States. We supply certain commercial bulk product to Sanofi. 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 and loss sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales of antibodies (subject to this agreement) outside the United States exceed $1.0 billion on a rolling twelve-month basis.

Immuno-Oncology

In 2015, we 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 Amended and Restated Immuno-oncology Discovery and Development Agreement (Amended IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the execution of the original Immuno-oncology Discovery and Development Agreement in 2015 (2015 IO Discovery Agreement), which has been replaced by the Amended IO Discovery Agreement (as discussed below), Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the 2015 IO Discovery Agreement, we were to 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, and Sanofi was to reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits. The original term of the 2015 IO Discovery Agreement was to continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget was 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.

Effective December 31, 2018, the Company and Sanofi entered into the Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company (IO Development Activities) under the 2015 IO Discovery Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 (the BCMAxCD3 Program) and (ii) MUC16 and CD3 (the MUC16xCD3 Program) through clinical proof-of-concept. The Amended IO Discovery Agreement provided for Sanofi's payment of $461.9 million to the Company as consideration for (x) the termination of the 2015 IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the 2015 IO Discovery Agreement during the fourth quarter of 2018.

Under the terms of the Amended IO Discovery Agreement, the Company is required to conduct development activities with respect to (i) the BCMAxCD3 Program through the earlier of clinical proof-of-concept or the expenditure of $70.0 million (the BCMAxCD3 Program Costs Cap) and (ii) the MUC16xCD3 Program through the earlier of clinical proof-of-concept or the expenditure of $50.0 million (the MUC16xCD3 Program Costs Cap); provided that under certain circumstances, Sanofi will have the option to increase the MUC16xCD3 Program Costs Cap to $70.0 million by making a payment to the Company in the amount of $20.0 million.

Pursuant to the Amended IO Discovery Agreement, we are primarily responsible for conducting the IO Development Activities (other than certain clinical trials that may be funded separately by Sanofi), including antibody development, preclinical activities, toxicology studies, manufacture of clinical supplies, filing of Investigational New Drug Applications (INDs), and clinical development through proof-of-concept. We are responsible for reimbursing Sanofi for half of the development costs they funded attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of profits from commercialized IO Collaboration products. As the scope of the IO Development Activities has been limited, the exclusivity obligations of the parties under the Amended IO Discovery Agreement have been narrowed.

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when (i) clinical proof-of-concept is established, (ii) the applicable Program Costs Cap is reached, or (iii) in certain other limited circumstances, Sanofi will have the option to license rights to the product candidate and other antibodies targeting the same targets for, with regard to BCMAxCD3, immuno-oncology indications, and with regard to MUC16xCD3, all indications, pursuant to the IO License and Collaboration Agreement, as amended. If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will receive a royalty on sales. Pursuant to the Amended IO Discovery Agreement, the parties agreed that (i) if Sanofi exercises its option with respect to a BCMAxCD3 Program antibody, Sanofi will lead the development and global commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) we will lead the development of such MUC16xCD3 Program antibody and commercialization of such MUC16xCD3 Program antibody within the United States and (y) Sanofi will lead the commercialization of such MUC16xCD3 Program antibody outside of the United States.

The Amended IO Discovery Agreement provides that Regeneron retains exclusive rights to all other immuno-oncology programs that were part of the 2015 IO Discovery Agreement, provided that Sanofi will receive a royalty on global sales of two product candidates currently in clinical development, REGN3767 and REGN4659. The Amended IO Discovery Agreement will terminate as of the earlier of (a) Sanofi having elected to exercise or not exercise its options with respect to the BCMAxCD3 Program and the MUC16xCD3 Program in accordance with the terms of the Amended IO Discovery Agreement and (b) December 31, 2022.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us in 2015. If Sanofi exercises its option to license rights to a BCMAxCD3 Program antibody or MUC16xCD3 Program antibody thereunder, it will co-develop these drug candidates with us through product approval under the terms of the IO License and Collaboration Agreement. Sanofi will fund development costs up front for a BCMAxCD3 Program antibody and we will reimburse half of the total development costs for such antibody 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 a MUC16xCD3 Program antibody. Each party will have the right to co-commercialize 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. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that immuno-oncology drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties are also co-developing and co-commercializing Libtayo (cemiplimab), an antibody targeting PD-1. We have principal control over the development of Libtayo, and the parties share equally, on an ongoing basis, agreed-upon development and commercialization expenses for Libtayo. Under the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligation with respect to Libtayo development costs for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to an aggregate of 800,000 shares (of which 373,880 currently remains available) of our Common Stock directly or indirectly owned by Sanofi.

If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo 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 Libtayo, we lead commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States and the parties equally share profits from worldwide sales. Sanofi has exercised its option to co-commercialize Libtayo 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 Libtayo), 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.

Collaboration with Bayer

EYLEA outside the United States

Since 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 currently entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

We are 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.

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

Collaboration with Teva

Fasinumab

In 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 Mitsubishi Tanabe Pharma Corporation (MTPC). 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. As of September 30, 2019, we had earned an aggregate of $120.0 million of development milestones from Teva and we are entitled to receive up to an aggregate of $340.0 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).

Collaboration with Alnylam

In April 2019, we and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference (RNAi) therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system (CNS), in addition to a select number of targets expressed in the liver. The collaboration is governed by a Master Collaboration Agreement (the Master Agreement) (including the form of a License Agreement and a Co-Commercialization Collaboration Agreement). Under the terms of the Master Agreement, we made an up-front payment of $400.0 million to Alnylam. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200.0 million in clinical proof-of-principle milestones for eye or CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Commercialization Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the Research Term). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more INDs (or their equivalent in certain other countries) for programs in the eye and CNS.

At the stage of designation of a lead candidate for CNS programs and liver programs, the parties have alternating rights to be a lead party for collaboration products. At the stage of designation of a lead candidate for eye programs, we have the sole right to take the product forward as a licensee. The lead party is required to take the program forward under the License Agreement structure unless the other party exercises its rights to opt-in to a Co-Commercialization Collaboration Agreement, in which case the lead party is required to take the program forward under the Co-Commercialization Collaboration Agreement structure. Alnylam does not have rights to opt-in to a Co-Commercialization Collaboration Agreement for eye programs.

Under a License Agreement, the lead party is designated as the licensee and has the right to develop and commercialize the collaboration product under such program. The licensee will be responsible for its own costs and expenses incurred in connection with the development and commercialization of the collaboration products under the License Agreement. The licensee will pay to the licensor certain development and/or commercialization milestone payments totaling up to $150.0 million for each collaboration product. In addition, following the first commercial sale of the applicable collaboration product under a License Agreement, the licensee is required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the licensor based on the aggregate annual net sales of the collaboration product, subject to customary reductions.

