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 June 30, 2020
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 July 23, 2020:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,848,970
Common Stock, $.001 par value	104,543,424

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,992.2	$ 1,617.8
Marketable securities	1,152.0	1,596.5
Accounts receivable - trade, net	1,991.0	2,100.0
Accounts receivable - Sanofi	389.2	260.6
Accounts receivable - other	431.1	425.0
Inventories	1,640.9	1,415.5
Prepaid expenses and other current assets	263.8	273.7
Total current assets	7,860.2	7,689.1
Marketable securities	2,587.6	3,256.8
Property, plant, and equipment, net	3,031.4	2,890.4
Deferred tax assets	774.0	824.2
Other noncurrent assets	175.5	144.7
Total assets	$ 14,428.7	$ 14,805.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 380.1	$ 418.1
Accrued expenses and other current liabilities	1,257.0	1,211.4
Debt	1,500.0	—
Deferred revenue - Sanofi	380.2	310.5
Deferred revenue - other	81.3	71.6
Other liabilities - Sanofi	103.8	85.0
Total current liabilities	3,702.4	2,096.6
Finance lease liabilities	715.9	713.9
Deferred revenue - Sanofi	37.8	27.7
Deferred revenue - other	67.0	77.6
Other liabilities - Sanofi	390.3	482.0
Other noncurrent liabilities	457.9	317.7
Total liabilities	5,371.3	3,715.5
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 2020 and 2019	—	—
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 119,757,931 in 2020 and 113,288,103 in 2019	0.1	0.1
Additional paid-in capital	6,263.0	4,428.6
Retained earnings	8,901.7	7,379.8
Accumulated other comprehensive income	35.5	21.1
Treasury Stock, at cost; 15,578,240 shares in 2020 and 4,860,123 shares in 2019	(6,142.9)	(739.9)
Total stockholders' equity	9,057.4	11,089.7
Total liabilities and stockholders' equity	$ 14,428.7	$ 14,805.2

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Statements of Operations				
Revenues:				
Net product sales	$ 1,226.9	$ 1,205.3	$ 2,463.6	$ 2,309.7
Sanofi collaboration revenue	269.1	75.8	516.0	57.8
Bayer collaboration revenue	244.2	277.2	525.6	541.2
Other revenue	211.8	19.5	275.0	41.7
	1,952.0	1,577.8	3,780.2	2,950.4
Expenses:				
Research and development	722.0	885.5	1,305.9	1,371.6
Selling, general, and administrative	348.3	294.6	715.6	585.7
Cost of goods sold	102.5	67.0	181.3	137.9
Cost of collaboration and contract manufacturing	173.0	78.8	311.5	180.0
Other operating (income) expense, net	(50.2)	(63.7)	(90.6)	(120.4)
	1,295.6	1,262.2	2,423.7	2,154.8
Income from operations	656.4	315.6	1,356.5	795.6
Other income (expense):				
Other income (expense), net	272.2	(82.9)	246.8	(9.1)
Interest expense	(9.7)	(8.0)	(15.8)	(15.7)
	262.5	(90.9)	231.0	(24.8)
Income before income taxes	918.9	224.7	1,587.5	770.8
Income tax expense	21.6	31.6	65.6	116.6
Net income	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
Net income per share - basic	$ 8.19	$ 1.77	$ 13.87	$ 6.00
Net income per share - diluted	$ 7.61	$ 1.68	$ 13.03	$ 5.69
Weighted average shares outstanding - basic	109.6	109.2	109.7	109.1
Weighted average shares outstanding - diluted	117.9	114.6	116.8	115.0
Statements of Comprehensive Income				
Net income	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
Other comprehensive income (loss), net of tax:				
Unrealized gain on debt securities	44.6	14.4	15.8	30.5
Unrealized loss on cash flow hedges	—	(1.4)	(1.4)	(2.4)
Comprehensive income	$ 941.9	$ 206.1	$ 1,536.3	$ 682.3

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					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Shares	Amount	Total Stockholders' Equity
Balance, December 31, 2019	1.8	—	113.3	$ 0.1	$ 4,428.6	$ 7,379.8	$ 21.1	(4.9)	$ (739.9)	$ 11,089.7
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	3.1	—	817.4	—	—	—	—	817.4
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.4)	—	(155.1)	—	—	—	—	(155.1)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	12.5	—	—	—	2.1	14.6
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.8)	(336.0)	(336.0)
Stock-based compensation charges	—	—	—	—	108.0	—	—	—	—	108.0
Net income	—	—	—	—	—	624.6	—	—	—	624.6
Other comprehensive loss, net of tax	—	—	—	—	—	—	(30.2)	—	—	(30.2)
Balance, March 31, 2020	1.8	—	116.0	0.1	5,211.4	8,004.4	(9.1)	(5.7)	(1,073.8)	12,133.0
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	4.4	—	1,355.5	—	—	—	—	1,355.5
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.6)	—	(416.5)	—	—	—	—	(416.5)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	7.4	—	—	—	2.7	10.1
Repurchases of Common Stock	—	—	—	—	—	—	—	(9.9)	(5,071.8)	(5,071.8)
Stock-based compensation charges	—	—	—	—	105.2	—	—	—	—	105.2
Net income	—	—	—	—	—	897.3	—	—	—	897.3
Other comprehensive income, net of tax	—	—	—	—	—	—	44.6	—	—	44.6
Balance, June 30, 2020	1.8	—	119.8	$ 0.1	$ 6,263.0	$ 8,901.7	$ 35.5	(15.6)	$ (6,142.9)	$ 9,057.4

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

	Class A Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Shares	Amount	Total Stockholders' Equity
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 for equity awards granted under long-term incentive plans	—	—	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 of Common Stock for 401(k) Savings Plan	—	—	—	—	4.3	—	—	0.1	6.2	10.5
Repurchases of Common Stock	—	—	—	—	—	—	—	(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 income, 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 for equity awards granted under long-term incentive plans	—	—	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 for 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 income, 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

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

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net income	$ 1,521.9	$ 654.2
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	114.9	103.1
Non-cash compensation expense	209.3	213.7
Other non-cash items, net	(175.8)	110.7
Deferred taxes	118.0	(125.3)
Changes in assets and liabilities:		
Increase in Sanofi, trade, and other accounts receivable	(47.1)	(247.5)
Increase in inventories	(233.4)	(168.2)
Decrease in prepaid expenses and other assets	33.8	33.2
Increase in deferred revenue	78.9	129.8
Increase in accounts payable, accrued expenses, and other liabilities	20.9	381.6
Total adjustments	119.5	431.1
Net cash provided by operating activities	1,641.4	1,085.3
Cash flows from investing activities:		
Purchases of marketable and other securities	(1,533.5)	(2,189.1)
Sales or maturities of marketable securities	2,843.7	745.9
Capital expenditures	(300.0)	(168.9)
Net cash provided by (used in) investing activities	1,010.2	(1,612.1)
Cash flows from financing activities:		
Proceeds from bridge loan facility	1,500.0	—
Proceeds from issuance of Common Stock	2,168.0	155.1
Payments in connection with Common Stock tendered for employee tax obligations	(571.6)	(40.5)
Repurchases of Common Stock	(5,373.6)	(10.0)
Net cash (used in) provided by financing activities	(2,277.2)	104.6
Net increase (decrease) in cash, cash equivalents, and restricted cash	374.4	(422.2)
Cash, cash equivalents, and restricted cash at beginning of period	1,630.3	1,480.2
Cash, cash equivalents, and restricted cash at end of period	$ 2,004.7	$ 1,058.0

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

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

1. Interim Financial Statements

Basis of Presentation

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, 2019 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, 2019.

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

Effective January 1, 2020, we changed the presentation of cost reimbursements from collaborators who are not deemed to be our customers from collaboration revenue to a reduction of the corresponding operating expense (*i.e.*, either Research and development or Selling, general, and administrative) incurred by us. We also changed the presentation of amounts recognized in connection with up-front and development milestone payments received from collaboration revenue to Other operating income. We made these changes in presentation because we believe the new presentation is preferable, as it better reflects the nature of the Company’s costs incurred and revenues earned pursuant to arrangements with collaborators and enhances the comparability of our financial statements with industry peers.

The change in presentation has been applied retrospectively. The tables below present the impact of the change on the Company’s previously-filed Consolidated Balance Sheet as of December 31, 2019, the Condensed Consolidated Statement of Operations for the three and six months ended June 30, 2019, and the Condensed Consolidated Statement of Cash Flows for the six months ended June 30, 2019. The Company’s previously-filed balance sheet has been updated to reflect the addition of the caption Other liabilities for the presentation of up-front and development milestones paid by collaborators that are deferred. There was no impact on the Company’s previously-filed Consolidated Statements of Stockholders’ Equity.

	December 31, 2019		
Balance Sheet Data:	**As Previously Reported**	**Adjustments**	**As Revised**
Accrued expenses and other current liabilities	$ 1,086.8	$ 124.6	$ 1,211.4
Deferred revenue - Sanofi (current)	$ 395.5	$ (85.0)	$ 310.5
Deferred revenue - other (current)	$ 196.2	$ (124.6)	$ 71.6
Other liabilities - Sanofi (current)	—	$ 85.0	$ 85.0
Deferred revenue - Sanofi (noncurrent)	$ 509.7	$ (482.0)	$ 27.7
Deferred revenue - other (noncurrent)	$ 109.3	$ (31.7)	$ 77.6
Other liabilities - Sanofi (noncurrent)	—	$ 482.0	$ 482.0
Other noncurrent liabilities	$ 286.0	$ 31.7	$ 317.7

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

	Three Months Ended June 30, 2019			Six Months Ended June 30, 2019		
Statement of Operations Data:	**As Previously Reported**	**Adjustments**	**As Revised**	**As Previously Reported**	**Adjustments**	**As Revised**
Sanofi collaboration revenue	$ 349.1	$ (273.3)	$ 75.8	$ 595.5	$ (537.7)	$ 57.8
Bayer collaboration revenue	$ 289.0	$ (11.8)	$ 277.2	$ 565.2	$ (24.0)	$ 541.2
Other revenue	$ 90.3	$ (70.8)	$ 19.5	$ 175.1	$ (133.4)	$ 41.7
Total revenues	$ 1,933.7	$ (355.9)	$ 1,577.8	$ 3,645.5	$ (695.1)	$ 2,950.4
Research and development	$ 1,048.3	$ (162.8)	$ 885.5	$ 1,690.1	$ (318.5)	$ 1,371.6
Selling, general, and administrative	$ 417.3	$ (122.7)	$ 294.6	$ 828.1	$ (242.4)	$ 585.7
Cost of collaboration and contract manufacturing(1)	$ 85.5	$ (6.7)	$ 78.8	$ 193.8	$ (13.8)	$ 180.0
Other operating (income) expense, net	—	$ (63.7)	$ (63.7)	—	$ (120.4)	$ (120.4)
Total operating expenses	$ 1,618.1	$ (355.9)	$ 1,262.2	$ 2,849.9	$ (695.1)	$ 2,154.8

(1) In addition to the reclassification of certain amounts in connection with the change in accounting presentation described above, the Company also reclassified certain immaterial reimbursements that were previously classified as collaboration revenue to Cost of collaboration and contract manufacturing.

	Six Months Ended June 30, 2019		
Cash Flows Data:	**As Previously Reported**	**Adjustments**	**As Revised**
Cash flows from operating activities:			
Increase in deferred revenue	$ 401.1	$ (271.3)	$ 129.8
Increase in accounts payable, accrued expenses, and other liabilities	$ 110.3	$ 271.3	$ 381.6

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The extent to which the COVID-19 pandemic may directly or indirectly impact our business, financial condition, and results of operations is highly uncertain and subject to change. We considered the potential impact of the COVID-19 pandemic on our estimates and assumptions and there was not a material impact to our condensed consolidated financial statements as of and for the three and six months ended June 30, 2020; however, actual results could differ from those estimates and there may be changes to our estimates in future periods.

Recently Adopted Accounting Standards

We adopted Accounting Standards Update 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as of January 1, 2020. 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 credit losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the previous other-than-temporary impairment model. The adoption of this standard did not have a material impact on our financial statements or a significant impact on our internal controls.

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

2. Product Sales

Net product sales consist of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
Net Product Sales in the United States	**2020**	**2019**	**2020**	**2019**
EYLEA®	$ 1,113.7	$ 1,160.3	$ 2,285.7	$ 2,234.4
Libtayo®	63.3	40.8	125.0	67.6
Praluent®	47.2	*	47.2 *	*
ARCALYST®	2.7	4.2	5.7	7.7
	$ 1,226.9	$ 1,205.3	$ 2,463.6	$ 2,309.7

* Effective April 1, 2020, the Company is solely responsible for the development and commercialization of Praluent in the United States and records net product sales of Praluent in the United States. See Note 3 for further details.

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for the three and six months ended June 30, 2020 and 2019. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	53 %	56 %	53 %	57 %
McKesson Corporation	32 %	34 %	34 %	32 %

3. Collaboration, License, and Other Agreements

We have entered into various collaborative arrangements to research, develop, manufacture, and commercialize product candidates and utilize our technology platforms. Although each of these arrangements is unique in nature, such arrangements involve a joint operating activity where both parties are active participants in the activities of the collaboration and exposed to significant risks and rewards dependent on the commercial success of the activities.

In arrangements where we do not deem our collaborator to be our customer, payments to and from our collaborator are presented in our statement of operations based on the nature of our business operations, the nature of the arrangement, including the contractual terms, and the nature of the payments, as summarized in the table and further described below.

