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		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 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		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2018	1.9	—	111.1	$ 0.1	$ 3,911.6	$ 5,254.3	$ (12.3)	(4.0)	$ (396.4)	$ 8,757.3
Issuance of Common Stock 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.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(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.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(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.

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

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.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(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:

	Statement of Operations Classification	Three Months Ended June 30,		Six Months Ended June 30,	
		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

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

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.

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

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

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.

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,		Six Months Ended June 30,	
		2020	2019	2020	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,		Six Months Ended June 30,	
		2020	2019	2020	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.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
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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	—	—

REGENERON PHARMACEUTICALS, INC.
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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,

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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.

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")	a	a	a	a
	- Diabetic macular edema ("DME")	a	a	a	a
	- Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	a	a	a	a
	- Myopic choroidal neovascularization ("mCNV")		a	a	a
	- Diabetic retinopathy	a			
	- Neovascular glaucoma ("NVG")			a	
Dupixent (dupilumab) Injection[3]	- Atopic dermatitis (in adults and adolescents)[7]	a	a	a	a
	- Atopic dermatitis (in pediatrics 6–11 years of age)	a			
	- Asthma (in adults and adolescents)	a	a	a	a
	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	a	a	a	a
Libtayo (cemiplimab) Injection[3][4]	- Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	a	a		a
Praluent (alirocumab) Injection[5]	- LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD") (in adults)	a	a	[9]	a
	- Cardiovascular risk reduction in patients with established cardiovascular disease	a	a		a
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	- Rheumatoid arthritis ("RA") (in adults)	a	a	a	a
ARCALYST® (rilonacept) Injection for Subcutaneous Use	- Cryopyrin-Associated Periodic Syndromes ("CAPS"), including Familial Cold Auto-inflammatory Syndrome ("FCAS") and Muckle-Wells Syndrome ("MWS")	a			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[8]	- Metastatic colorectal cancer ("mCRC")	a	a	a	a

[1] Refer to label information in each territory for specific indication

[2] In collaboration with Bayer (outside the United States)

[3] In collaboration with Sanofi

[4] 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,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
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,						% Change (Total Sales)
		2020			2019			
		U.S.	ROW	Total	U.S.	ROW	Total	
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)

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.

Antibody

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	Three Months Ended June 30, 2019*	$ Change	Six Months Ended June 30, 2020	Six Months Ended June 30, 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)

Exhibit 10.2.1

AMENDMENT NO. 1 TO THE CREDIT AGREEMENT

Dated as of June 11, 2020

AMENDMENT NO. 1 TO THE CREDIT AGREEMENT (this "Amendment"; and such Credit Agreement, as amended, restated, supplemented or otherwise modified from time to time, the "Credit Agreement") dated as of May 25, 2020, among REGENERON PHARMACEUTICALS, INC., a New York corporation (the "Borrower"), the Lenders party thereto, and GOLDMAN SACHS BANK USA, as administrative agent thereunder (the "Administrative Agent").

WHEREAS, the Borrower and the Lenders parties hereto are parties to the Credit Agreement. Capitalized terms not otherwise defined in this Amendment have the same meanings as specified in the Credit Agreement.

WHEREAS, the Borrower and the Lenders parties hereto have agreed to amend the Credit Agreement pursuant to Section 9.02 of the Credit Agreement as hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and agreements, provisions and covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

SECTION 1. Amendment to Credit Agreement. The Credit Agreement is, effective as of the date hereof and subject to the satisfaction of the conditions precedent set forth in Section 2, hereby amended as follows:

(a) Section 1.01 of the Credit Agreement is amended to insert the following defined terms therein in the appropriate alphabetical order:

""Margin Stock" has the meaning assigned to such term in Regulation U."

""Regulation U" means Regulation U of the Board as from time to time in effect and all official rulings and interpretations thereunder or thereof."

(b) Section 2.14(a) of the Credit Agreement is deleted and replaced as follows:

"(a) [Reserved]."

(c) Section 9.19 of the Credit Agreement is added with the following language:

"SECTION 9.19. Acknowledgement Regarding Any Supported QFCs. To the extent that the Loan Documents provide support, through a guarantee or otherwise, for any Swap Agreement or any other agreement or instrument that is a QFC (such support, "QFC Credit Support", and each such QFC, a "Supported QFC"), the parties acknowledge and agree as follows with respect to the resolution power of the Federal Deposit Insurance Corporation under the Federal Deposit Insurance Act and Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act (together with the regulations promulgated thereunder, the "U.S. Special Resolution Regimes") in respect of such Supported QFC and QFC Credit Support (with the provisions below applicable notwithstanding that the Loan Documents and any Supported QFC may in fact be stated to be governed by the laws of the State of New York and/or of the United States or any other state of the United States):