For CNS programs and liver programs, as soon as a party is designated as a lead party, the other company has rights to opt-in to a Co-Commercialization Collaboration Agreement as a participating party. Under a Co-Commercialization Collaboration Agreement, the party designated as the lead party has operational responsibility and final decision-making authority on development and commercialization of the program and the parties will split profits and share costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions. If a party exercises its co-funding opt-out right, the lead party will be required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the other party based on the aggregate annual net sales of the collaboration product and the timing of the exercise of the co-funding opt-out right, subject to customary reductions. If the non-lead party does not initially opt-in to a Co-Commercialization Collaboration Agreement, the lead party has the right to take the program forward under a License Agreement structure.

Under the collaboration, when we are the licensee under a License Agreement or the lead party under a Co-Commercialization Collaboration Agreement, Alnylam will be responsible for the manufacture and supply of the product to us for Phase 1 and Phase 2 clinical trials.

In connection with the collaboration, we and Alnylam also entered into a Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, we purchased 4,444,445 shares of Alnylam common stock for aggregate cash consideration of $400.0 million.

In August 2019, the parties entered into a Co-Commercialization Collaboration Agreement for a silencing RNA (siRNA) therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic and a fully human monoclonal antibody targeting C5 being developed by us, with us as the licensee. The C5 siRNA Co-Commercialization Collaboration Agreement is consistent with the financial terms contained in the form of the existing Co-Commercialization Collaboration Agreement with

Alnylam. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on our potential future net sales of the combination product only subject to customary reductions, as well as up to $325.0 million in commercial milestones.

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.

The information contained on our websites and social media channels is not included as a part of, or incorporated by reference into, this report.

Results of Operations

Three and Nine Months Ended September 30, 2019 and 2018

Net Income

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except per share data)	**2019**	**2018**	**2019**	**2018**
Revenues	$ 2,048.4	$ 1,663.5	$ 5,693.9	$ 4,783.0
Operating expenses	(1,309.9)	(1,036.6)	(4,159.8)	(2,966.7)
Income from operations	738.5	626.9	1,534.1	1,816.3
Other income (expense), net	30.0	9.0	5.2	61.0
Income before income taxes	768.5	635.9	1,539.3	1,877.3
Income tax expense	(98.9)	(41.2)	(215.5)	(253.3)
Net income	$ 669.6	$ 594.7	$ 1,323.8	$ 1,624.0
Net income per share - diluted	$ 5.86	$ 5.17	$ 11.54	$ 14.14

Revenues

	Three Months Ended September 30,		Increase	Nine Months Ended September 30,		Increase
(In millions)	**2019**	**2018**	**(Decrease)**	**2019**	**2018**	**(Decrease)**
Net product sales in the United States:						
EYLEA	$ 1,187.7	$ 1,021.8	$ 165.9	$ 3,422.1	$ 2,997.8	$ 424.3
Libtayo	47.6	—	47.6	115.2	—	115.2
ARCALYST	3.0	3.7	(0.7)	10.7	12.0	(1.3)
Sanofi and Bayer collaboration revenue:						
Sanofi	404.2	256.3	147.9	999.7	683.5	316.2
Bayer	302.8	264.4	38.4	868.0	775.2	92.8
Other revenue	103.1	117.3	(14.2)	278.2	314.5	(36.3)
Total revenues	$ 2,048.4	$ 1,663.5	$ 384.9	$ 5,693.9	$ 4,783.0	$ 910.9

Net Product Sales

Net product sales of EYLEA in the United States increased for the three and nine months ended September 30, 2019, compared to the same periods in 2018, due to higher sales volume, partly offset by an increase in sales-related deductions primarily due to higher rebates and discounts. There were no sales of Libtayo for the three and nine months ended September 30, 2018 as the FDA approved Libtayo for the treatment of patients with metastatic or locally advanced CSCC on September 28, 2018.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts; distribution-related fees; and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	**Rebates, Chargebacks, and Discounts**	**Distribution-Related Fees**	**Other Sales-Related Deductions**	**Total**
Balance as of December 31, 2018	$ 41.1	$ 42.0	$ 8.3	$ 91.4
Provisions	78.6	52.8	16.1	147.5
Credits/payments	(60.8)	(47.9)	(0.4)	(109.1)
Balance as of March 31, 2019	58.9	46.9	24.0	129.8
Provisions	106.5	61.2	17.2	184.9
Credits/payments	(78.7)	(40.0)	(30.5)	(149.2)
Balance as of June 30, 2019	86.7	68.1	10.7	165.5
Provisions	115.9	63.3	12.7	191.9
Credits/payments	(126.3)	(84.6)	(9.8)	(220.7)
Balance as of September 30, 2019	$ 76.3	$ 46.8	$ 13.6	$ 136.7
Balance as of December 31, 2017	$ 29.9	$ 34.1	$ 21.3	$ 85.3
Provisions	48.5	51.7	11.2	111.4
Credits/payments	(30.7)	(42.0)	(14.7)	(87.4)
Balance as of March 31, 2018	47.7	43.8	17.8	109.3
Provisions	49.2	50.4	8.7	108.3
Credits/payments	(60.4)	(56.5)	(9.7)	(126.6)
Balance as of June 30, 2018	36.5	37.7	16.8	91.0
Provisions	61.4	53.4	9.8	124.6
Credits/payments	(54.8)	(52.4)	(11.3)	(118.5)
Balance as of September 30, 2018	$ 43.1	$ 38.7	$ 15.3	$ 97.1

Sanofi Collaboration Revenue

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Antibody:				
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	$ 60.2	$ 76.2	$ 216.5	$ 201.0
Reimbursement of Regeneron commercialization-related expenses[(1)]	111.6	103.7	349.3	292.8
Reimbursement for Regeneron's manufacturing of commercial supplies[(2)]	78.5	40.3	133.3	94.4
Regeneron's share of profits (losses) in connection with commercialization of antibodies	94.2	(38.9)	105.2	(182.6)
Other	4.8	(7.2)	(0.6)	(12.3)
Total Antibody	349.3	174.1	803.7	393.3
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses - Discovery Agreement	12.9	34.7	37.8	108.4
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	25.1	40.1	83.1	117.3
Reimbursement of Regeneron commercialization-related expenses[(1)]	3.0	3.2	7.0	6.5
Amounts recognized in connection with up-front payments received	18.5	7.9	73.8	65.2
Other	(4.6)	(3.7)	(5.7)	(7.2)
Total Immuno-oncology	54.9	82.2	196.0	290.2
Total Sanofi collaboration revenue	$ 404.2	$ 256.3	$ 999.7	$ 683.5

[(1)] The corresponding commercialization-related costs incurred by us are recorded within Selling, general and administrative expense.
[(2)] The corresponding costs incurred by us in connection with such production is recorded within Cost of collaboration and contract manufacturing.