Nature/Type of Payment	Statement of Operations Presentation
Regeneron's share of profits or losses in connection with commercialization of products	Collaboration revenue
Reimbursement for manufacturing of commercial supplies	Collaboration revenue
Royalties and/or sales-based milestones earned	Collaboration revenue
Reimbursement of Regeneron's research and development expenses	Reduction to Research and development expenses
Regeneron's obligation for its share of collaborator's research and development expenses	Research and development expense
Up-front and development milestone payments to collaborator	Research and development expense
Reimbursement of Regeneron's commercialization-related expenses	Reduction to Selling, general, and administrative expense
Regeneron's obligation for its share of collaborator's commercialization-related expenses	Selling, general, and administrative expense
Regeneron's obligation to pay collaborator for its share of gross profits when Regeneron is deemed to be the principal	Cost of goods sold
Up-front and development milestones earned (when we have a combined unit of account which includes a license and providing research and development services)	Other operating income

In agreements involving multiple goods or services promised to be transferred to our collaborator, we must assess, at the inception of the contract, whether each promise represents a separate obligation (*i.e.*, is "distinct"), or whether such promises should be combined as a single unit of account. When we have a combined unit of account which includes a license and providing research and development services to our collaborator, recognition of up-front payments and development milestones earned from our collaborator is deferred (as a liability) and recognized over the development period (*i.e.*, over time). In arrangements where we satisfy our obligation(s) during the development phase over time, we recognize amounts initially deferred over time typically using an input method on the basis of our research and development costs incurred relative to the total expected cost which determines the extent of our progress toward completion. We review our estimates each period and make revisions to such estimates as necessary.

When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts in the period in which such costs are incurred. In connection with the commercialization phase of our collaborative arrangements, we may be obligated to perform commercialization-related activities on behalf of the collaboration. If we are reimbursed for all or a portion of costs incurred for the commercialization-related activities, we record those reimbursable amounts in the period in which such costs are incurred.

Under certain of the Company's collaboration agreements, product sales and cost of sales may be recorded by the Company's collaborators as they are deemed to be the principal in the transaction. In arrangements where we:

- are obligated to use commercially reasonable efforts to supply commercial product to our collaborator, we may be reimbursed for our manufacturing costs as commercial product is shipped to the collaborator; however, recognition of such cost reimbursements is deferred until the product is sold by our collaborator to third-party customers;
- share in any profits or losses arising from the commercialization of such products, we record our share of the variable consideration, representing net product sales less cost of goods sold and shared commercialization and other expenses, in the period in which such underlying sales occur and costs are incurred by the collaborator; and
- receive royalties and/or sales-based milestone payments from our collaborator, we recognize such amounts in the period earned.

Our collaborators provide us with estimates of product sales and our share of profits or losses, as applicable, for such quarter. These estimates are reconciled to actual results in the subsequent fiscal quarter, and collaboration revenue is adjusted accordingly, as necessary.

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

a. Sanofi

Amounts recognized in our Statements of Operations in connection with our collaborations with Sanofi are detailed below:

		Three Months Ended June 30,		Six Months Ended June 30,	
	Statement of Operations Classification	**2020**	**2019**	**2020**	**2019**
Antibody:					
Regeneron's share of profits in connection with commercialization of antibodies	Sanofi collaboration revenue	$ 171.9	$ 38.8	$ 342.8	$ 11.0
Reimbursement for manufacturing of commercial supplies	Sanofi collaboration revenue	$ 100.6	$ 43.9	$ 180.7	$ 58.4
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 51.3	$ 81.8	$ 128.9	$ 156.3
Regeneron's obligation for its share of Sanofi research and development expenses	Research and development expense	$ (24.9)	$ (12.2)	$ (41.6)	$ (19.6)
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 86.0	$ 121.1	$ 177.2	$ 237.7
Immuno-oncology:					
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	Sanofi collaboration revenue	$ (6.4)	$ (6.9)	$ (12.6)	$ (11.6)
Reimbursement for manufacturing of commercial supplies	Sanofi collaboration revenue	$ 3.0	—	$ 5.1	—
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 47.0	$ 36.5	$ 86.9	$ 82.9
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 14.3	$ 1.8	$ 24.7	$ 4.0
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ (28.2)	$ (19.0)	$ (55.0)	$ (31.4)
Amounts recognized in connection with up-front payments received	Other operating income	$ 20.5	$ 29.0	$ 37.0	$ 55.3

See Note 8 and Note 10 for information regarding Sanofi's sale of our Common Stock during the second quarter of 2020.

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 (the "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 ("Shared Phase 3 Trial Costs") are generally shared 80% by Sanofi and 20% by Regeneron. All other agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi.

Effective January 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 and Note 10 for additional information regarding shares purchased by us from Sanofi during the three and six months ended June 30, 2020 and 2019.

Sanofi leads commercialization activities for products developed under the Antibody Collaboration, subject to the Company's right to co-commercialize such products. See discussion below related to the development and commercialization of Praluent effective April 1, 2020. 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 after aggregate annual sales of antibodies outside the United States (including Praluent) exceed $1.0 billion on a rolling twelve-month basis.

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

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

	June 30, 2020	December 31, 2019
Accounts receivable	$ 383.1	$ 272.7
Deferred revenue	$ 405.5	$ 328.8

In April 2020, the Company and Sanofi entered into an amendment to the LCA in connection with, among other things, the removal of Praluent from the LCA such that (i) effective April 1, 2020, the LCA no longer governs the development, manufacture, or commercialization of Praluent and (ii) the quarterly period ended March 31, 2020 is the last quarter for which Sanofi and the Company will share profits and losses for Praluent under the LCA. The parties also entered into a Praluent Cross License & Commercialization Agreement (the "Praluent Agreement") pursuant to which, effective April 1, 2020, the Company, at its sole cost, is solely responsible for the development and commercialization of Praluent in the United States, and Sanofi, at its sole cost, is solely responsible for the development and commercialization of Praluent outside of the United States. Under the Praluent Agreement, Sanofi will pay the Company a 5% royalty on Sanofi's net product sales of Praluent outside the United States until March 31, 2032. The Company will not owe Sanofi royalties on the Company's net product sales of Praluent in the United States. Although each party will be responsible for manufacturing Praluent for its respective territory, the parties have entered into definitive supply agreements under which, for a certain transitional period, the Company will continue to supply drug substance to Sanofi and Sanofi will continue to supply finished product to Regeneron.

With respect to any intellectual property or product liability litigation relating to Praluent, the parties have agreed that, effective April 1, 2020, Regeneron and Sanofi each will be solely responsible for any such litigation (including damages and other costs and expenses thereof) in the United States and outside the United States, respectively, arising out of Praluent sales or other activities on or after April 1, 2020 (subject to Sanofi's right to set off a portion of any third-party royalty payments resulting from certain patent litigation proceedings against up to 50% of any Praluent royalty payment owed to Regeneron). The parties will each bear 50% of any damages arising out of Praluent sales or other activities prior to April 1, 2020. See Note 12 for discussion of legal proceedings related to Praluent.

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 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. 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 certain shares of our Common Stock directly or indirectly owned by Sanofi through September 30, 2020. If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. See Note 10 for additional information regarding shares purchased by us from Sanofi during the three and six months ended June 30, 2020 and 2019.

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

The Company has principal control over the development of Libtayo and leads commercialization activities in the United States (see Note 2 for related product sales information), while Sanofi leads commercialization activities outside of the United States and the parties equally share profits and losses from worldwide sales.

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

	June 30, 2020	December 31, 2019
Accounts receivable, net	$ (2.2)	$ (16.7)
Deferred revenue	$ 12.5	$ 9.4
Other liabilities	$ 486.7	$ 558.6

Other liabilities include up-front payments received from Sanofi for which recognition has been deferred.

The aggregate amount of the estimated consideration under the IO Collaboration related to the Company's obligation that was unsatisfied (or partially unsatisfied) as of June 30, 2020 was $1.020 billion. This amount is expected to be recognized over the remaining period in which the Company is obligated to satisfy its obligation in connection with performing development activities.

b. Bayer

Amounts recognized in our Statements of Operations in connection with our Bayer EYLEA collaboration are as follows:

	Statement of Operations Classification	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	Bayer collaboration revenue	$ 230.9	$ 269.0	$ 484.7	$ 518.3
Reimbursement for manufacturing of commercial supplies	Bayer collaboration revenue	$ 13.3	$ 8.2	$ 40.9	$ 22.9
Reimbursement of development expenses	Reduction of Research and development expense	$ 10.8	$ 8.0	$ 22.8	$ 10.6
Regeneron's obligation for its share of Bayer research and development expenses	Research and development expense	$ (5.3)	$ (2.0)	$ (13.4)	$ (6.6)
Reimbursement of other expenses	Cost of collaboration and contract manufacturing	$ 1.6	$ 4.1	$ 3.3	$ 12.9

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 through 2021, and thereafter, the companies will share equally in profits and losses from sales of EYLEA. In addition, the Company and Bayer share the funding of agreed-upon EYLEA development costs.

The following table summarizes contract balances in connection with our Bayer EYLEA collaboration:

	June 30, 2020	December 31, 2019
Accounts receivable - other	$ 245.8	$ 311.6
Deferred revenue	$ 125.3	$ 123.0

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

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. 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.

Amounts recognized in our Statements of Operations in connection with the Teva Collaboration Agreement are as follows:

	Statement of Operations Classification	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 31.0	$ 36.5	$ 56.2	$ 68.7
Amounts recognized in connection with up-front and development milestone payments received	Other operating income	$ 20.7	$ 24.5	$ 37.3	$ 46.0

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

	June 30, 2020	December 31, 2019
Accounts receivable - other	$ 28.5	$ 21.2
Other liabilities	$ 77.9	$ 114.4

Other liabilities include up-front and development milestone payments received from Teva for which recognition has been deferred.

The aggregate amount of estimated consideration under the Teva Collaboration Agreement related to the Company's obligation that was unsatisfied (or partially unsatisfied) as of June 30, 2020 was $173.3 million. This amount is expected to be recognized over the remaining period in which the Company is obligated to satisfy its obligation in connection with performing development activities.

d. Intellia

In 2016, we entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas9 gene-editing technology for *in vivo* therapeutic development. The parties collaborate to conduct research for the discovery, development, and commercialization of new therapies, in addition to the research and technology development of the CRISPR/Cas9 platform.

Under the terms of the 2016 agreement, the parties agreed to a target selection process, whereby the Company may obtain exclusive rights in up to 10 targets to be chosen by the Company during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Certain targets that either we or Intellia select pursuant to the target selection process may be subject to a co-development and co-commercialization arrangement at our option or Intellia's option, as applicable.

In May 2020, we expanded our existing collaboration with Intellia to provide us with rights to develop products for additional *in vivo* CRISPR/Cas9-based therapeutic targets and for the parties to jointly develop potential products for the treatment of hemophilia A and B. In addition, we also received non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products. In connection with the agreement, we made a $70.0 million up-front payment, which was recorded to Research and development expense in the second quarter of 2020, and purchased 925,218 shares of Intellia common stock for an aggregate purchase price of $30.0 million. The amount paid in excess of the fair market value of the shares purchased, or $15.0 million, was also recorded to Research and development expense in the second quarter of 2020.

e. Biomedical Advanced Research Development Authority ("BARDA")

In the first quarter of 2020, we announced an expansion of our Other Transaction Agreement ("OTA") with BARDA, pursuant to which U.S. Department of Health and Human Services ("HHS") is obligated to fund 80% of our costs incurred for certain research and development activities related to COVID-19 treatments. In July 2020, we entered into an agreement with entities acting at the direction of BARDA and the U.S. Department of Defense to manufacture and deliver filled and finished REGN-COV2 to the U.S. Government. The agreement could result in payments to the Company of up to $450.2 million in the aggregate for bulk manufacturing of the drug substance, as well as fill/finish and storage activities.

4. Net Income Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income - basic and diluted	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
(Shares in millions)				
Weighted average shares - basic	109.6	109.2	109.7	109.1
Effect of dilutive securities:				
Stock options	7.8	5.4	6.7	5.9
Restricted stock	0.5	—	0.4	—
Weighted average shares - diluted	117.9	114.6	116.8	115.0
Net income per share - basic	$ 8.19	$ 1.77	$ 13.87	$ 6.00
Net income per share - diluted	$ 7.61	$ 1.68	$ 13.03	$ 5.69

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(Shares in millions)	2020	2019	2020	2019
Stock options	0.1	18.3	3.5	18.1
Restricted stock	—	0.4	—	—

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

5. Marketable Securities

Marketable securities as of June 30, 2020 and December 31, 2019 consist of both available-for-sale debt securities of investment grade issuers (see below and Note 6) as well as equity securities of publicly traded companies (see Note 6).

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

	Amortized	Unrealized		Fair
As of June 30, 2020	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 2,393.2	$ 41.9	$ (0.7)	$ 2,434.4
U.S. government and government agency obligations	81.6	1.1	—	82.7
Sovereign bonds	27.0	1.2	—	28.2
Commercial paper	283.1	0.6	—	283.7
Certificates of deposit	105.4	0.1	—	105.5
	$ 2,890.3	$ 44.9	$ (0.7)	$ 2,934.5
As of December 31, 2019				
Corporate bonds	$ 3,960.5	$ 27.8	$ (0.2)	$ 3,988.1
U.S. government and government agency obligations	54.3	0.2	(0.1)	54.4
Sovereign bonds	26.9	0.4	—	27.3
Commercial paper	92.3	—	—	92.3
Certificates of deposit	72.3	0.1	—	72.4
	$ 4,206.3	$ 28.5	$ (0.3)	$ 4,234.5

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of June 30, 2020 mature at various dates through July 2025. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	June 30, 2020	December 31, 2019
Maturities within one year	$ 1,152.0	$ 1,596.5
Maturities after one year through five years	1,779.6	2,638.0
Maturities after five years	2.9	—
	$ 2,934.5	$ 4,234.5

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

	Less than 12 Months		12 Months or Greater		Total	
As of June 30, 2020	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 247.9	$ (0.7)	—	—	$ 247.9	$ (0.7)
As of December 31, 2019						
Corporate bonds	$ 257.2	$ (0.2)	—	—	$ 257.2	$ (0.2)
U.S. government and government agency obligations	17.3	(0.1)	—	—	17.3	(0.1)
	$ 274.5	$ (0.3)	—	—	$ 274.5	$ (0.3)

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

For the three and six months ended June 30, 2020, realized gains on sales of marketable securities were $28.0 million and $28.3 million, respectively, and realized losses were not material. There were no realized losses on sales of marketable securities, and realized gains were not material, for the three and six months ended June 30, 2019.