Antibody

During the three and nine months ended September 30, 2019 and 2018, we and Sanofi shared commercial expenses related to Dupixent, Praluent, and Kevzara in accordance with the companies' Antibody 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 combined profits/losses in connection with the companies commercializing Dupixent, Praluent, and Kevzara within Sanofi collaboration revenue. During the three and nine months ended September 30, 2019, Sanofi collaboration revenues in connection with commercialization of antibodies increased primarily due to our share of higher Dupixent profits. Sanofi provides us with an estimate of our share of the profits or 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 profits or losses is adjusted accordingly, as necessary.

Regeneron's share of profits (losses) in connection with the commercialization of Dupixent, Praluent, and Kevzara is summarized below:

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Dupixent, Praluent, and Kevzara net product sales*	$ 757.6	$ 367.7	$ 1,918.4	$ 878.0
Regeneron's share of collaboration profits (losses)	$ 105.0	$ (38.9)	$ 120.1	$ (182.6)
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(10.8)	—	(14.9)	—
Regeneron's share of profits (losses) in connection with commercialization of antibodies	$ 94.2	$ (38.9)	$ 105.2	$ (182.6)
Regeneron's share of collaboration profits as a percentage of Dupixent, Praluent, and Kevzara net product sales	12%	**	5%	**

* Global net product sales of Dupixent, Praluent, and Kevzara are recorded by Sanofi

** Percentage not meaningful

Immuno-Oncology

Sanofi's reimbursement of immuno-oncology research and development costs under our IO Discovery Agreement decreased in the third quarter and first nine months of 2019, compared to the same periods in 2018, due to the impact of the Amended IO Discovery Agreement (see "Collaboration Agreements - Collaborations with Sanofi" above).

Bayer Collaboration Revenue

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 275.0	$ 243.2	$ 793.3	$ 721.5
Reimbursement of Regeneron development expenses	5.0	0.5	15.6	8.3
Other	22.8	20.7	59.1	45.4
Total Bayer collaboration revenue	$ 302.8	$ 264.4	$ 868.0	$ 775.2

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

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
EYLEA net product sales outside the United States	$ 730.2	$ 654.6	$ 2,114.9	$ 1,944.5
Regeneron's share of collaboration profit from sales outside the United States	$ 289.2	$ 256.7	$ 835.5	$ 761.1
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(14.2)	(13.5)	(42.2)	(39.6)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 275.0	$ 243.2	$ 793.3	$ 721.5
Regeneron's net profit as a percentage of EYLEA net product sales outside the United States	38%	37%	38%	37%

Bayer records net product 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.

Other Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2019**	**2018**	**2019**	**2018**
Teva collaboration revenue:				
Reimbursement of Regeneron research and development expenses	$ 34.2	$ 27.6	$ 102.9	$ 101.1
Other	23.2	41.5	69.3	95.5
Total Teva collaboration revenue	57.4	69.1	172.2	196.6
Other revenue	45.7	48.2	106.0	117.9
Total other revenue	$ 103.1	$ 117.3	$ 278.2	$ 314.5

In addition to Teva collaboration revenue (which is earned in connection with the development of fasinumab), "Other revenue" in the table above includes, but is not limited to:

- 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.
- 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.
- Recognition of revenue in connection with our agreements with BARDA related to REGN-EB3 for the treatment of Ebola.
- Recognition of revenue in connection with sequencing of samples by the Regeneron Genetics Center® (RGC) for its customers.

Expenses

	Three Months Ended September 30,		Increase	Nine Months Ended September 30,		Increase
(In millions, except headcount data)	**2019**	**2018**	**(Decrease)**	**2019**	**2018**	**(Decrease)**
Research and development	$ 663.4	$ 557.0	$ 106.4	$ 2,353.5	$ 1,584.8	$ 768.7
Selling, general, and administrative	419.9	369.2	50.7	1,248.0	1,064.9	183.1
Cost of goods sold[(1)]	115.9	30.8	85.1	253.8	136.1	117.7
Cost of collaboration and contract manufacturing[(2)]	110.7	79.6	31.1	304.5	180.9	123.6
Total operating expenses	$ 1,309.9	$ 1,036.6	$ 273.3	$ 4,159.8	$ 2,966.7	$ 1,193.1
Average headcount	7,925	7,147	778	7,674	6,763	911

(1) Cost of goods sold includes costs in connection with producing commercial supplies for products that are sold by Regeneron in the United States (*i.e.*, EYLEA, Libtayo, and ARCALYST) and any royalties we are obligated to pay on such sales, period costs for our Limerick manufacturing facility, and amounts we are obligated to pay to Sanofi for its share of Libtayo U.S. gross profits.

(2) Cost of collaboration and contract manufacturing primarily includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer.

Operating expenses included a total of $117.1 million and $111.4 million in the third quarter of 2019 and 2018, respectively, and $330.8 million and $300.6 million in the first nine months of 2019 and 2018, respectively, of non-cash compensation expense related to employee stock options and restricted stock. Non-cash compensation expense in the first nine months of 2018 was lower than the corresponding period in 2019 primarily due to the impact of a 2018 change in our estimate of the number of stock options that were 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, 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, and other costs related to activities that benefit multiple projects. Clinical manufacturing costs primarily consist of costs to manufacture bulk drug product (including pre-launch commercial supplies which were not capitalized as inventory) at our manufacturing facilities, as well as external drug filling, packaging, and labeling costs.

	Three Months Ended September 30,		Increase	Nine Months Ended September 30,		Increase
(In millions)	**2019**	**2018***	**(Decrease)**	**2019**	**2018***	**(Decrease)**
Direct research and development expenses:						
Fasinumab	$ 57.0	$ 32.5	$ 24.5	$ 166.7	$ 131.6	$ 35.1
Libtayo (cemiplimab)	33.6	34.2	(0.6)	112.0	89.4	22.6
Dupixent (dupilumab)	22.6	28.9	(6.3)	67.9	85.9	(18.0)
Praluent (alirocumab)	10.6	14.9	(4.3)	32.1	44.4	(12.3)
Evinacumab	9.6	4.7	4.9	24.6	14.4	10.2
Up-front payments related to license and collaboration agreements	—	—	—	400.0	—	400.0
Other product candidates in clinical development and other research programs	92.4	55.4	37.0	263.7	140.7	123.0
Total direct research and development expenses	225.8	170.6	55.2	1,067.0	506.4	560.6
Indirect research and development expenses:						
Payroll and benefits	171.8	152.8	19.0	510.5	433.7	76.8
Lab supplies and other research and development costs	32.8	25.4	7.4	94.3	71.3	23.0
Occupancy and other operating costs	79.6	63.5	16.1	226.7	185.8	40.9
Total indirect research and development expenses	284.2	241.7	42.5	831.5	690.8	140.7
Clinical manufacturing costs	153.4	144.7	8.7	455.0	387.6	67.4
Total research and development expenses	$ 663.4	$ 557.0	$ 106.4	$ 2,353.5	$ 1,584.8	$ 768.7

* Certain prior year amounts have been reclassified to conform to the current year's presentation.

Research and development expenses in the first nine months of 2019 included a $400.0 million up-front payment to Alnylam (see "Collaboration Agreements - Collaboration with Alnylam" above). Research and development expenses included non-cash compensation expense of $60.0 million and $60.4 million in the third quarter of 2019 and 2018, respectively, and $178.0 million and $160.8 million in the first nine months of 2019 and 2018, 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 and other applicable 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 third quarter and first nine months of 2019, compared to the same periods in 2018, primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Dupixent and EYLEA, and higher contributions to independent not-for-profit patient assistance organizations. Selling, general, and administrative expenses also included non-cash compensation expense of $40.8 million and $42.9 million in the third quarter of 2019 and 2018, respectively, and $122.3 million and $118.4 million in the first nine months of 2019 and 2018, respectively.

Cost of Goods Sold

The increase in cost of goods sold for the three and nine months ended September 30, 2019, compared to the same periods in 2018, was primarily due to our obligation to pay Sanofi its share of Libtayo U.S. gross profits, higher period costs at our Limerick manufacturing facility, and higher inventory reserves and write-offs.

Cost of Collaboration and Contract Manufacturing

The increase in cost of collaboration and contract manufacturing for the three and nine months ended September 30, 2019, compared to the same periods in 2018, was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent and higher inventory reserves and write-offs. In addition, the increase in cost of collaboration and contract manufacturing for the nine months ended September 30, 2019, compared to the same period in 2018, was partly driven by expenses in connection with process validation at our Limerick manufacturing facility.

Other Income (Expense)

Other income (expense), net, for the three and nine months ended September 30, 2019, compared to the same periods in 2018, was positively impacted by increased interest income earned on available-for-sale debt securities primarily due to higher average investment balances. Other income (expense), net, was also impacted for the three and nine months ended September 30, 2019 and 2018 by the recognition of unrealized gains and losses on equity securities.

Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except effective tax rate)	**2019**	**2018**	**2019**	**2018**
Income tax expense	$ 98.9	$ 41.2	$ 215.5	$ 253.3
Effective tax rate	12.9%	6.5%	14.0%	13.5%

Our effective tax rate for the three and nine months ended September 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by federal tax credits for research activities, the foreign-derived intangible income deduction, and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee. Our effective tax rate for the three and nine months ended September 30, 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the tax benefit associated with tax planning in connection with the "Tax Cuts and Jobs Act," the federal tax credit for research activities, and, to a lesser extent, stock-based compensation and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	September 30, 2019	December 31, 2018	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	$ 1,384.8	$ 1,467.7	$ (82.9)
Marketable securities - current	1,493.1	1,342.2	150.9
Marketable securities - noncurrent	3,112.6	1,755.0	1,357.6
	$ 5,990.5	$ 4,564.9	$ 1,425.6
Working capital:			
Current assets	$ 7,109.1	$ 6,447.6	$ 661.5
Current liabilities	1,765.4	1,442.8	322.6
	$ 5,343.7	$ 5,004.8	$ 338.9

As of September 30, 2019, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Nine Months Ended September 30, 2019 and 2018

(In millions)	September 30, 2019	September 30, 2018	Increase (Decrease)
Cash flows provided by operating activities	$ 1,642.6	$ 1,466.3	$ 176.3
Cash flows used in investing activities	$ (1,819.1)	$ (1,197.1)	$ (622.0)
Cash flows provided by financing activities	$ 93.6	$ 5.9	$ 87.7

Cash Flows from Operating Activities

Our net income of $1,323.8 million for the first nine months of 2019 was negatively impacted by an up-front payment of $400.0 million made to Alnylam pursuant to our collaboration agreement (as described in "Collaboration Agreements - Collaborations with Alnylam" above) and $58.4 million related to unrealized losses (net) on equity securities (included in other non-cash items). Deferred taxes as of September 30, 2019 increased by $110.0 million, compared to December 31, 2018, primarily due to the tax treatment of the up-front payment made to Alnylam and non-cash compensation expense. Deferred revenue increased in the first nine months of 2019 primarily due to the receipt of a $461.9 million payment from Sanofi in connection with the Amended IO Discovery Agreement (as described in "Collaboration Agreements - Collaborations with Sanofi," above).

Cash Flows from Investing Activities

In the first nine months of 2019, we purchased $400.0 million of Alnylam common stock in connection with entering into the collaboration agreement. Capital expenditures were $290.6 million and $297.6 million in the first nine months of 2019 and 2018, respectively. We expect to incur capital expenditures of $390 million to $420 million for the full year of 2019 primarily in connection with expanding a portion of our manufacturing facilities, including an investment in fill/finish facilities and equipment, and laboratory expansion and renovations at our Tarrytown, New York facilities.

Share Repurchase Program

In November 2019, our board of directors authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. The share repurchase program permits the Company to effect repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. Repurchases may be made from time to time at management’s discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The program has no time limit and can be discontinued at any time. No shares have been repurchased under the program to date, and there can be no assurance as to the timing or number of shares of any repurchases in the future. We plan to finance the share repurchase program with available cash.

Sanofi Funding of Certain Development Costs

As described above in "Collaboration Agreements - Collaborations with Sanofi," effective January 7, 2018, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development and/or Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares (of which 869,828 shares remain available to be sold as of September 30, 2019) of our Common Stock directly or indirectly owned by Sanofi. During the first nine months of 2019, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 210,733 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded $73.3 million related to the shares received as Treasury Stock during the first nine months of 2019. In addition, during the first nine months of 2019, Sanofi elected to sell, and we elected to purchase (in cash), 93,286 shares of the Company's Common Stock in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments. Consequently, we recorded the cost of the shares received, or $29.4 million, as Treasury Stock during the first nine months of 2019.