With respect to marketable securities, for the three and six months ended June 30, 2020 and 2019, amounts reclassified from Accumulated other comprehensive income into Other income (expense), net were related to realized gains on sales of available-for-sale debt securities (as described above).

6. Fair Value Measurements

The table below summarizes the Company's assets which are measured at fair value on a recurring basis. The following fair value hierarchy is used to classify assets, based on inputs to valuation techniques utilized to measure fair value:

- Level 1 - Quoted prices in active markets for identical assets
- Level 2 - Significant other observable inputs, such as 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
- Level 3 - Significant other unobservable inputs

		Fair Value Measurements at Reporting Date	
As of June 30, 2020	**Fair Value**	**Level 1**	**Level 2**
Available-for-sale debt securities:			
Corporate bonds	$ 2,434.4	—	$ 2,434.4
U.S. government and government agency obligations	82.7	—	82.7
Sovereign bonds	28.2	—	28.2
Commercial paper	283.7	—	283.7
Certificates of deposit	105.5	—	105.5
Equity securities (unrestricted)	37.8	$ 37.8	—
Equity securities (restricted)	767.3	751.9	15.4
	$ 3,739.6	$ 789.7	$ 2,949.9
As of December 31, 2019			
Available-for-sale debt securities:			
Corporate bonds	$ 3,988.1	—	$ 3,988.1
U.S. government and government agency obligations	54.4	—	54.4
Sovereign bonds	27.3	—	27.3
Commercial paper	92.3	—	92.3
Certificates of deposit	72.4	—	72.4
Equity securities (unrestricted)	61.6	$ 61.6	—
Equity securities (restricted)	557.2	557.2	—
	$ 4,853.3	$ 618.8	$ 4,234.5

The Company held certain restricted equity securities as of June 30, 2020 which are subject to transfer restrictions that expire at various dates through 2024.

During the three and six months ended June 30, 2020, we recorded $228.1 million and $171.3 million of net unrealized gains, respectively, on equity securities in Other income (expense), net. During the three and six months ended June 30, 2019, we recorded $116.9 million and $74.1 million, respectively, of net unrealized losses on equity securities in Other income (expense), net.

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

In addition to the investments summarized in the table above, as of June 30, 2020 and December 31, 2019, the Company had $70.6 million and $55.6 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets.

7. Inventories

Inventories consist of the following:

	June 30, 2020	December 31, 2019
Raw materials	$ 306.3	$ 216.3
Work-in-process	696.9	727.7
Finished goods	132.0	70.6
Deferred costs	505.7	400.9
	$ 1,640.9	$ 1,415.5

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred (see Note 3).

8. Debt

As described in Note 10, we purchased shares of our Common Stock from Sanofi, in connection with Sanofi's secondary offering of our Common Stock held by Sanofi, with a combination of cash on hand, proceeds from the sale of marketable securities, and proceeds from loans under a $1.5 billion senior unsecured 364-day bridge loan facility (the "Bridge Facility") which was entered into in May 2020. The loans under the Bridge Facility bear interest at a variable interest rate based on either the London Interbank Offered Rate or the alternate base rate, plus an applicable margin that varies with our debt rating and total leverage ratio. The interest rate on the loans under the Bridge Facility was 2.75% as of June 30, 2020. The Bridge Facility will mature, and all amounts outstanding thereunder will become due and payable, in May 2021. Amounts borrowed under the Bridge Facility may be prepaid at any time without premium or penalty. As of June 30, 2020, $ 1.5 billion remained outstanding under the Bridge Facility.

The credit agreement governing the Bridge Facility (the "Bridge Credit Agreement") contains financial and operating covenants, which are substantially similar to the covenants set forth in our existing $750.0 million senior unsecured five-year revolving credit facility. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Bridge Credit Agreement as of June 30, 2020.

9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 2.4% and 14.1% for the three months ended June 30, 2020 and 2019, respectively, and 4.1% and 15.1% for the six months ended June 30, 2020 and 2019, respectively. The Company's effective tax rate for the three and six months ended June 30, 2020 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation, and, to a lesser extent, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and federal tax credits for research activities.

The Company's effective tax rate for the three and six months ended June 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, stock-based compensation, federal tax credits for research activities, and, to a lesser extent, the foreign-derived intangible income deduction, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee.

10. Stockholders' Equity

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. There can be no assurance as to the timing or number of shares of any repurchases in the future.

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

The table below summarizes the shares of our Common Stock we repurchased during 2020 under the program and the cost of the shares received, which were recorded as Treasury Stock. There were no shares repurchased under the program during the three months ended June 30, 2020.

	Six Months Ended June 30, 2020
Number of shares repurchased	719,167
Total cost of shares received	$ 272.8

As of June 30, 2020, the Company had $473.1 million which remained available for share repurchases under the program.

Sanofi Funding of Certain Development Costs

As described in Note 3, effective January 2018, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development costs and/or Dupilumab/REGN3500 Eligible Investments by selling our Common Stock directly or indirectly owned by Sanofi. The table below summarizes the shares of our Common Stock Sanofi elected to sell, and we elected to purchase, to satisfy Sanofi's funding obligations and the cost of the shares received, which were recorded as Treasury Stock:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Libtayo:				
Number of shares purchased (by issuing a credit towards the amount owed by Sanofi)	34,050	—	77,677	106,972
Total cost of shares received	$ 20.3	—	$ 41.7	$ 44.0
Dupilumab/REGN3500:				
Number of shares purchased (in cash)	86,184	—	171,471	24,143
Total cost of shares received	$ 51.5	—	$ 93.3	$ 10.0

As of June 30, 2020, 279,766 shares of our Common Stock remained available for sale by Sanofi to satisfy its funding obligations with respect to Libtayo development costs and/or Dupilumab/REGN3500 Eligible Investments through September 30, 2020.

Additional Stock Purchased from Sanofi

In May 2020, a secondary offering of 13,014,646 shares of our Common Stock (the "Secondary Offering") held by Sanofi was completed. In connection with the Secondary Offering, we also purchased 9,806,805 shares directly from Sanofi for an aggregate purchase amount of $5 billion (the "Stock Purchase"). As a result of the Secondary Offering and the Stock Purchase, Sanofi disposed of all of its shares of our Common Stock, other than 400,000 shares that it retained as of the closing of the Secondary Offering and the Stock Purchase (which Sanofi has used, and may continue to use, for the funding of certain development costs described above). See Note 8 for additional information.

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

11. Statement of Cash Flows

The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheet to the total of the same such amounts shown in the Condensed Consolidated Statement of Cash Flows:

	June 30, 2020	June 30, 2019
Cash and cash equivalents	$ 1,992.2	$ 1,045.5
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	$ 2,004.7	$ 1,058.0

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 June 30, 2020 and December 31, 2019 were $87.4 million and $133.7 million, respectively, of accrued capital expenditures. Included in accounts payable, accrued expenses, and other liabilities as of June 30, 2019 and December 31, 2018 were $74.7 million and $54.5 million, respectively, of accrued capital expenditures.

12. 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. As of June 30, 2020 and December 31, 2019, the Company had accruals for loss contingencies of $132.2 million and $100.0 million, respectively. 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. An oral hearing was held on February 11–12, 2020. On June 24, 2020, the Supreme Court of the United

Kingdom overturned the decision of the Court of Appeal on validity and held that the '287 and '163 Patents are each invalid on the ground of insufficiency.

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. (and/or its affiliated entities) against the Company and/or Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent. See Note 3 for a description of the Company's and Sanofi's arrangement regarding the costs resulting from or associated with such actions.

United States

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.

Europe

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"). Amgen subsequently enforced the injunction and, as a result, commercialization of Praluent in Germany has been discontinued. 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 (originally scheduled for April 2, 2020) has been rescheduled for November 5, 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 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 rescheduled.

On December 17, 2019, Amgen initiated a lawsuit alleging infringement of the Dutch designation of the '124 Patent in the District Court of The Hague in the Netherlands, against Sanofi-Aventis Netherlands B.V. and Sanofi-Aventis Groupe S.A. The Company has not been named as a defendant in this action. Amgen alleges, among other things, patent infringement based on the production, importation, and commercialization of Praluent (alirocumab) in the Netherlands. Amgen's requests are made on an accelerated basis and include, among other things, a request for a permanent injunction, damages, an order for customer information, a recall order, a destruction order, and an order for costs. A trial has been scheduled for October 30, 2020.

On December 20, 2019, Amgen filed a lawsuit for infringement of the Italian designation of the '124 Patent in the Tribunale di Milano - Enterprise Chamber in Milan, Italy, against Sanofi-Aventis Groupe S.A., Sanofi Chimie, and Sanofi SpA. The Company has not been named as a defendant in this action. Amgen alleges that the production, importation, and commercialization of Praluent (alirocumab) in Italy infringes the '124 Patent. The writ of summons filed by Amgen seeks, among other things, a declaration of infringement, a permanent injunction, withdrawal of product from the market, and damages. On June 24, 2020, Amgen also filed a preliminary injunction motion against the Sanofi parties.

On December 20, 2019, Amgen also filed a lawsuit alleging infringement of the Spanish designation of the '124 Patent in the Juzgado de lo Mercantil No. 5 (Commercial Court) in Barcelona, Spain, against Sanofi-Aventis, S.A. The Company has not been named as a defendant in this action. Amgen alleges, among other things, patent infringement based on the manufacture, offering for sale, introduction into the market, use, and importation or possession of Praluent (alirocumab) in Spain. Amgen seeks, among other things, a permanent injunction, withdrawal of Praluent from the market, seizure and destruction of Praluent from the market and in storage, and damages in the form of lost profits and costs and expenses. On May 12, 2020, the court stayed this lawsuit until October 30, 2020 on terms mutually agreed by the parties.

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 rescheduled for October 28–29, 2020.

Other

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. Sanofi K.K. appealed the IPHC's decision in the infringement proceedings to the Supreme Court of Japan on November 12, 2019. On April 24, 2020, the Supreme Court of Japan declined to hear the appeal filed by Sanofi K.K. in the infringement proceedings and the injunction issued by the Tokyo District Court became effective. Sanofi K.K. subsequently complied with the injunction and, as a result, the commercialization of Praluent in Japan has been discontinued. On March 31, 2020, Amgen filed a related lawsuit in the Tokyo District Court against Sanofi K.K. seeking damages incurred by Amgen as a result of the finding of infringement of the '333 Patent and the '288 Patent. The Company has not been named as a defendant in this damages action.

Proceedings Relating to Dupixent (dupilumab) Injection

United States

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, and oral argument has been scheduled for August 5, 2020.

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.

Europe

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.

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. On June 24, 2020, the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint in the U.S. District Court for the District of Massachusetts alleging violations of the federal Anti-Kickback Statute, and asserting causes of action under the federal False Claims Act and state law.

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.

Proceedings Relating to EYLEA (aflibercept) Injection Pre-filled Syringe

On June 19, 2020, Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") filed a complaint with the U.S. International Trade Commission (the "ITC") pursuant to Section 337 of the Tariff Act of 1930 requesting that the ITC institute an investigation relating to the importation into the United States and/or sale within the United States after importation of EYLEA pre-filled syringes ("PFS") and/or components thereof which allegedly infringe Novartis's U.S. Patent No. 9,220,631 (the "'631 Patent"). Novartis also requested a permanent limited exclusion order forbidding entry into the United States of EYLEA PFS or components thereof; a permanent cease-and-desist order from the importation, sale, offer for sale, advertising, packaging, or solicitation of any sale by the Company of EYLEA PFS or components thereof; and a bond should the Company continue to import EYLEA PFS (if found to infringe) during, if applicable, any 60-day Presidential review period (*i.e.*, the period when the President of the United States (or his designee) can disapprove any ITC decision to issue an exclusion order or cease-and-desist order).

On June 19, 2020, Novartis also filed a patent infringement lawsuit in the U.S. District Court for the Northern District of New York asserting claims of the '631 Patent and seeking preliminary and permanent injunctions to prevent the Company from continuing to infringe the '631 Patent. Novartis also seeks a judgment of patent infringement of the '631 Patent, monetary damages (together with interest), treble damages, costs and expenses of the lawsuits, and attorneys' fees. On July 30, 2020, the court granted the Company's motion to stay these proceedings until a determination in the ITC proceedings discussed above, including any appeals therefrom, becomes final.

On July 16, 2020, the Company initiated two IPR petitions in the USPTO seeking a declaration of invalidity of the '631 Patent on two separate grounds.

On July 17, 2020, the Company filed an antitrust lawsuit against Novartis and Vetter Pharma International Gmbh in the United States District Court for the Southern District of New York seeking a declaration that the '631 Patent is unenforceable and a judgment that the defendants' conduct violates Sections 1 and 2 of the Sherman Antitrust Act of 1890, as amended. The Company is also seeking injunctive relief and treble damages.

Proceedings Relating to fasinumab

On May 21, 2020, the Company and Teva Pharmaceutical Industries Limited filed a lawsuit against Rinat Neurosciences Corp. ("Rinat"), a wholly owned subsidiary of Pfizer Inc., in the English High Court of Justice in London, seeking invalidation and revocation of Rinat's European Patent No. 2,270,048 (the "'048 Patent"), European Patent No. 1,871,416 (the "'416 Patent"), and European Patent No. 2,305,711 (the "'711 Patent"), each of which pertains to the use of NGF monoclonal antibodies to treat certain symptoms in patients suffering from osteoarthritis. On July 21, 2020, Rinat filed its defense and counterclaim seeking a declaration of infringement of the '048 Patent by fasinumab. The counterclaim also seeks a permanent injunction, damages, an accounting of profits, and costs and interest. A trial has been scheduled to commence in late November or early December 2021.

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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and our product candidates and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Libtayo® (cemiplimab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, REGN-COV2, Regeneron's oncology programs (including its costimulatory bispecific portfolio), Regeneron's earlier-stage programs, and the use of human genetics in Regeneron's research programs; the likelihood and timing of achieving any of our anticipated development milestones referenced in this report; safety issues resulting from the administration of Regeneron's Products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for Regeneron's Products, including without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, REGN-COV2, and REGN1979; the extent to which the results from the research and development programs conducted by us and/or our collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products (such as EYLEA, Dupixent, Libtayo, Praluent, and Kevzara), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize Regeneron's Products and product candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and product candidates; 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 Regeneron's Products and product candidates; the availability and extent of reimbursement of Regeneron's Products 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; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; 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 EYLEA, Dupixent, and Praluent described further in Note 12 to our Condensed Consolidated Financial Statements included in this report), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 12 to our Condensed Consolidated Financial Statements included in this report), 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, pain, infectious diseases, 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 June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2020**	**2019***	**2020**	**2019***
Revenues	$ 1,952.0	$ 1,577.8	$ 3,780.2	$ 2,950.4
Net income	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
Net income per share - diluted	$ 7.61	$ 1.68	$ 13.03	$ 5.69

* Certain revisions have been made to the previously reported June 30, 2019 revenues. See Note 1 to our Condensed Consolidated Financial Statements for further details.

Marketed Products

We currently have seven products that have received marketing approval, which are currently marketed by us, Bayer, and/or Sanofi:

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	✔			
	- Neovascular glaucoma ("NVG")			✔	
Dupixent (dupilumab) Injection(3)	- Atopic dermatitis (in adults and adolescents)(7)	✔	✔	✔	✔
	- Atopic dermatitis (in pediatrics 6–11 years of age)	✔			
	- Asthma (in adults and adolescents)	✔	✔	✔	✔
	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔	✔
Libtayo (cemiplimab) Injection(3)(4)	- Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔		✔
Praluent (alirocumab) Injection(5)	- LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD") (in adults)	✔	✔	(9)	✔
	- Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔		✔
Kevzara (sarilumab) Solution for Subcutaneous Injection(3)	- Rheumatoid arthritis ("RA") (in adults)	✔	✔	✔	✔
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(8)	- 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) In collaboration with Sanofi prior to April 2020. Effective April 2020, the Company is solely responsible for the development and commercialization of Praluent in the United States, and Sanofi is solely responsible for the development and commercialization of Praluent outside of the United States. Pursuant to the April 2020 agreement, Sanofi pays us a royalty on net product sales of Praluent outside the United States. Refer to "Collaboration and License Agreements" section below for further details.
(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
(7) Approval in Japan is for adults and adolescents 15 years of age and older
(8) 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 product sales of ZALTRAP
(9) No longer marketed by Sanofi in Japan due to injunction (see Note 12 to our Condensed Consolidated Financial Statements for further details)

Net Product Sales of Regeneron-Discovered Products

	Net Product Sales Recorded by Regeneron	Three Months Ended June 30, 2020			2019			% Change
		U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA(a)	U.S.	$ 1,113.7	$ 641.0	$ 1,754.7	$ 1,160.3	$ 715.3	$ 1,875.6	(6 %)
Dupixent	(b)	$ 770.4	$ 174.6	$ 945.0	$ 454.7	$ 102.6	$ 557.3	70 %
Libtayo(b)	U.S.	$ 63.3	$ 16.7	$ 80.0	$ 40.8	—	$ 40.8	96 %
Praluent(c)	U.S.	$ 47.2	$ 39.4	$ 86.6	$ 26.5	$ 47.2	$ 73.7	18 %
Kevzara	(b)	$ 36.5	$ 31.8	$ 68.3	$ 34.2	$ 24.3	$ 58.5	17 %
ZALTRAP	(b)	$ 1.7	$ 25.0	$ 26.7	$ 1.3	$ 25.3	$ 26.6	— %
ARCALYST	U.S.	$ 2.7	—	$ 2.7	$ 4.2	—	$ 4.2	(36 %)

	Net Product Sales Recorded by Regeneron	Six Months Ended June 30, 2020			2019			% Change
		U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA(a)	U.S.	$ 2,285.7	$ 1,322.7	$ 3,608.4	$ 2,234.4	$ 1,384.7	$ 3,619.1	— %
Dupixent	(b)	$ 1,449.4	$ 350.8	$ 1,800.2	$ 757.7	$ 173.3	$ 931.0	93 %
Libtayo(b)	U.S.	$ 125.0	$ 29.8	$ 154.8	$ 67.6	—	$ 67.6	129 %
Praluent(c)	U.S.	$ 82.3	$ 84.1	$ 166.4	$ 49.4	$ 88.2	$ 137.6	21 %
Kevzara	(b)	$ 71.8	$ 56.6	$ 128.4	$ 54.9	$ 37.3	$ 92.2	39 %
ZALTRAP	(b)	$ 3.2	$ 51.5	$ 54.7	$ 1.8	$ 49.3	$ 51.1	7 %
ARCALYST	U.S.	$ 5.7	—	$ 5.7	$ 7.7	—	$ 7.7	(26 %)

(a) Regeneron records net product sales of EYLEA in the United States. Bayer records net product sales of EYLEA outside the United States. The Company records its share of profits/losses in connection with sales of EYLEA outside the United States.

(b) Regeneron records net product sales of Libtayo in the United States. Sanofi records net product sales of Libtayo outside the United States and global net product sales of Dupixent, Kevzara, and ZALTRAP. The Company records its share of profits/losses in connection with (i) sales of Libtayo outside the United States, and (ii) global sales of Dupixent and Kevzara. Sanofi pays the Company a percentage of net sales of ZALTRAP.

(c) Effective April 1, 2020, Regeneron records net product sales of Praluent in the United States. Also effective April 1, 2020, Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales. Previously, Sanofi recorded global net product sales of Praluent and the Company recorded its share of profits/losses in connection with such sales. Refer to "Marketed Products" section above and "Collaboration and License Agreements - Sanofi" section below for further details.

Programs in Clinical Development

All 23 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. 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. The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results.

We and our collaborators conduct clinical trials in multiple countries across the world. The COVID-19 pandemic and the restrictions adopted around the globe to reduce the spread of the disease have impacted and will continue to impact our clinical development programs. We continue to evaluate the impact of the COVID-19 pandemic on an individual trial basis and are working to ensure patient safety, provide sufficient supply of product candidates for the studies, and oversee trial management. At this time, we expect fully enrolled clinical studies to remain generally on track. While the COVID-19 pandemic and the resulting constraints on healthcare resources and local or regional restrictions initially adversely impacted new clinical studies and recruitment of new patients into open studies, enrollment in both new and ongoing clinical studies started to resume as regions relaxed their restrictions and healthcare resources started to become more available for non-COVID-19 activities. However, there has been a resurgence of COVID-19 cases in many regions across the world, and any resurgence of COVID-19 cases in the regions in which we or our collaborators conduct clinical trials may require our expectations relating to the impacted studies to adjust. The ultimate impact (including possible delays) resulting from the COVID-19 pandemic will depend, among other factors, on the extent of the pandemic in the areas with study sites for our or our collaborators' clinical programs. It is possible that the COVID-19 pandemic may cause clinical disruptions beyond those we have described. In addition, there may be delays in the timing of regulatory review and other projected milestones discussed in the table below.

Refer to Part II, Item 1A. "Risk Factors" for a description of these and other risks and uncertainties that may affect our clinical programs, including those related to the COVID-19 pandemic.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
Ophthalmology						
EYLEA[b]		- High-dose formulation in wet AMD	- Retinopathy of prematurity ("ROP")[c] - High-dose formulation in wet AMD - High-dose formulation in DME		- Approved by Ministry of Health, Labour and Welfare ("MHLW") for NVG in Japan - Pre-filled syringe approved by European Commission ("EC")	
Immunology & Inflammatory Diseases						
Dupixent (dupilumab)[a] *Antibody to IL-4R alpha subunit*		- Peanut allergy	- 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] in adults, adolescents, and pediatrics - Chronic obstructive pulmonary disease ("COPD") - Bullous pemphigoid (Phase 2/3)[c] - Chronic spontaneous urticaria - Prurigo nodularis	- Atopic dermatitis in pediatrics (6–11 years of age) (EU)[d] - Auto-injector for 300 mg dose (Japan)	- Approved by FDA for expanded atopic dermatitis indication in pediatrics (6–11 years of age) - Approved by National Medical Products Administration ("NMPA") in China for adults with atopic dermatitis - Approved by MHLW for CRSwNP in Japan - Approved by FDA for 300 mg auto-injector - Reported that Part A of the Phase 3 trial in adult and adolescent patients with EoE met both co-primary endpoints - Presented results from Phase 2a trial in grass allergy - Initiated second confirmatory Phase 3 trial in COPD	- EC decision for expanded atopic dermatitis indication in pediatrics (6–11 years of age) (second half 2020) - Report results from Phase 3 study for atopic dermatitis in pediatric patients (6 months–5 years of age) (2022) - Report results from Phase 3 study for asthma in pediatric patients (6–11 years of age) (second half 2020) - Resubmit supplemental Biologics License Application ("sBLA") for 200 mg auto-injector (second half 2020) - Report results from Phase 2 study in peanut allergy (second half 2020) - Report results from Part B of the Phase 3 study in adults and adolescents with EoE (2022)

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Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review(i)	2020 Events to Date	Select Upcoming Milestones(k)
			- Allergic bronchopulmonary aspergillosis ("ABPA")			- Initiate Phase 3 study in hand and foot atopic dermatitis (second half 2020)
Kevzara (sarilumab)(a) *Antibody to IL-6R*		- Polyarticular-course juvenile idiopathic arthritis ("pcJIA") - Systemic juvenile idiopathic arthritis ("sJIA")	- Hospitalized "critical" COVID-19 patients (outside the United States)		- Stopped Phase 3 U.S. trial in COVID-19 patients due to study not meeting its primary and key secondary endpoints - Discontinued clinical development in polymyalgia rheumatica and giant cell arteritis	- Report results from Phase 3 study outside the United States in COVID-19 (second half 2020)
REGN3500(a) *Antibody to IL-33. Studied as monotherapy and in combination with Dupixent.*		- Asthma - COPD			- Discontinued further clinical development in atopic dermatitis due to lack of efficacy	
REGN1908-1909(f) *Multi-antibody therapy to Feld1*		- Cat allergy				- Report results from Phase 2 study in cat allergic asthmatics (first half 2021)
REGN5713-5714-5715 *Antibody to Betv1*	- Birch allergy					
Oncology						
Libtayo (cemiplimab)(a)(h) *Antibody to PD-1*	- Solid tumors and advanced hematologic malignancies	- Basal cell carcinoma ("BCC") (potentially pivotal study)	- First-line non-small cell lung cancer ("NSCLC"), monotherapy		- Reported that Phase 3 monotherapy trial in first-line NSCLC met its primary endpoint. The Independent Data Monitoring Committee ("IDMC") recommended stopping the trial early due to highly significant improvement in overall survival.	- Submit sBLA and Marketing Authorization Application ("MAA") for first-line NSCLC, monotherapy (second half 2020)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
		- Metastatic or locally advanced CSCC[d] - Neoadjuvant CSCC	- First-line NSCLC, chemotherapy combination - Second-line cervical cancer[e] - Adjuvant CSCC		- Reported that Phase 2 study in BCC demonstrated clinically-meaningful and durable responses	- Complete patient enrollment in Phase 3 first-line NSCLC chemotherapy combination study (second half 2020) - Submit sBLA and MAA for BCC (second half 2020) - Interim analysis from Phase 3 study in cervical cancer (2021)
REGN1979 *Bispecific antibody targeting CD20 and CD3*	- Certain B-cell malignancies[c]	- B-cell non-Hodgkin lymphoma ("B-NHL") (potentially pivotal study)			- Expanded potentially pivotal Phase 2 program with different subtypes of NHL	- Report updated results from initial study in certain B-cell malignancies (second half 2020)
REGN5458[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma					- Report updated results from initial study in multiple myeloma (second half 2020)
REGN5459[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma					
REGN4018[a] *Bispecific antibody targeting MUC16 and CD3*	- Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	- Prostate cancer					
REGN5093 *Bispecific antibody targeting two distinct MET epitopes*	- MET-altered advanced NSCLC					
REGN3767[f] *Antibody to LAG-3*	- Solid tumors and advanced hematologic malignancies					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review(i)	2020 Events to Date	Select Upcoming Milestones(k)
Cardiovascular/Metabolic Diseases						
Praluent (alirocumab)(j) *Antibody to PCSK9*			- Homozygous familial hypercholesterolemia ("HoFH")(c) in adults and pediatrics - HeFH in pediatrics	- HoFH in adults (U.S.)(c)	- Reported results from Phase 3 study in adult patients with HoFH	- FDA decision on sBLA for HoFH in adults (target action date of April 4, 2021)
Evinacumab(f) (REGN1500) *Antibody to ANGPTL3*		- Refractory hypercholesterolemia (both HeFH and non-FH) - Severe hypertriglyceridemia		- HoFH (U.S.)(c)(d)	- Submitted MAA for HoFH	- FDA decision on BLA and EC decision on MAA for HoFH (first half 2021)
Pozelimab(f) (REGN3918) *Antibody to C5*		- Paroxysmal nocturnal hemoglobinuria ("PNH")(c) - CD55-deficient protein-losing enteropathy(c)				- Initiate combination program with Alnylam's cemdisiran (second half 2020) - Initiate Phase 3 program in PNH (next 12 months)
Garetosmab(f) (REGN2477) *Antibody to Activin A*		- Fibrodysplasia ossificans progressiva ("FOP")(c)(d)(e) (potentially pivotal study)			- Reported results from Phase 2 study in FOP	- Submit BLA and MAA for FOP (first half 2021) - Initiate Phase 3 study for FOP in pediatrics (first half 2021)
REGN4461(f) *Agonist antibody to leptin receptor ("LEPR")*		- Generalized lipodystrophy(e)				
Pain						
Fasinumab(l)(f) (REGN475) *Antibody to NGF*			- Osteoarthritis pain of the knee or hip(e)		- Reported top-line results from Phase 3 trials in osteoarthritis pain of the knee or hip	- Report additional longer-term safety results from Phase 3 studies in osteoarthritis pain of the knee or hip (first half 2021)
REGN5069 *Antibody to GFRα3*		- Osteoarthritis pain of the knee(e)				- Report results from Phase 2 study in osteoarthritis pain of the knee (second half 2020)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
Infectious Diseases						
REGN-EB3[f][g] (REGN3470-3471-3479) *Multi-antibody therapy to Ebola virus infection ("Ebola")*				- Ebola (U.S.)[c][d]		- FDA decision on BLA for Ebola (target action date of October 25, 2020)
REGN-COV2[g] (REGN10933-10987) *Multi-antibody therapy to SARS-CoV-2 virus*	- COVID-19 multi-dose safety study	- COVID-19 treatment (Phase 2/3)	- COVID-19 prevention[m]		- Two papers published in *Science* describing REGN-COV2	- Report initial virology and biomarker results from treatment trials (September 2020)

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 Bayer outside of the United States

[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] 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 and development 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] In collaboration with Sanofi prior to April 2020. Effective April 2020, the Company is solely responsible for the development and commercialization of Praluent in the United States, and Sanofi is solely responsible for the development and commercialization of Praluent outside of the United States. Refer to "Collaboration and License Agreements" section below for further details.