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, 2018 (filed February 7, 2019). Except as described in Note 1 and Note 8 to our Condensed Consolidated Financial Statements included in this report related to the adoption of Accounting Standards Codification (ASC) 842, *Leases*, there were no material changes to our critical accounting policies and use of estimates during the nine months ended September 30, 2019.

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, 2018 (filed February 7, 2019). There have been no material changes to our market risks or to our management of such risks as of September 30, 2019.

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 September 30, 2019 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 the nine months ended September 30, 2019 and 2018, EYLEA net sales in the United States represented 60% and 63% of our total revenues, respectively. 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.

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 degree of commercial success of our marketed products (in particular, EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) will continue to 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 U.S. and foreign payer restrictions on eligible patient populations and the reimbursement process (including drug price control measures that may be introduced in the United States by various federal and state authorities);
- 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 existing and potential new competition for EYLEA (discussed further under "*The commercial success of our products and product candidates is subject to strong competition* - Marketed Products - EYLEA" below) and 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;
- serious complications or side effects in connection with the use of our marketed products, as discussed 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 - *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*" below;
- 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), as well as 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 outcome of the pending government investigations described in Note 11 to our Condensed Consolidated Financial Statements included in this report;
- 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 price reporting and other disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescribing practices and payer coverage.

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 products we or our collaborators commercialize. 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 products we or they commercialize (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) 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 - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring 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.

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, Kevzara, and Libtayo) 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 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 maintain, among other things, our FDA registration and our National Drug Code, formulary approval by pharmacy benefits managers, and 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, as discussed further below) 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, such as step therapy (*i.e.*, requiring the use of less costly medications before more costly medications are approved for coverage). 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.

Further, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation and policies designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. At the federal level, the current administration's budget proposal for fiscal year 2019 contained drug price control measures that have been subsequently rolled into the budget proposal for fiscal year 2020 and could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B (such as EYLEA); to allow some states to negotiate drug prices under Medicaid; and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services has been soliciting feedback on some of these measures and may implement others impacting our business under its existing authority. CMS has also recently sought public comment on how best to leverage its authority provided under the Competitive Acquisition Program and introduce competition into Medicare Part B by allowing CMS to bring on vendors to negotiate payment amounts for Medicare Part B drugs. In addition, since January 1, 2019, CMS has allowed Medicare Advantage (MA) plans to use step therapy for Part B drugs (such as EYLEA). On October 25, 2018, President Trump announced that CMS was evaluating a program that proposes to set the Medicare payment amount for Part B single-source drugs and biologics to more closely align with international drug prices (also referred to as reference or international price index (IPI) drug pricing) and pay physicians and hospitals participating in such program a set drug add-on payment for administered drugs. CMS also issued an advance notice of proposed rulemaking that requested public comment on the proposed program, which is contemplated to initially cover fifty percent of Medicare Part B spending on separately payable Part B drugs (such as EYLEA), with the IPI-based price for each such drug to be phased in over a period of five years; notice of proposed rulemaking on this program is currently under review by the Office of Management and Budget. In addition, in July 2019, President Trump indicated that his administration was considering an executive order to establish a "most favored nation" pricing plan. While the scope and details of this contemplated executive action (including whether and how its mechanism may differ from that of the proposed IPI drug pricing program discussed above) are not clear, this seems to signal that the U.S. administration will continue to seek new measures to constrain drug costs and Medicare payments for drugs. Similarly, various members of the current U.S. Congress and potential 2020 presidential candidates have indicated that lowering drug prices continues to be a legislative and political priority, and some have introduced proposals aimed at drug pricing. At the state level, legislatures are becoming increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and price and marketing cost disclosure and transparency measures. In some cases, these measures are designed to encourage importation from other countries and bulk purchasing. A reduction in the availability or extent of reimbursement from U.S. government programs (including based on the proposals and initiatives described above) 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.

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 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 larger pharmaceutical or biotechnology 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 vascular endothelial growth factor (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, mCNV, and ROP. Novartis announced in October 2019 that it received FDA approval for Beovu® (brolucizumab), its humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A, for the treatment of wet AMD in the United States. Novartis has also reported regulatory submissions in the EU and other jurisdictions for approval of brolucizumab in wet AMD and ongoing Phase 3 studies of brolucizumab in DME and RVO. 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) and Formycon AG is developing FY203 and has indicated that it intends to initiate a Phase 3 trial in mid-2020. Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Formycon AG (in collaboration with Bioeq GmbH) is developing FYB201 (a Phase 3 trial in patients with wet AMD has been completed), Samsung Bioepis Co., Ltd. is developing SB11 (currently in a Phase 3 trial in patients with wet AMD), and Pfenex Inc. is developing PF582 (a Phase 1b/2a trial in patients with wet AMD has been completed).

Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, RVO, and diabetic retinopathy, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. Allergan is developing abicipar pegol for wet AMD and related conditions and recently announced regulatory submissions in the United States and the EU in wet AMD. Chengdu Kanghong Pharmaceutical Industry Group Co., Ltd. is conducting non-inferiority Phase 3 trials in the United States and Europe comparing conbercept, an anti-VEGF fusion protein, against EYLEA in wet AMD. Conbercept is approved in the wet AMD and myopic choroidal neovascularization indications in China. Genentech/Roche is developing a port delivery system implant for ranibizumab (currently in Phase 3 studies in wet AMD and DME). Kodiak Sciences Inc. is developing KSI-301, an anti-VEGF biologic therapy that is conjugated to a phosphorylcholine-based biopolymer to extend its half-life, for wet AMD, DME, and RVO. A Phase 1 study of KSI-301 in patients with DME met its primary safety and tolerability endpoint, and Kodiak is conducting a Phase 1b open label study in patients with wet AMD, DME, and RVO. A Phase 2 study comparing KSI-301 against EYLEA in wet AMD has also been reported to have begun recruiting patients. In addition, 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 bispecific antibody, faricimab (RG7716), that targets both VEGF and Ang2 for wet AMD and DME (currently in Phase 3 non-inferiority studies comparing faricimab against EYLEA in DME and wet AMD). 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 for wet AMD and previously announced that a Phase 2 trial met the primary endpoint of superiority to Lucentis monotherapy. 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 (currently in a Phase 2a trial in DME and RVO and a Phase 2b trial in wet AMD). Ocular Therapeutix, Inc. is developing OTX-TKI, a bioresorbable hydrogel formulated with tyrosine kinase inhibitor particles in an injectable fiber, for wet AMD and initiated a Phase 1 trial in February 2018. PanOptica, Inc. is developing PAN-90806, a topically administered tyrosine kinase inhibitor (Phase 1/2 trial for wet AMD completed). Competitors are also developing other eye-drop formulations, devices, oral therapies, and gene/cell therapies (such as REGENXBIO Inc.'s RGX-314) for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

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.