[k] As described in the section preceding the table above and Part II, Item 1A. "Risk Factors," development timelines may be further subject to change as a result of the impact of the COVID-19 pandemic

[l] In collaboration with Teva and Mitsubishi Tanabe Pharma

[m] Conducted jointly with the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH")

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 our marketed products. 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.

Additional Information - Clinical Development Programs

REGN-COV2

We are using our end-to-end antibody technologies to discover and develop brand new therapeutic antibodies for COVID-19. The Company is advancing REGN-COV2, a novel investigational antibody "cocktail" treatment designed to prevent and treat infection from the SARS-CoV-2 virus. The use of our two-antibody "cocktail" is intended to diminish the risk of viral escape by effectively binding to the virus's critical spike protein in two separate, non-overlapping locations. In April 2020, the Company moved its leading neutralizing antibodies into pre-clinical and clinical-scale cell production lines, and in June 2020, initiated its first clinical trial of REGN-COV2. Following a positive review from the IDMC of REGN-COV2 Phase 1 safety results in an initial cohort, the program advanced to late-stage clinical trials (see table above for further details). The REGN-COV2 clinical program consists of the following separate study populations: hospitalized COVID-19 patients, non-hospitalized symptomatic COVID-19 patients, and uninfected people with close exposure to a COVID-19 patient (such as the patient's housemate).

Fasinumab

In August 2020, we announced that two Phase 3 trials, FACT OA1 and FACT OA2, achieved the co-primary endpoints for fasinumab 1 mg monthly, demonstrating significant improvements in pain and physical function over placebo at week 16 and week 24, respectively. Fasinumab 1 mg monthly also showed nominally significant benefits in physical function in both trials and pain in one trial, when compared to the maximum FDA-approved prescription doses of non-steroidal anti-inflammatory drugs for osteoarthritis.

The FACT OA1 trial included an additional treatment arm, fasinumab 1 mg every two months, which showed numerical benefit over placebo, but did not reach statistical significance.

In initial safety analyses from the Phase 3 trials, there was an increase in arthropathies reported with fasinumab. In a sub-group of patients from one Phase 3 long-term safety trial, there was an increase in joint replacement with fasinumab 1 mg monthly treatment during the off-drug follow-up period, although this increase was not seen in the other trials to date. Additional longer-term safety data from the ongoing trials are being collected and are expected to be reported early next year.

Agreements with BARDA

In the first quarter of 2020, the Company announced an expansion of its Other Transaction Agreement ("OTA") with BARDA, pursuant to which HHS is obligated to fund 80% of our costs incurred for certain research and development activities related to COVID-19 treatments. In July 2020, the Company also announced an agreement with entities acting at the direction of BARDA and the U.S. Department of Defense to manufacture and deliver filled and finished REGN-COV2 to the U.S. Government. This agreement could result in payments to the Company of up to $450.2 million in the aggregate for bulk manufacturing of the drug substance, beginning in the summer of 2020, as well as fill/finish and storage activities starting in the third quarter of 2020.

In 2015, we and BARDA entered into an agreement pursuant to which HHS provides certain funding to develop, test, and manufacture a treatment for Ebola virus infection. In July 2020, HHS exercised its option under the existing agreement to provide up to $344.6 million of additional funding for the manufacture and supply of REGN-EB3. Contingent upon FDA approval of REGN-EB3, we expect to deliver an established number of treatment doses over the course of approximately six years.

Collaboration and License Agreements

Sanofi

In May 2020, a secondary offering of 13,014,646 shares of our Common Stock held by Sanofi was completed. We also purchased 9,806,805 shares directly from Sanofi for an aggregate purchase amount of $5 billion. Pursuant to the offering and purchase, Sanofi disposed of all of its shares of common stock in Regeneron, other than 400,000 shares that it retained as of the closing of these transactions (which Sanofi has used, and may continue to use, for the funding of certain development costs as described below).

Antibody

As of June 30, 2020, we were collaborating with Sanofi on the global development and commercialization of Dupixent, Kevzara, and REGN3500 (the "Antibody Collaboration"). See discussion below for updates related to the development and commercialization of Praluent effective April 1, 2020. Under the terms of the Antibody License and Collaboration Agreement (the "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 generally 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.

In 2018, we and Sanofi entered into a letter agreement (the "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 certain shares of our Common Stock directly or indirectly owned by Sanofi. Refer to the "*Immuno-Oncology*" section below for further details regarding the Letter Agreement and this funding arrangement.

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 in the United States and in certain countries outside the United States. We currently anticipate commencing co-commercialization of Dupixent in such countries outside the United States at the end of 2020 or early 2021. 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 an aggregate of $250.0 million in milestone payments upon achievement of specified aggregate annual sales of antibodies outside the United States (including Praluent) on a rolling twelve-month basis. The Company will be entitled to receive the first sales milestone payment from Sanofi, in the amount of $50.0 million, when such sales outside the United States exceed $1.0 billion.

In April 2020, the Company and Sanofi entered into an amendment to the LCA in connection with, among other things, the removal of Praluent from the LCA such that (i) effective April 1, 2020, the LCA no longer governs the development, manufacture, or commercialization of Praluent and (ii) the quarterly period ended March 31, 2020 was the last quarter for which Sanofi and the Company will share profits and losses for Praluent under the LCA. The parties also entered into a Praluent

Cross License & Commercialization Agreement (the "Praluent Agreement") pursuant to which, effective April 1, 2020, the Company, at its sole cost, is solely responsible for the development and commercialization of Praluent in the United States, and Sanofi, at its sole cost, is solely responsible for the development and commercialization of Praluent outside of the United States. Under the Praluent Agreement, Sanofi will pay the Company a 5% royalty on Sanofi's net product sales of Praluent outside the United States until March 31, 2032. The Company will not owe Sanofi royalties on the Company's net product sales of Praluent in the United States. Although each party will be responsible for manufacturing Praluent for its respective territory, the parties have entered into definitive supply agreements under which, for a certain transitional period, the Company will continue to supply drug substance to Sanofi and Sanofi will continue to supply finished product to Regeneron. With respect to any intellectual property or product liability litigation relating to Praluent, the parties have agreed that, effective April 1, 2020, Regeneron and Sanofi each will be solely responsible for any such litigation (including damages and other costs and expenses thereof) in the United States and outside the United States, respectively, arising out of Praluent sales or other activities on or after April 1, 2020 (subject to Sanofi's right to set off a portion of any third-party royalty payments resulting from certain patent litigation proceedings against up to 50% of any Praluent royalty payment owed to Regeneron). The parties will each bear 50% of any damages arising out of Praluent sales or other activities prior to April 1, 2020.

In December 2019, the Company and Sanofi also announced their intent to restructure their antibody collaboration for Kevzara. The companies continue to assess potential terms of this restructuring in light of the clinical program evaluating Kevzara in patients hospitalized with COVID-19 infection.

Immuno-Oncology

We are collaborating with Sanofi on the development and commercialization of 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 (the "Amended IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement (the "IO License and Collaboration Agreement").

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 original 2015 Immuno-oncology Discovery and Development Agreement (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 obligated to reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the Amended IO Discovery Agreement from our share of profits from commercialized IO Collaboration products.

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.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us. If Sanofi exercises its option to license rights to a 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 IO 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, 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 certain shares of our Common Stock directly or indirectly owned by Sanofi. As of June 30, 2020, 279,766 shares of our Common Stock remained eligible for sale by Sanofi in order to satisfy its funding obligations with respect to Libtayo development costs and/or, as noted above, Dupilumab/REGN3500 Eligible Investments.

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. Refer to the *"Antibody"* section above for a description of share transactions related to Dupilumab/REGN3500 Eligible Investments.

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.

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 entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales through 2021, and thereafter, the companies will share equally in profits and losses from the sales of EYLEA.

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.

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. We lead global development activities, and the parties share equally, on an ongoing basis, development costs under a global development plan. As of June 30, 2020, 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 billion 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).

Zai Lab

REGN1979

In April 2020, we entered into an agreement with Zai Lab Limited to develop and commercialize REGN1979 in mainland China, Hong Kong, Taiwan, and Macau (the "Zai Territories"). In connection with the agreement, Zai made a $30.0 million non-refundable up-front payment to the Company. We will continue to lead global development activities for REGN1979, and Zai will be responsible for funding a portion of the global development costs for certain clinical trials.

We are responsible for the manufacture and supply of clinical and commercial product of REGN1979 to Zai. If REGN1979 is commercialized in the Zai Territories, we will supply the product to Zai at a tiered purchase price, which is calculated as a percentage of net sales of the product (subject to adjustment in certain circumstances), and are eligible to receive up to $160.0 million in additional regulatory and sales milestone payments.

Intellia

In 2016, we entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas9 gene-editing technology for *in vivo* therapeutic development. In May 2020, we expanded our existing collaboration with Intellia Therapeutics, Inc. to provide us with rights to develop products for additional *in vivo* CRISPR/Cas9-based therapeutic targets and for the companies to jointly develop potential products for the treatment of hemophilia A and B. In addition, we also received non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products. In connection with the agreement, we made a $70.0 million up-front payment and purchased 925,218 shares of Intellia common stock for an aggregate purchase price of $30.0 million. The amount paid in excess of the fair market value of the shares purchased, or $15.0 million, was recorded to Research and development expense.

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 Six Months Ended June 30, 2020 and 2019

Certain revisions have been made to the previously reported June 30, 2019 amounts below in connection with changing the presentation of certain amounts earned from collaborators; see Note 1 to our Condensed Consolidated Financial Statements for further details.

Net Income

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2020**	**2019**	**2020**	**2019**
Revenues	$ 1,952.0	$ 1,577.8	$ 3,780.2	$ 2,950.4
Operating expenses	1,295.6	1,262.2	2,423.7	2,154.8
Income from operations	656.4	315.6	1,356.5	795.6
Other income (expense), net	262.5	(90.9)	231.0	(24.8)
Income before income taxes	918.9	224.7	1,587.5	770.8
Income tax expense	21.6	31.6	65.6	116.6
Net income	$ 897.3	$ 193.1	$ 1,521.9	$ 654.2
Net income per share - diluted	$ 7.61	$ 1.68	$ 13.03	$ 5.69

Revenues

	Three Months Ended June 30,			Six Months Ended June 30,		
(In millions)	**2020**	**2019**	**$ Change***	**2020**	**2019**	**$ Change***
Net product sales in the United States:						
EYLEA	$ 1,113.7	$ 1,160.3	$ (46.6)	$ 2,285.7	$ 2,234.4	$ 51.3
Libtayo	63.3	40.8	22.5	125.0	67.6	57.4
Praluent	47.2	*	*	47.2	*	*
ARCALYST	2.7	4.2	(1.5)	5.7	7.7	(2.0)
Sanofi and Bayer collaboration revenue:						
Sanofi	269.1	75.8	193.3	516.0	57.8	458.2
Bayer	244.2	277.2	(33.0)	525.6	541.2	(15.6)
Other revenue	211.8	19.5	192.3	275.0	41.7	233.3
Total revenues	$ 1,952.0	$ 1,577.8	$ 374.2	$ 3,780.2	$ 2,950.4	$ 829.8

* Net product sales of Praluent in the United States were recorded by Sanofi prior to April 1, 2020

Net Product Sales

Net product sales of EYLEA in the United States decreased for the three months ended June 30, 2020, compared to the same period in 2019, due to lower sales volume primarily attributable to the COVID-19 pandemic and an increase in sales-related deductions primarily due to higher discounts. Net product sales of EYLEA in the United States increased for the six months ended June 30, 2020, compared to the same period in 2019, due to higher sales volume partly offset by an increase in sales-related deductions, primarily due to higher rebates and discounts, as well as the impact of the COVID-19 pandemic. Overall U.S. EYLEA demand was lower in April 2020 compared to the same period of 2019. While we observed an increase in U.S. EYLEA demand during the remainder of the second quarter of 2020 relative to April 2020, we are unable to predict whether there will be additional adverse impact on net product sales if shelter-in-place and social distancing orders are reintroduced or imposed in additional geographies.