In addition, ophthalmologists are using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, bevacizumab, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged bevacizumab presents a significant competitive challenge for EYLEA in these indications. Bevacizumab is also being evaluated in eye diseases in clinical trials in certain countries. 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. Additionally, Outlook Therapeutics, Inc. is enrolling patients in Phase 3 trials in wet AMD for

ONS-5010, a proprietary ophthalmic formulation of bevacizumab. The potential FDA approval of an ophthalmic formulation of bevacizumab may also affect market dynamics for EYLEA in the United States.

Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, but there is a risk that third parties 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. The market for Dupixent's current and potential future indications is competitive. In atopic dermatitis, Pfizer Inc.'s Eucrisa® (crisaborole), a topical ointment, competes with Dupixent and there are several other topical agents in development. In addition, a number of companies are developing antibodies against IL-13 for the treatment of atopic dermatitis, including LEO Pharma A/S (in collaboration with AstraZeneca PLC) with tralokinumab (currently in several Phase 3 trials) and Dermira, Inc. (in collaboration with Genentech/Roche) with lebrikizumab (currently in Phase 3 trials). Antibodies targeting OX40 are also in development for atopic dermatitis, with Glenmark Pharmaceuticals Ltd., Kyowa Hakko Kirin Co., Ltd., and Kymab Ltd conducting Phase 2 trials of their respective programs (GBR-830, KHK4083, and KY-1005). Galderma S.A. has initiated Phase 3 trials of nemolizumab, an antibody against IL-31R, in atopic dermatitis. XBiotech Inc. has completed a Phase 2 trial of bermekimab, an anti-IL-1alpha antibody. Orally administered small molecules are also being developed for atopic dermatitis, and, if approved, may compete with Dupixent in atopic dermatitis and other potential future indications. Several companies are studying JAK inhibitors for atopic dermatitis, including AbbVie Inc.'s upadacitinib, Pfizer's abrocitinib (PF-04965842) (two Phase 3 studies reported to have met their respective primary endpoints), Eli Lilly and Company's baricitinib (three atopic dermatitis Phase 3 studies reported to have met their respective primary endpoints), and Asana BioSciences, LLC's ASN002 (currently in Phase 2 development).

In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor such as GlaxoSmithKline plc's Nucala® (mepolizumab), AstraZeneca's Fasenra® (benralizumab), and Teva's Cinqair® (reslizumab), all of which are approved for asthma in the United States and other jurisdictions. Novartis and Genentech/Roche's Xolair® (omalizumab) is also approved for asthma in multiple jurisdictions. In CRSwNP, competitors to Dupixent may include, if approved, Xolair (two CRSwNP Phase 3 trials reported in June 2019 to have met their respective primary endpoints) as well as Nucala and Fasenra (each in Phase 3 development for CRSwNP). Orally administered small molecule agents may also compete with Dupixent in asthma and potential future indications. For example, Novartis is developing fevipiprant, an oral prostaglandin D2 receptor 2 (CRTh2/DP2) antagonist, in multiple Phase 3 trials for asthma. Inhaled products may also compete with Dupixent in asthma and potential future indications, including Pieris Pharmaceuticals, Inc.'s PRS-060 (an anticalin being developed in partnership with AstraZeneca against IL-4R) and Novartis' CSJ117 (an antibody fragment against thymic stromal lymphopoietin).

There are several other potentially competitive products in development that may compete with Dupixent in both the atopic dermatitis and asthma indications, as well as potential future indications. For example, Amgen/AstraZeneca's tezepelumab, an antibody against thymic stromal lymphopoietin, or TSLP, is currently in Phase 3 development for asthma and Phase 2 development for atopic dermatitis. Antibodies against the IL-33 ligand or the IL-33 receptor (ST2) may also be competitive with Dupixent across multiple indications. Phase 2 trials are ongoing in atopic dermatitis and asthma for etokimab (ANB-020), an antibody against IL-33 developed by AnaptysBio, Inc. Genentech/Roche is developing RG6149, an anti-ST2 antibody, in Phase 2 trials for asthma and atopic dermatitis. GlaxoSmithKline plc (GSK) is developing GSK3772847, an anti-ST2 antibody, in a Phase 2 trial for asthma (reported to have met proof-of-concept), and completed a Phase 1 trial that included atopic dermatitis patients. Eli Lilly is developing LY3375880, an anti-IL-33 antibody, in a Phase 2 trial for atopic dermatitis.

Praluent. Amgen's Repatha, an antibody targeting PCSK9, has received regulatory approvals in jurisdictions including the U.S., the EU, and Japan, and has captured a significant market share in certain jurisdictions. Repatha also received regulatory approval for cardiovascular risk reduction before Praluent in certain jurisdictions, including the U.S. In addition, LIB Therapeutics LLC is conducting Phase 2 studies with LIB003, a recombinant fusion protein targeting PCSK9, in ASCVD, and has initiated a Phase 3 trial in HoFH. Other companies with development programs for injectables against PCSK9 include Alnylam Pharmaceuticals, Inc. (in collaboration with The Medicines Company), which is developing inclisiran, an RNAi molecule targeting PCSK9 (a Phase 3 trial in ASCVD has been completed and other Phase 3 trials in ASCVD and HeFH are ongoing). 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. (submitted for regulatory review in the U.S. and EU).

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 R-Pharm JSC and BIOCAD, have antibodies against IL-6 or IL-6R in clinical development for rheumatoid arthritis. Biosimilar versions of Actemra may also compete with Kevzara, such as Mycenax Biotech Inc.'s LuciNex (a Phase 1 trial has been completed). Further, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz® (tofacitinib), Eli Lilly's Olumiant® (baricitinib), AbbVie's Rinvoq® (upadacitinib), Gilead Sciences, Inc.'s filgotinib, and Astellas Pharma Inc.'s peficitinib pose a competitive threat for Kevzara.

Libtayo. There are several competitors that are marketing and/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), Merck KGaA/Pfizer's Bavencio® (avelumab), Novartis' spartalizumab (PDR001), BeiGene Ltd.'s tislelizumab (BGB-A317), GSK's dostarlimab (TSR-042), Agenus Inc.'s AGEN2034, and Incyte Corporation's INCMGA0012.