Effective April 1, 2020, the Company is solely responsible for the development and commercialization of Praluent in the United States and records net product sales of Praluent in the United States. Refer to "Collaboration and License Agreements - *Sanofi - Antibody*" section above for further details.

Sanofi Collaboration Revenue

(In millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 171.9	$ 38.8	$ 342.8	$ 11.0
Reimbursement for manufacturing of commercial supplies(1)	100.6	43.9	180.7	58.4
Total Antibody	272.5	82.7	523.5	69.4
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(6.4)	(6.9)	(12.6)	(11.6)
Reimbursement for manufacturing of commercial supplies(1)	3.0	—	5.1	—
Total Immuno-oncology	(3.4)	(6.9)	(7.5)	(11.6)
Total Sanofi collaboration revenue	$ 269.1	$ 75.8	$ 516.0	$ 57.8

(1) The corresponding costs incurred by us in connection with such production is recorded within Cost of collaboration and contract manufacturing.

<u>*Antibody*</u>

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. During the three and six months ended June 30, 2020, the change in our share of profits in connection with commercialization of antibodies, compared to the same period in 2019, was primarily driven by higher Dupixent profits as well as our new agreement with Sanofi under which, effective April 1, 2020, we are no longer sharing in losses with Sanofi in connection with the commercialization of Praluent (see further information below). The increase in reimbursements for manufacturing of commercial supplies is primarily driven by higher Dupixent sales, as revenue recognition for such cost reimbursements is deferred until the product is sold by Sanofi to third-party customers.

Regeneron's share of profits in connection with the commercialization of Dupixent, Praluent (through March 31, 2020), and Kevzara is summarized below:

(In millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Dupixent, Praluent, and Kevzara net product sales(1)	$ 1,013.3	$ 689.5	$ 2,008.4	$ 1,160.8
Regeneron's share of collaboration profits	$ 191.4	$ 43.0	$ 384.4	$ 15.2
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	19.5	4.2	41.6	4.2
Regeneron's share of profits in connection with commercialization of antibodies	$ 171.9	$ 38.8	$ 342.8	$ 11.0
Regeneron's share of collaboration profits as a percentage of Dupixent, Praluent, and Kevzara net product sales(1)	17 %	6 %	17 %	1 %

(1) Global net product sales of Dupixent and Kevzara are recorded by Sanofi. The quarter ended March 31, 2020 was the last quarter for which Sanofi and the Company shared profits and losses in connection with Sanofi's global net sales and the related commercialization of Praluent (see further details below); therefore, the quarter ended March 31, 2020 was the last quarter for which net product sales of Praluent were included in the table above.

As described above under "Collaboration and License Agreements - *Sanofi - Antibody*", effective April 1, 2020, the Company is solely responsible for the development and commercialization of Praluent in the United States. Under the new agreement, Sanofi is solely responsible for the development and commercialization of Praluent outside of the United States, and will pay the Company a 5% royalty on Sanofi's net product sales of Praluent outside the United States.

Bayer Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 230.9	$ 269.0	$ 484.7	$ 518.3
Reimbursement for manufacturing of commercial supplies(1)	13.3	8.2	40.9	22.9
Total Bayer collaboration revenue	$ 244.2	$ 277.2	$ 525.6	$ 541.2

(1) The corresponding costs incurred by us in connection with such production is recorded within Cost of collaboration and contract manufacturing.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
EYLEA net product sales outside the United States	$ 641.0	$ 715.3	$ 1,322.7	$ 1,384.7
Regeneron's share of collaboration profit from sales outside the United States	$ 245.3	$ 282.9	$ 513.5	$ 546.3
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(14.4)	(13.9)	(28.8)	(28.0)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 230.9	$ 269.0	$ 484.7	$ 518.3
Regeneron's net profit as a percentage of EYLEA net product sales outside the United States	36 %	38 %	37 %	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

Other revenue increased during the three and six months ended June 30, 2020, compared to the same periods of 2019, primarily due to:

- recognition of revenue in connection with our agreements with BARDA related to funding of certain development activities for REGN-EB3 for the treatment of Ebola and antibodies for the treatment of COVID-19;
- $30.0 million up-front payment received from Zai Lab in connection with our collaboration agreement; and
- effective April 1, 2020, Sanofi's reimbursement for manufacturing commercial supplies of Praluent and royalties of 5% on Sanofi's net product sales of Praluent outside the United States.

Expenses

(In millions, except headcount data)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	$ Change	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	$ Change
Research and development[1]	$ 722.0	$ 885.5	$ (163.5)	$ 1,305.9	$ 1,371.6	$ (65.7)
Selling, general, and administrative[1]	348.3	294.6	53.7	715.6	585.7	129.9
Cost of goods sold[2]	102.5	67.0	35.5	181.3	137.9	43.4
Cost of collaboration and contract manufacturing[3]	173.0	78.8	94.2	311.5	180.0	131.5
Other operating (income) expense, net	(50.2)	(63.7)	13.5	(90.6)	(120.4)	29.8
Total operating expenses	$ 1,295.6	$ 1,262.2	$ 33.4	$ 2,423.7	$ 2,154.8	$ 268.9
Average headcount	8,254	7,649	605	8,142	7,549	593

[1] Includes costs incurred as well as cost reimbursements from collaborators who are not deemed to be our customers

[2] 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.,* for which we record net product sales) 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

[3] Cost of collaboration and contract manufacturing includes costs we incur in connection with producing commercial drug supplies for collaborators and others

Operating expenses included a total of $103.5 million and $105.8 million for the three months ended June 30, 2020 and 2019, respectively, and $209.3 million and $213.7 million for the six months ended June 30, 2020 and 2019, respectively, of non-cash compensation expense related to equity awards granted under our long-term incentive plans.

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 for clinical development purposes as well as related external drug filling, packaging, and labeling costs. Clinical manufacturing costs also includes pre-launch commercial supplies which did not meet the criteria to be capitalized as inventory.

(In millions)	Three Months Ended June 30, 2020	2019*	$ Change	Six Months Ended June 30, 2020	2019*	$ Change
Direct research and development expenses:						
Fasinumab	$ 43.2	$ 59.6	$ (16.4)	$ 83.7	$ 109.7	$ (26.0)
Libtayo (cemiplimab)	35.4	34.4	1.0	71.4	78.4	(7.0)
Dupixent (dupilumab)	31.7	19.6	12.1	66.2	45.3	20.9
REGN-COV2	14.1	—	14.1	14.1	—	14.1
EYLEA	11.2	12.2	(1.0)	28.8	25.3	3.5
Evinacumab	8.8	8.4	0.4	18.8	15.0	3.8
Up-front payments related to license and collaboration agreements	85.0	400.0	(315.0)	85.0	400.0	(315.0)
Other product candidates in clinical development and other research programs	148.4	81.4	67.0	253.6	167.5	86.1
Total direct research and development expenses	377.8	615.6	(237.8)	621.6	841.2	(219.6)
Indirect research and development expenses:						
Payroll and benefits	193.4	171.8	21.6	391.4	338.7	52.7
Lab supplies and other research and development costs	30.6	33.8	(3.2)	65.5	61.4	4.1
Occupancy and other operating costs	80.8	75.2	5.6	162.7	147.2	15.5
Total indirect research and development expenses	304.8	280.8	24.0	619.6	547.3	72.3
Clinical manufacturing costs	181.2	151.9	29.3	361.5	301.6	59.9
Reimbursement of research and development expenses by collaborators	(141.8)	(162.8)	21.0	(296.8)	(318.5)	21.7
Total research and development expenses	$ 722.0	$ 885.5	$ (163.5)	$ 1,305.9	$ 1,371.6	$ (65.7)

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

Research and development expenses for the three and six months ended June 30, 2020 included $85.0 million in aggregate up-front payments made in connection with our collaboration agreement with Intellia (see "Collaboration and License Agreements - Intellia" above). Direct research and development expenses in 2020 also include costs incurred in connection with Kevzara for the treatment of COVID-19 patients (included within "Other product candidates in clinical development and other research programs" in the table above). Research and development expenses for the three and six months ended June 30, 2019 included a $400.0 million up-front payment to Alnylam.

Research and development expenses included non-cash compensation expense of $56.9 million and $59.3 million for the three months ended June 30, 2020 and 2019, respectively, and $113.6 million and $118.0 million for the six months ended June 30, 2020 and 2019, 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" (including those relating to the disruptions caused by the COVID-19 pandemic). 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 for the three and six months ended June 30, 2020, compared to the same periods in 2019, primarily due to higher headcount-related costs, additional accruals for loss contingencies associated with ongoing litigation, higher contributions to independent not-for-profit patient assistance organizations, and, effective April 1, 2020, no longer receiving Praluent-related cost reimbursements from Sanofi for Regeneron-incurred expenses. Selling, general, and administrative expenses also increased for the six months ended June 30, 2020, compared to the same period in 2019, due to an increase in commercialization-related expenses for EYLEA. Selling, general, and administrative expenses also included non-cash compensation expense of $38.2 million and $37.7 million for the three months ended June 30, 2020 and 2019, respectively, and $78.5 million and $81.5 million for the six months ended June 30, 2020 and 2019, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased for the three and six months ended June 30, 2020, compared to the same periods in 2019, primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent, process validation costs in connection with manufacturing REGN-EB3 under our BARDA agreement, and recognition of costs in connection with manufacturing ex-U.S. commercial supplies of Praluent for Sanofi under our new agreement (see "Collaboration and License Agreements - *Sanofi - Antibody*" above for further details).

Other Operating (Income) Expense

Other operating (income) expense, net, includes recognition of a portion of amounts previously deferred in connection with up-front and development milestone payments, as applicable, received in connection with Sanofi IO, Teva, and MTPC collaborative arrangements.

Other Income (Expense)

Other income (expense), net, for the three and six months ended June 30, 2020, compared to the same periods in 2019, was positively impacted by the recognition of unrealized gains on equity securities.

Income Taxes

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except effective tax rate)	**2020**	**2019**	**2020**	**2019**
Income tax expense	$ 21.6	$ 31.6	$ 65.6	$ 116.6
Effective tax rate	2.4 %	14.1 %	4.1 %	15.1 %

Our effective tax rate for the three and six months ended June 30, 2020 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation, and, to a lesser extent, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and federal tax credits for research activities. Our effective tax rate for the three and six months ended June 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, stock-based compensation, federal tax credits for research activities, and, to a lesser extent, the foreign-derived intangible income deduction, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	June 30, 2020	December 31, 2019	$ Change
Financial assets:			
Cash and cash equivalents	$ 1,992.2	$ 1,617.8	$ 374.4
Marketable securities - current	1,152.0	1,596.5	(444.5)
Marketable securities - noncurrent	2,587.6	3,256.8	(669.2)
	$ 5,731.8	$ 6,471.1	$ (739.3)
Working capital:			
Current assets	$ 7,860.2	$ 7,689.1	$ 171.1
Current liabilities	3,702.4	2,096.6	1,605.8
	$ 4,157.8	$ 5,592.5	$ (1,434.7)

As of June 30, 2020, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Six Months Ended June 30, 2020 and 2019

(In millions)	June 30, 2020	June 30, 2019	$ Change
Cash flows provided by operating activities	$ 1,641.4	$ 1,085.3	$ 556.1
Cash flows provided by (used in) investing activities	$ 1,010.2	$ (1,612.1)	$ 2,622.3
Cash flows (used in) provided by financing activities	$ (2,277.2)	$ 104.6	$ (2,381.8)

Cash Flows from Operating Activities

Our net income for the six months ended June 30, 2020 included up-front payments of $85.0 million made to Intellia and a $30.0 million up-front payment received from Zai Lab pursuant to our collaboration agreements. Our net income for the six months ended June 30, 2020 also included $171.3 million related to unrealized gains (net) on equity securities (included in other non-cash items). Deferred taxes as of June 30, 2020 decreased by $118.0 million, compared to December 31, 2019, primarily due to non-cash compensation expense and unrealized gains (net) on equity securities as described above.

Cash Flows from Investing Activities

Sales of marketable securities during the six months ended June 30, 2020 included proceeds in connection with funding our stock repurchase from Sanofi (as described below). Capital expenditures during the six months ended June 30, 2020 included costs associated with (i) the expansion of our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, including construction of a fill/finish facility and related equipment, and (ii) laboratory expansion and renovations at our Tarrytown, New York facilities. We expect to incur capital expenditures of $540 million to $590 million for the full year of 2020 primarily in connection with these projects.

Cash Flows from Financing Activities

During the six months ended June 30, 2020, we paid an aggregate of $5.4 billion to purchase shares of our Common Stock, a portion of which was funded with the proceeds from a $1.5 billion senior unsecured 364-day bridge loan facility. See further descriptions under "*Share Repurchase Program,*" "*Sanofi Funding of Certain Development Costs,*" *and* "*Dispositions of Regeneron Common Stock Held by Sanofi*" below.

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $2.2 billion during the six months ended June 30, 2020 compared to $155.1 million during the six months ended June 30, 2019.

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. 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.

During the six months ended June 30, 2020, we repurchased 719,167 shares of our Common Stock under the program and recorded the cost of the shares received, or $272.8 million, as Treasury Stock. As of June 30, 2020, the Company had $473.1 million which remained available for share repurchases under the program.

Sanofi Funding of Certain Development Costs

As described above in "Collaboration and License Agreements - 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 shares (of which 279,766 shares remain available to be sold as of June 30, 2020) of our Common Stock directly or indirectly owned by Sanofi. During the six months ended June 30, 2020, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 77,677 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded $41.7 million related to the shares received as Treasury Stock during the six months ended June 30, 2020. In addition, during the six months ended June 30, 2020, Sanofi elected to sell, and we elected to purchase (in cash), 171,471 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 $93.3 million, as Treasury Stock during the six months ended June 30, 2020.