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. Competitors to evinacumab include Ionis Pharmaceuticals, Inc./Akcea Therapeutics, Inc.'s AKCEA-ANGPTL3-LRx, a ligand conjugated antisense drug against ANGPTL3, and Arrowhead Pharmaceuticals, Inc.'s ARO-ANG3, an RNAi therapeutic against ANGPTL3. We are also aware of several companies developing or marketing small molecules 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, Kevzara, and Libtayo, 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 (and, in Japan, Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate) for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, while we have elected to co-commercialize 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 for such products. Moreover, even though we lead commercialization efforts for Libtayo in the United States, Sanofi has exercised its option to co-commercialize Libtayo in the United States in accordance with the terms of our IO Collaboration. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of Dupixent, Praluent, Kevzara, or Libtayo (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 payers relating to such products and product candidates. We also rely on Sanofi for sales, marketing, and distribution of Dupixent, Praluent, Kevzara, and Libtayo 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, our Antibody Collaboration, or our IO 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 our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and 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 products we commercialize in the United States and our collaborators' sales of products they commercialize under our collaboration agreements with them in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under the relevant collaboration agreements 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 and IO Collaboration with Sanofi, pricing and reimbursement for the products commercialized thereunder outside the United States are 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 States. 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. 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.

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, Libtayo, and ARCALYST 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 nine months ended September 30, 2019, our gross product sales of such products to two customers accounted on a combined basis for 90% 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 these products will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of these products 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-commercialize 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.

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 or our collaborators 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 or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products (or are materially delayed in doing so), the value of our Company and 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 (which, for purposes of this risk factor, includes our collaborators, unless otherwise stated or required by the context) 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 for 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.

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 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 additional information, see "Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring 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 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. We and our collaborators must maintain regulatory compliance for the products we or they commercialize in foreign jurisdictions. From time to time, we may hold a product's marketing approval in a jurisdiction outside the United States where we may have less experience and where our regulatory capabilities may be more limited. 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 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 products and product candidates (such as Libtayo and Dupixent) 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.

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. As a result, the ongoing osteoarthritis trials have been modified accordingly and we discontinued dosing patients in the clinical study of fasinumab in chronic low back pain in patients with concomitant osteoarthritis of the knee and hip since this study was using only higher doses. 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.

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 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.

Dupixent and Libtayo are being studied in additional indications, as shown in the table under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Programs in Clinical Development." There is no guarantee that marketing approval of Dupixent or Libtayo (as applicable) in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include hypersensitivity reactions, conjunctivitis and keratitis, injection-site reactions, eye and eyelid inflammation, cold sores, oropharyngeal pain, and eosinophilia; and the side effects previously reported for Libtayo include certain immune-mediated adverse reactions, such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea. These and other complications or side effects could harm further development and/or commercialization of Dupixent and Libtayo (as applicable).

There also are risks inherent in subcutaneous injections (which are used for administering most of 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 utilizing this method of administration, 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.

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, commercialization, and other risks.

Many of our products (including EYLEA, Dupixent, Praluent, and Kevzara) are used and some of our products and product candidates may be used, if approved, in combination with a drug-delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. For example, the FDA recently approved the 2mg EYLEA pre-filled syringe, which has not yet been launched commercially. The success of our products and 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 and manufacture the devices; to conduct the studies and prepare related documentation 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 or 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 and manufacture 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.

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property 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 could 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 European Patent Office (EPO) (currently pending before its Boards of Appeal), as described in Note 11 to our Condensed Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (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 also currently hold issued trademark registrations and have trademark applications pending in the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering, or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected.

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 (including those relating to trademarks, copyrights, and trade secrets). 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 and/or our collaborator Sanofi 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 patents that 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), Kevzara (sarilumab), and Libtayo (cemiplimab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF, and evinacumab, an antibody to ANGPTL3.

Although we do not believe that any of our products or our late-stage antibody-based product candidates infringe 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 products or 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. For example, in August 2018, we and Sanofi entered into a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, and Ono Pharmaceutical to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. 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 or other means of defending our intellectual property 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 federal Patient Protection and Affordable Care Act (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 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 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 if, for example, the PPACA is amended.

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. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. As discussed under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to strong competition*" above, there are several companies developing biosimilar versions of EYLEA. The loss of market exclusivity for a product (such as EYLEA) would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

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, Kevzara, and Libtayo and, if approved, our product candidates or other indications for our marketed products, and to advance our clinical pipeline.

We have large-scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. Our manufacturing facilities would be inadequate to produce the active pharmaceutical ingredients of (a) our current marketed products, including EYLEA, Dupixent, Praluent, Kevzara, and Libtayo, 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 continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. 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 our dependence on our collaborators and/or contract manufacturers may increase, 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, including with respect to drug-delivery devices (such as a pre-filled syringe, patch pump, auto-injector, or other delivery system). 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 and establishing fill/finish capabilities 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.

In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or conduct fill/finish or other related activities in the future. 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. This also holds true for establishing fill/finish capabilities in the future, for which we have taken initial steps. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill/finish activities. 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 and any future fill/finish activities 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 or any future fill/finish 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, Kevzara, and Libtayo, 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 or our collaborators' manufacturing activities, or the activities of other 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 (including our ability to conduct any fill/finish activities in the future), the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other 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 or our collaborators' manufacturing activities, or the activities of other 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 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, Kevzara, or Libtayo 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 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 write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, 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, the manufacturing facilities of our collaborators, or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborators' facilities. We and our collaborators would be unable to manufacture these materials if the relevant facility 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 or our collaborators 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 or our collaborators' 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 or our collaborators are required to substitute for these sources to comply with European regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring 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 collaborators and other 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 facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. Our inability, or the inability of our collaborators and 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 our collaborators or other 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. Recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal anti-kickback statute.

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 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 described further in Note 11 to our Condensed Consolidated Financial Statements included in this report, we are cooperating with pending government investigations concerning certain of our business activities. Any adverse finding, allegation, or exercise of enforcement or regulatory discretion in such investigations could harm our business, prospects, operating results, and financial condition.

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 continue to dedicate significant resources to comply with these requirements and need 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 ability to expand internationally, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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 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, government reimbursement changes and drug price control measures, and changes in the existing treaty and trade relationships with other countries), as evidenced by statements and actions of President Trump and certain members of Congress (including those discussed above under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *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*"). 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. For example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could materially and adversely affect our business.

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, 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;
- 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, in a referendum held in the United Kingdom, voters have approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, the British government has been negotiating the terms of the United Kingdom's future relationship with the EU. The outcome of these negotiations is uncertain, and we do not know to what extent Brexit (or the expectations that Brexit will occur) will ultimately 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 the vicinity of 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, changes in tax laws and regulations, and tax effects of the accounting for stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control). Changes in tax laws of various jurisdictions in which we do business could also result from 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.