Secondary Offering and Purchase of Regeneron Common Stock Held by Sanofi

As described above in "Collaboration and License Agreements - Sanofi," in May 2020, a secondary offering of 13,014,646 shares of our Common Stock (the "Secondary Offering") held by Sanofi was completed. In connection with the Secondary Offering, we also purchased 9,806,805 shares of our Common Stock directly from Sanofi for an aggregate purchase amount of $5 billion (the "Stock Purchase"). As a result of the Secondary Offering and the Stock Purchase, Sanofi disposed of all of its shares of our Common Stock, other than 400,000 shares that it retained as of the closing of the Secondary Offering and the Stock Purchase (which Sanofi has used, and may continue to use, for the funding of certain Libtayo development costs and/or Dupilumab/REGN3500 Eligible Investments as described above).

We funded the Stock Purchase with a combination of cash on hand, proceeds from the sale of marketable securities, and proceeds from loans under a $1.5 billion senior unsecured 364-day bridge loan facility (the "Bridge Facility") which was entered into in May 2020. The loans under the Bridge Facility bear interest at a variable interest rate based on either the London Interbank Offered Rate or the alternate base rate, plus an applicable margin that varies with our debt rating and total leverage ratio. The Bridge Facility will mature, and all amounts outstanding thereunder will become due and payable, in May 2021. We intend to refinance the Bridge Facility prior to its maturity by entering into new debt financing arrangements. Amounts borrowed under the Bridge Facility may be prepaid at any time without premium or penalty. As of June 30, 2020, $1.5 billion remained outstanding under the Bridge Facility.

The credit agreement governing the Bridge Facility (the "Bridge Credit Agreement") contains financial and operating covenants, which are substantially similar to the covenants set forth in our existing $750.0 million senior unsecured five-year revolving credit facility. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Bridge Credit Agreement as of June 30, 2020.

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, 2019 (filed February 7, 2020). Except as described in Note 1 to our Condensed Consolidated Financial Statements included in this report, there were no material changes to our critical accounting policies and use of estimates during the six months ended June 30, 2020.

Future Impact of Recently Issued Accounting Standards

As of June 30, 2020, the future adoption of recently issued accounting standards is not expected to have a material impact on the Company's financial position or results of operations.

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, 2019 (filed February 7, 2020). There have been no material changes to our market risks or to our management of such risks as of June 30, 2020.

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 June 30, 2020 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 12 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. For purposes of this section, references to our products encompass products marketed by us and/or our collaborators under our collaboration agreements with them, unless otherwise stated or required by the context.

Risks Related to the COVID-19 Pandemic

Our business may be further adversely affected by the effects of the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. It has since spread around the world, including the United States; and, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. This pandemic has adversely affected or has the potential to adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate; our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, and business partners and customers; and the demand for our marketed products.

The COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including governmental orders across the globe, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, maintain social distancing, and order cessation of non-essential travel. As a result of these developments, we have implemented work-from-home policies for a significant part of our employees (except those deemed critical, including those working in our laboratories and manufacturing facilities). The effects of shelter-in-place and social distancing orders, government-imposed quarantines, and work-from-home policies may further negatively impact productivity, disrupt our business, and delay our clinical programs and development timelines beyond the delays we have already experienced and disclosed, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Such restrictions and limitations may also further negatively impact our access to regulatory authorities (which are affected, among other things, by applicable travel restrictions and may be delayed in responding to inquiries, reviewing filings, and conducting inspections); our ability to perform regularly scheduled quality checks and maintenance; and our ability to obtain services from third-party specialty vendors and other providers or to access their expertise as fully and timely as needed. The COVID-19 pandemic may also result in the loss of some of our key personnel, either temporarily or permanently. In addition, our sales and marketing efforts have been negatively impacted and may be further negatively impacted by postponement or cancellation of face-to-face meetings and restrictions on access by non-essential personnel to hospitals or clinics to the extent such measures slow down adoption or further commercialization of our marketed products. The demand for our marketed products may also be adversely impacted by the restrictions and limitations adopted in response to the COVID-19 pandemic, particularly to the extent they affect the patients' ability or willingness to start or continue treatment with our marketed products. Any of the foregoing factors may result in lower net product sales of our marketed products. For example, net product sales of EYLEA in the United States decreased for the three months ended June 30, 2020, compared to the same period in 2019, due in part to the impact of the COVID-19 pandemic. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations" for a discussion of our net product sales. Demand for some or all of our marketed products may continue to be reduced while the shelter-in-place or social distancing orders are in effect and, as a result, some of our inventory may become obsolete and may need to be written off, impacting our operating results. These and similar, and perhaps more severe, disruptions in our operations may materially adversely impact our business, operating results, and financial condition.

Quarantines, shelter-in-place, social distancing, and similar government orders (or the perception that such orders, shutdowns, or other restrictions on the conduct of business operations could occur) related to COVID-19 or other infectious diseases are impacting personnel at our research and manufacturing facilities, our suppliers, and other third parties on which we rely, and are also impacting the availability or cost of materials produced by or purchased from such parties, resulting in supply chain strains or disruptions that may become material. While some materials may be obtained from more than one supplier, port closures and other restrictions resulting from the COVID-19 pandemic could materially disrupt our supply chain or limit our ability to obtain sufficient materials for the production, including fill/finish, of our products and development of our product candidates as well as our research efforts. If microbial, viral (including COVID-19), or other contaminations are discovered in our products, product candidates, the materials used for their production, or in our facilities, or in the facilities of our collaborators, third-party contract manufacturers, or other contractors or suppliers, the affected facilities may need to be closed or may otherwise be affected for an extended period of time, or the contamination may result in other delays or disruptions in our direct or indirect supply chain.

In addition, infections and deaths related to COVID-19 have disrupted and may continue to disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay, FDA review and potential approval of our product candidates and new indications for our marketed products. It is unknown how long these disruptions could continue. In addition, some of our clinical trials have been and may continue to be affected by the COVID-19 pandemic. This impact includes delays in site initiation and patient enrollment due to prioritization of hospital resources toward the COVID-19 pandemic and patients' inability to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been and may continue to be delayed or disrupted. For example, as noted above in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Programs in Clinical Development," we experienced an initial adverse impact on enrollment into new clinical studies and recruitment of new patients into open studies. While enrollment in both new and ongoing clinical studies started to resume as regions relaxed their restrictions and healthcare resources started to become more available for non-COVID-19 activities, there has been a resurgence of COVID-19 cases in many regions across the world, and any resurgence in the regions in which we or our collaborators conduct clinical trials may require our expectations relating to the impacted studies to adjust. We will continue to evaluate the adverse impact of the COVID-19 pandemic on an individual trial basis. The disruptions caused by the COVID-19 pandemic may further negatively impact the progress of our clinical trials, including the readouts of trial results. Further, while we are focused on developing novel therapies to address the COVID-19 pandemic, our research programs and the development of our other product candidates may need to be further de-prioritized. Any elongation or de-prioritization of our research and development programs and clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates, which would increase our operating expenses and may have a material adverse effect on our operating results.

The U.S. Government may exercise or assert certain rights with respect to our inventions, products, or product candidates. For example, under the Defense Production Act, the U.S. Government may, among other things, require domestic industries to provide essential goods and services needed for the national defense, such as drug material or other supplies needed to treat COVID-19 patients, which could require us to allocate manufacturing capacity in a way that impacts our regular operations. In addition, our agreements with the U.S. Government contain provisions granting the U.S. Government certain rights relating to products, product candidates, and related inventions (as applicable) covered by those agreements. For example, in July 2020, we entered into an agreement to manufacture and deliver REGN-COV2 to the U.S. Government over the remainder of 2020.

Among other rights, this agreement gives the U.S. Government the right to require us to grant a non-exclusive license to applicable inventions to a third party if such action is deemed necessary to alleviate certain health or safety needs. This right may be triggered if we, for example, do not manufacture or supply sufficient product to address such needs. If the U.S. Government exercises or asserts any such rights or imposes these or similar measures with respect to our products, product candidates, or related inventions (including REGN-COV2), it may adversely impact our business and results of operations. Foreign governments (including the government of Ireland, where we have manufacturing facilities) may have similar rights or attempt to assert any such rights.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it recently caused significant disruption of global financial markets and could cause more economic disruption in the future. This disruption, if sustained or recurrent, could make it more difficult for us to access capital if needed. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our Common Stock.

The global COVID-19 pandemic continues to rapidly evolve. The ultimate impact of this pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. These effects could have a material impact on our operations.

To the extent the COVID-19 pandemic adversely affects our business, prospects, operating results, or financial condition, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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 and Dupixent.

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 six months ended June 30, 2020 and 2019, EYLEA net sales in the United States represented 60% and 76% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States or if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States (including as a result of the COVID-19 pandemic discussed above), 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.

In addition, we have been increasingly dependent on our share of profits from the commercialization of Dupixent under our Antibody Collaboration with Sanofi. If we or Sanofi were to experience any difficulty with the commercialization of Dupixent or if we or Sanofi are unable to maintain current marketing approvals of Dupixent, we may experience a reduction in revenue 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 will continue to depend on many factors, including the following (as applicable):

- the continued impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on our business and the demand for our marketed products, as well as its continued impact on, among other things, our employees, collaborators, suppliers, and other third parties on which we rely, our ability to continue to manage our supply chain, and the global economy (as further discussed above under "Risks Related to the COVID-19 Pandemic - *Our business may be further adversely affected by the effects of the COVID-19 pandemic*");
- 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 payors, including Medicare and Medicaid in the United States and other government and private payors in the United States and foreign jurisdictions, as well as U.S. and foreign payor 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 significant competition* - Marketed Products" below) and the willingness of retinal specialists and patients to start or continue treatment with EYLEA or to switch from another product to 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 12 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 proceedings and investigations described in Note 12 to our Condensed Consolidated Financial Statements included in this report (including the civil complaint filed against us on June 24, 2020 in the U.S. District Court for the District of Massachusetts by the U.S. Attorney's Office for the District of Massachusetts);
- 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 payor 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 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 payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales of our marketed products in the United States are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor 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 payors 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 payors cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payors more expensive for patients. Third-party payors 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 (which will likely be exacerbated as a result of the COVID-19 pandemic), 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 payors (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 (the "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 payors (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; this trend may be further accelerated as a result of the COVID-19 pandemic.

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, some of the Trump administration's prior budget proposals contained drug price control measures that may be included in 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 pending 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; and, in July 2020, President Trump announced that an executive order (the text of which is not yet available) utilizing a "most favored nation" pricing mechanism and/or potentially other drug-pricing measures could go into effect in late August 2020 unless an alternative proposal that substantially reduces drug prices is advanced by the pharmaceutical industry. While the scope and details of these contemplated executive actions (including whether and how their mechanism may differ from that of the proposed IPI drug pricing program discussed above) are not clear, this continues to signal that the U.S. administration intends to pursue new measures to constrain drug costs and Medicare payments for drugs. Similarly, various members of the current U.S. Congress and 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 as a result of the proposals, initiatives, and developments 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 payor 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 significant 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 faces significant competition in the marketplace. For example, EYLEA competes in one or more of its approved indications with other VEGF inhibitors, including Novartis and Genentech/Roche's Lucentis® (ranibizumab) and Novartis' Beovu® (brolucizumab). Ophthalmologists are also using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, bevacizumab, for the treatment of certain of EYLEA's indications, and we are aware of another company developing an ophthalmic formulation of such product. In DME and RVO, EYLEA also competes with intravitreal implants of corticosteroids. We are also aware of a number of companies working on the development of product candidates and extended delivery devices for the potential treatment of one or more of EYLEA's indications, including those that act by blocking VEGF and VEGF receptors (including therapies designed to extend the treatment interval) and/or other targets (such as Ang2). In addition, we are aware of several companies developing biosimilar versions of EYLEA and other approved anti-VEGF treatments. Other potentially competitive products in development include products for use in combination with EYLEA and/or other anti-VEGF treatments, small-molecule tyrosine kinase inhibitors, gene therapies, and other eye-drop formulations, devices, and oral therapies. There also is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, even though ZALTRAP has not been manufactured and formulated for use in intravitreal injections. 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.

The market for Dupixent's current and potential future indications is also competitive. In atopic dermatitis, there are several topical ointments or agents either approved or in development. In addition, a number of companies are developing antibodies against IL-13, IL-13Ra1, OX40, IL-31R, and/or IL-1alpha. Several companies are also studying JAK inhibitors for atopic dermatitis. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor or immunoglobulin E; and some of these antibodies, if approved in this indication, may also compete with Dupixent in CRSwNP. Dupixent also faces competition from orally administered small molecule agents and inhaled products in asthma and potential future indications. There are several other potentially competitive products in development that may compete with Dupixent in either or both of the atopic dermatitis and asthma indications, as well as potential future indications, including antibodies against thymic stromal lymphopoietin ("TSLP"), the IL-33 ligand, or the IL-33 receptor (ST2).

Libtayo also faces significant competition. There are several competitors that are marketing and/or developing antibodies against PD-1 and/or PDL-1, including Merck's Keytruda® (pembrolizumab), Bristol-Myers Squibb's Opdivo® (nivolumab), Roche's Tecentriq® (atezolizumab), and AstraZeneca's Imfinzi® (durvalumab).

There is also significant actual and potential future competition for other products marketed by us and/or our collaborators under our collaboration agreements with them. For example, there are several companies that are marketing and/or developing antibodies or other molecules (such as siRNAs) against PCSK9 and IL-6 and/or IL-6R, which currently (or, for product candidates in development, may in the future if approved) compete with Praluent and Kevzara, respectively.

Product Candidates

Our other late-stage and earlier-stage clinical candidates in development are all fully human antibodies. Our *VelocImmune®* technology, other 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 other 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. We are also aware of other 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 product 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 some of our marketed products.

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, as in effect from time to time) for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, under the terms of our Antibody Collaboration and our IO Collaboration, we and Sanofi co-commercialize Dupixent and Libtayo in the United States. As a result, we rely in part on Sanofi's sales and marketing organization in the United States for these products. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of any of such products may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent in the United States. For example, Sanofi records product sales for Dupixent in the United States and leads negotiations with payors relating to this product. We also rely on Sanofi for sales, marketing, and distribution of Dupixent and Libtayo in countries outside the United States. Effective April 1, 2020, we and Sanofi amended the Antibody Collaboration to remove Praluent from the LCA such that, among other things, the LCA no longer governs the development, manufacture, or commercialization of Praluent. Effective as of the same date, we and Sanofi entered into the Praluent Cross License & Commercialization Agreement whereby we, at our sole cost, are solely responsible for the development and commercialization of Praluent in the United States, and Sanofi, at its sole cost, is solely responsible for the development and commercialization of Praluent outside of the United States; and Sanofi pays us a 5% royalty on Sanofi's net product sales of Praluent outside the United States until March 31, 2032.

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 payors 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, payors, 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, Praluent, and ARCALYST in the United States to several distributors and specialty pharmacies, as applicable. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the six months ended June 30, 2020, our gross product sales of such products to two customers accounted on a combined basis for 87% 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 are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, 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. We will need to establish commercial capabilities outside the United States as a result of any exercise of our option to co-commercialize a product outside the United States. For example, we recently exercised our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States. In addition, there may be other circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to 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 or co-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 or the co-commercialization of a product 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, and may ask for additional data in order to begin a clinical study. 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 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, clinical trial design that may not make it possible to enroll a sufficient number of patients to achieve a statistically significant result or the desired level of statistical significance, 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 Practice requirements ("GLPs") or GCPs. A clinical trial may also fail because it did not include and/or 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 osteoarthritis trials were 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 - Overview - 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), 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.

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 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, in the United States EYLEA is approved in the 2mg pre-filled syringe. 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 are not well established, 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 (the "EPO") (currently pending before its Boards of Appeal), as described in Note 12 to our Condensed Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (the "USPTO"), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review or *inter partes* review under the America Invents Act of 2011 or *ex parte* reexamination. For example, on February 11, 2020, anonymous parties filed two requests for *ex parte* reexamination of two of our patents - U.S. Patent Nos. 10,406,226 (the "'226 Patent") and 10,464,992 (the "'992 Patent"). The '226 Patent concerns methods for manufacturing VEGF antagonist fusion proteins, including aflibercept, and the '992 Patent concerns formulations and vials containing VEGF antagonist fusion proteins, including aflibercept. The USPTO has granted both requests to initiate reexamination proceedings. 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 Sanofi are currently party to patent infringement proceedings initiated by Amgen against us and/or Sanofi relating to Praluent and patent infringement proceedings relating to Dupixent, as described in Note 12 to our Condensed Consolidated Financial Statements. In addition, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as described in Note 12 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), Libtayo (cemiplimab), Praluent (alirocumab), and Kevzara (sarilumab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF; evinacumab, an antibody to ANGPTL3; REGN-EB3, a multi-antibody therapy for Ebola; garetosmab, an antibody to Activin A; pozelimab, an antibody to C5; and REGN1979, a bispecific antibody targeting CD20 and CD3.

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 (the "PPACA"), there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to 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. We are aware of several companies developing biosimilar versions of EYLEA. In the United States, the regulatory exclusivity period for EYLEA (*i.e.*, the period during which no biosimilar product can be approved by the FDA) expires on November 18, 2023, with the possibility of an additional six months of regulatory exclusivity (*i.e.*, until May 18, 2024) if the FDA grants pediatric exclusivity based on our completion of certain studies evaluating EYLEA in pediatric patients with retinopathy of prematurity and submission of the data from these studies to the FDA no later than 15 months before the date on which regulatory exclusivity would otherwise expire. 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 adversely affect our ability to commercialize our marketed products and, if approved, our product candidates and to advance our clinical pipeline.

We have large-scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. Manufacturing facilities operated by us and by third-party contract manufacturers engaged by us would be inadequate to produce the active pharmaceutical ingredients of our current marketed products and our product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. For example, our internal manufacturing capacity will likely not be sufficient to cover the demand for REGN-COV2, our novel investigational antibody "cocktail" treatment designed to prevent and treat infection from the SARS-CoV-2 virus, if clinical trials evaluating this treatment are successful and we receive regulatory approval. 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 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 with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, 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 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 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 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, time, 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 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, 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. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as described in Note 12 to our Condensed Consolidated Financial Statements. 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 our marketed products 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 each case, including as a result of the COVID-19 pandemic). 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 testing of our products and product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain regulatory restrictions on using these biological source materials. If we or our collaborators are required to substitute for these sources to comply with such 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 product candidates or new indications for our marketed products. 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 payor. 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 12 to our Condensed Consolidated Financial Statements included in this report, we are party to a civil complaint filed in June 2020 by the U.S. Attorney's Office for the District of Massachusetts concerning our support of 501(c)(3) organizations that provide financial assistance to patients; and we are cooperating with a pending government investigation concerning certain other business activities. Any adverse decision, finding, allegation, or exercise of enforcement or regulatory discretion in any such proceedings or 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 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 fully integrated biotechnology 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, intellectual property rights, and the framework for dispute resolution and asserting our rights against others, 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 Trump 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 payors, 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, effective January 31, 2020, the United Kingdom commenced an exit from the EU, commonly referred to as "Brexit." During a transition period (set to expire on December 31, 2020), the British government will continue to negotiate 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 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). Recommendations by the Organization for Economic Co-operation and Development and the European Union Anti-Tax Avoidance Directive require companies to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny. Even though we regularly assess the information provided to tax authorities in determining the appropriateness of our tax reserves, such tax authorities could take a position that is contrary to our expectations, and the result could adversely affect our provision for income tax and our current rate.

We face potential liability related to the personal information we collect from individuals, data brokers, or research institutions or obtain from clinical trials sponsored by us or our collaborators.

Most U.S. 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, we could 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. There are instances where we collect and maintain sensitive personally identifiable information, which may include health information outside of the scope of HIPAA. This information may be received throughout the clinical trial process, in the course of our research collaborations, directly from individuals who enroll in our patient assistance programs, and from our own employees in a pandemic response process (such as in connection with the COVID-19 pandemic). In the case of a breach of personal information we may be subject to state breach notification laws requiring notification of affected individuals and state regulators.

Our patient assistance programs and product marketing activities as part of which we collect California resident personal data are subject to the California Consumer Privacy Act of 2018 (the "CCPA"). The CCPA is a consumer protection law that provides California residents with personal data privacy rights and became effective on January 1, 2020. The CCPA requires us, among other things, to update our notices and develop new processes internally and with our partners. There are fines, penalties, and a private right of action resulting from non-compliance with the CCPA. Several other U.S. states have introduced similar consumer protection laws that may go into effect in the near future.

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) implicate international data protection laws, including the European Union's General Data Protection Regulation (the "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)). 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 risk of substantial financial penalties for insufficient notice and consent, failure to respond to data subject rights requests, lack of a legal basis for the transfer of personal information out of the EU, 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, health privacy laws, data breach notification laws, consumer protection laws, data localization 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, individuals about whom we or our collaborators obtain health or other personal information, as well as the providers and third parties who share this information with us, may have statutory or contractual limits that impact 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, local, or foreign 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 a 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 the products that we are co-developing with Sanofi under our Antibody Collaboration (currently consisting of Dupixent, Kevzara, and REGN3500), 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 or our IO Collaboration (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, 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 the products subject to such collaborations, 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, as in effect from time to time, 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 issues for 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 Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, 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 and 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 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. These systems are also critical to enable remote working arrangements, which have been growing in importance due in part to the COVID-19 pandemic and our implementation of work-from-home policies for a significant part of our employees. 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 net product sales of EYLEA and funding we receive under our collaboration agreements (including our share of profits in connection with commercialization of EYLEA and Dupixent under our collaboration agreements with Bayer and Sanofi, respectively), 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 our current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements (including our share of profits in connection with commercialization of EYLEA and Dupixent under our collaboration agreements with Bayer and Sanofi, respectively), 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, we intend to refinance the Bridge Facility (which we entered into in May 2020, as described in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations") prior to its maturity in May 2021 by entering into new debt financing arrangements. In addition, 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 Tarrytown, 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 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.

Our indebtedness could adversely impact our business.

We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of June 30, 2020, we had an aggregate of $2.216 billion of outstanding indebtedness under the Bridge Facility and the lease financing facility. We may also incur additional debt in the future. Any such indebtedness could:

- limit our ability to access capital markets and incur additional debt in the future;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts, research and development, and mergers and acquisitions; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to competitors that have less debt.

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, Canadian dollar, 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 June 30, 2020, we had $1.992 billion in cash and cash equivalents and $3.740 billion in marketable securities (including $805.1 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.

The elimination of LIBOR could adversely affect our business, operating results, and financial condition.

In July 2017, the United Kingdom regulator that regulates the London Interbank Offered Rate ("LIBOR") announced its intention to phase out LIBOR rates by the end of 2021. No consensus exists as to what rate or rates may become accepted alternatives to LIBOR or whether LIBOR rates will cease to be published or supported before or after 2021. A transition away from LIBOR as a benchmark for establishing the applicable interest rate may adversely affect our outstanding variable-rate indebtedness and interest rate swaps, as well as floating-rate debt securities we hold. For example, if a published U.S. dollar LIBOR rate is unavailable after 2021, the rent payments for the leased facilities in Tarrytown, New York and the interest payments under the Bridge Facility, which are indexed to LIBOR, will be determined using various alternative methods, any of which may result in interest obligations which are more than, or do not otherwise correlate over time with, the payments that would have been made on such debt if U.S. dollar LIBOR was available in its current form.

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;
- impact of the COVID-19 pandemic;
- 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 or other employees, directors, or significant shareholders (or the expectation of any such sales);
- 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) may be lower than the public float of other large public companies with broader public ownership. Therefore, the trading price of our Common Stock 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 June 30, 2020, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 35.2% 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 June 30, 2020. If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, 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 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 continue to repurchase shares of our Common Stock or that we will repurchase shares at favorable prices.

Our board of directors previously authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock (of which $473.1 million remained available as of June 30, 2020). Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will continue to 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 June 30, 2020, holders of Class A Stock held 15.1% 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 June 30, 2020:

- our current executive officers and directors beneficially owned 8.9% 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 June 30, 2020, and 20.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2020; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 35.2% 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 June 30, 2020. In addition, these five shareholders plus our Chief Executive Officer held approximately 43.0% 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 June 30, 2020.

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, as amended, 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. A similar "standstill" prohibition applies to Bayer pursuant to our 2014 PDGFR-beta license and collaboration agreement with Bayer (which agreement was terminated on July 31, 2017 by agreement of the parties but whose "standstill" provisions continue to be in effect until July 31, 2022 unless they expire earlier upon the occurrence of certain specified events).

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 long-term incentive plans may become fully vested in connection with a "change in control" of our Company, as defined in the plans. 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 table below reflects shares of Common Stock purchased directly from Sanofi, Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under one of our long-term incentive plans, and Common Stock we elected to purchase from Sanofi 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, during the three months ended June 30, 2020. Refer to Part I, Item 2. "Liquidity and Capital Resources" for further information.

Period	Total Number of Shares Purchased	Average Price Paid per Share		Total Number of Shares Purchased as Part of a Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program(1)
4/1/2020–4/30/2020	1,122	$	510.37	—	473,117,435
5/1/2020–5/31/2020	9,806,805	$	509.85	—	473,117,435
6/1/2020–6/30/2020	120,234	$	597.48	—	473,117,435
Total	9,928,161			—	

(1) Relates to our share repurchase program. Refer to Part I, Item 2. "Liquidity and Capital Resources - *Share Repurchase Program*" for further details.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1+	Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 16, 2020.)
10.2	Credit Agreement, dated as of May 25, 2020, by and among the Registrant, as borrower; Goldman Sachs Bank USA, as administrative agent, sole bookrunner, sole lead arranger, and a lender; and the other lenders party thereto from time to time. (Incorporated by reference from the Form 8-K for the Registrant, filed May 29, 2020.)
10.2.1	Amendment No. 1 to Credit Agreement, dated as of June 11, 2020, by and between the Registrant, as borrower, and Goldman Sachs Bank USA, as administrative agent.
10.3*	Third Amendment to Amended and Restated License and Collaboration Agreement, dated as of April 5, 2020, and effective as of April 1, 2020, by and between the Registrant, Sanofi Biotechnology SAS, and Sanofi.
10.4*	Praluent Cross License & Commercialization Agreement, dated as of April 5, 2020, and effective as of April 1, 2020, by and between the Registrant and Sanofi Biotechnology SAS.
10.5	Stock Repurchase Agreement, dated as of May 25, 2020, by and between the Registrant and Sanofi. (Incorporated by reference from the Form 8-K for the Registrant, filed May 29, 2020.)
10.6	Amendment to the Amended and Restated Investor Agreement, dated as of May 25, 2020, by and among the Registrant, Sanofi, Sanofi-Aventis US LLC, and Aventisub LLC. (Incorporated by reference from the Form 8-K for the Registrant, filed May 29, 2020.)
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 June 30, 2020 and December 31, 2019; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2020 and 2019; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2020 and 2019; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2020 and 2019; 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).

+ Indicates a management contract or compensatory plan or arrangement.

* Certain confidential portions of this exhibit were omitted in accordance with Item 601(b)(10) of Regulation S-K.

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:	August 5, 2020	By:	/s/ Robert E. Landry
			Robert E. Landry Executive Vice President, Finance and Chief Financial Officer (Duly Authorized Officer)