We face potential liability related to the privacy of health information and other personal 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 to fund the generation of genetic exome sequence data from the UK Biobank health resource) may implicate international data protection laws, including the European Union's General Data Protection Regulation (GDPR). The GDPR has created a range of new compliance obligations, including increased transparency requirements and new data subject rights. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). In addition to the GDPR, certain EU Member States have issued or will be issuing their own implementation legislation. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving privacy and data protection laws. Complying with varying jurisdictional requirements could increase the costs and complexity of compliance, 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 and other personal information. Moreover, patients about whom we or our collaborators obtain health or other personal 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, prevent, or substantially increase the cost of marketing and sales of any affected products that we are able to commercialize. 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 our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.

We rely on funding and support from Sanofi to develop, manufacture, and commercialize certain of our products and product candidates. With respect to Dupixent, Praluent, Kevzara, and REGN3500, which we are co-developing with Sanofi under our Antibody Collaboration, Sanofi funds a significant portion of development expenses incurred in connection with the development of these products. In addition, we rely on Sanofi to lead much of the clinical development efforts, assist with or lead efforts to obtain and maintain regulatory approvals, and lead the commercialization efforts for these products and product candidates.

As a result of the amendment and restatement of our IO Discovery and Development Agreement with Sanofi (which forms part of our IO Collaboration), we have all rights to, and we fund and conduct on our own all research, development, manufacturing, and commercialization activities to support, all of our immuno-oncology product candidates other than MUC16xCD3 Program antibodies (such as REGN4018) and BCMAxCD3 Program antibodies (such as REGN5458 and REGN5459). If Sanofi does not elect to co-develop MUC16xCD3 Program antibodies or BCMAxCD3 Program antibodies under our IO Collaboration, or opts out of their development under our IO Collaboration, we will be required to fund and conduct on our own all such efforts to support those product candidates, unless we enter into arrangements with other parties.

If Sanofi elects to co-develop BCMAxCD3 Program antibodies and/or MUC16xCD3 Program antibodies under our IO Collaboration, Sanofi will initially fund the development expenses incurred in connection with the development of BCMAxCD3 Program antibodies, for which Sanofi will be the principal controlling party, and half of the development expenses incurred in connection with the clinical development of MUC16xCD3 Program antibodies, for which we will be the principal controlling party. Under our IO Collaboration, Sanofi also funds half of the development expenses incurred in connection with the clinical development of Libtayo, subject to an agreed-upon development budget. In addition, if Sanofi elects to co-develop BCMAxCD3 Program antibodies, Sanofi will lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. We also rely on Sanofi to lead commercialization efforts outside the United States for Libtayo. Following regulatory approval, we will rely on Sanofi to lead (i) the commercialization efforts in the United States for BCMAxCD3 Program antibodies and (ii) the commercialization efforts outside the United States for MUC16xCD3 Program antibodies and BCMAxCD3 Program antibodies.

If Sanofi terminates the Antibody Collaboration 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, or our IO Collaboration, such as Libtayo (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 Antibody Collaboration or the IO Collaboration would create substantial new and additional risks to the successful development and commercialization of (i) Dupixent, Praluent, and Kevzara and (ii) Libtayo, 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 and/or lower revenues 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' 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; and George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, 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.

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.

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. 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 150 acres of predominately office buildings and laboratory space located in the towns of Mount Pleasant and Greenburgh, New York, 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. Conversely, 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 September 30, 2019, we had $1,384.8 million in cash and cash equivalents and $4,605.7 million in marketable securities (including $429.7 million in equity securities). Our investments consist primarily of debt 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 by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

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 (as recorded by us or our collaborators), in particular EYLEA, Dupixent, and Libtayo, 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, Dupixent, and Libtayo;
- 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;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all;
- 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. 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 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 September 30, 2019, our five largest shareholders (including our largest shareholder Sanofi) plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 44.8% 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 September 30, 2019. As of September 30, 2019, Sanofi beneficially owned 23,350,365 shares of our Common Stock, representing approximately 21.7% 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 869,828 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*" and which currently remain available to be sold in accordance with the letter agreement). 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. 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.

There can be no assurance that we will repurchase shares of our Common Stock or that we will repurchase shares at favorable prices.

Our board of directors has authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, if at all.

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 September 30, 2019, holders of Class A Stock held 14.6% 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 September 30, 2019:

- our current executive officers and directors beneficially owned 9.5% 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 September 30, 2019, and 20.3% 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 September 30, 2019; and
- our five largest shareholders (including our largest shareholder Sanofi) plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 44.8% 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 September 30, 2019. In addition, these five shareholders plus our Chief Executive Officer held approximately 51.1% 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 September 30, 2019.

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.

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 Libtayo set forth in the IO License and Collaboration Agreement and (b) the allocation of additional funds to certain proposed activities relating to 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 Libtayo 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 (of which 373,880 currently remains available) 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 (of which 495,948 currently remains available). 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 Libtayo 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.*"

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, pursuant to our 2016 ANG2 license and collaboration agreement with Bayer (which was terminated on November 1, 2018 by agreement of the parties but whose "standstill" provisions continue to be in effect as described below), 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) November 1, 2023; (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, equity 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

The following table reflects shares of Common Stock we elected to purchase from Sanofi during the third quarter of 2019 pursuant to the terms of the Letter Agreement relating to Sanofi's funding obligation in connection with (i) Libtayo development costs incurred under the IO License and Collaboration Agreement and (ii) certain activities relating to dupilumab and REGN3500 incurred under the LCA. See Part I, Item 2. "Liquidity and Capital Resources - Sanofi Funding of Certain Development Costs" for further information.

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
9/1/2019–9/30/2019	172,904	$ 281.15	—	—

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
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 Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2019 and 2018; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2019 and 2018; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018; and (v) the notes to the Registrant's Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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:	November 5, 2019	By:	/s/ Robert E. Landry
			Robert E. Landry Executive Vice President, Finance and Chief Financial Officer (Duly Authorized Officer)

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2019	/s/ Leonard S. Schleifer
	Leonard S. Schleifer, M.D., Ph.D.
	President and Chief Executive Officer
	(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert E. Landry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2019	/s/ Robert E. Landry
	Robert E. Landry
	Executive Vice President, Finance and Chief Financial Officer
	(Principal Financial Officer)

Exhibit 32

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
November 5, 2019

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
November 5, 2019