(a) In the event a Covered Entity that is party to a Supported QFC (each, a "Covered Party") becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer of such Supported QFC and the benefit of such QFC Credit Support (and any interest and obligation in or under such Supported QFC and such QFC Credit Support, and any rights in property securing such Supported QFC or such QFC Credit Support) from such Covered Party will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if the Supported QFC and such QFC Credit Support (and any such interest, obligation and rights in property) were governed by the laws of the United States or a state of the United States. In the event a Covered Party or a BHC Act Affiliate of a Covered Party becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under the Loan Documents that might otherwise apply to such Supported QFC or any QFC Credit Support that may be exercised against such Covered Party are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if the Supported QFC and the Loan Documents were governed by the laws of the United States or a state of the United States. Without limitation of the foregoing, it is understood and agreed that rights and remedies of the parties with respect to a Defaulting Lender shall in no event affect the rights of any Covered Party with respect to a Supported QFC or any QFC Credit Support.

(b) As used in this Section 9.19, the following terms have the following meanings:

"BHC Act Affiliate" of a party means an "affiliate" (as such term is defined under, and interpreted in accordance with, 12 U.S.C. 1841(k)) of such party.

"Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

"QFC" has the meaning assigned to the term "qualified financial contract" in, and shall be interpreted in accordance with, 12 U.S.C. 5390(c)(8)(D)."

(d) Section 8.01(f) of the Credit Agreement is deleted and replaced as follows:

"(f) The Administrative Agent may at any time give its notice of resignation to the Lenders and the Borrower. Upon delivery of any such notice of resignation, the Required Lenders shall have the right (with the consent of the Borrower (such consent not to be unreasonably withheld or delayed); provided that no consent of the Borrower shall be required if an Event of Default has occurred and is continuing); to appoint a successor. If no successor shall have been so appointed by the Required Lenders and shall have accepted such appointment within thirty (30) days after the retiring Administrative Agent gives notice of its resignation (the "Resignation Effective Date"), then the retiring Administrative Agent may (but shall not be obligated to), on behalf of the Lenders, appoint a successor Administrative Agent which shall be a bank with an office in New York, New York, or an Affiliate of any such bank. Whether or not such successor has been appointed, such resignation shall become effective in accordance with such notice on the Resignation Effective Date. With effect from the Resignation Effective Date (1) the retiring or removed Administrative Agent shall be discharged from its duties and obligations hereunder and under the other Loan Documents and (2) except for any indemnity payments or other amounts then owed to the retiring or removed Administrative Agent, all payments, communications and determinations provided to be made by, to or through the Administrative Agent shall instead be made by or to each Lender directly, until such time, if any, as the Required Lenders appoint a successor Administrative Agent as provided for above. Upon the acceptance of its appointment as Administrative Agent hereunder by a successor, such successor shall succeed to and become vested with all the rights, powers, privileges and duties of the retiring Administrative Agent, and the retiring Administrative Agent shall be discharged from its duties and obligations hereunder. The fees payable by the Borrower to a successor Administrative Agent shall be the same as those payable to its predecessor unless otherwise agreed between the Borrower and such successor.

After the Administrative Agent's resignation hereunder, the provisions of this Article and Section 9.03 shall continue in effect for the benefit of such retiring Administrative Agent, its sub-agents and their respective Related Parties in respect of any actions taken or omitted to be taken by any of them while it was acting as Administrative Agent."

SECTION 2. Conditions to Effectiveness. This Amendment shall become effective as of the date first above written when, and only when, the Administrative Agent shall have received counterparts of this Amendment executed by the Borrower and the Required Lenders and all reasonable and documented out-of-pocket costs and expenses in connection with the preparation, execution, and delivery of this Amendment (to the extent invoiced at least one (1) Business Day prior to the date hereof). This Amendment is subject to the provisions of Section 9.02 of the Credit Agreement.

SECTION 3. Representations and Warranties of the Borrower. The Borrower represents and warrants as follows as of the date hereof:

(a) The execution, delivery and performance by the Borrower of this Amendment are within the Borrower's corporate power, and this Amendment has been duly executed and delivered by the Borrower and constitutes a legal, valid and binding obligation of the Borrower, enforceable against the Borrower in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, examinership, reorganization, moratorium or other laws affecting creditors' rights generally, (ii) general principles of equity, regardless of whether considered in a proceeding in equity or at law and (iii) requirements of reasonableness, good faith and fair dealing.

(b) The execution, delivery and performance of this Amendment (i) do not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority, except such as are not material or have been, or will be by the time required, obtained or made and are, or will be by the time required, in full force and effect, (ii) will not violate in any material respect any applicable material law or regulation or the charter, by-laws, constitution or other organizational documents of the Borrower or any material order of any Governmental Authority binding upon the Borrower or any of the Material Subsidiaries or its assets, (iii) will not violate in any material respect or result in a default under any indenture, material agreement or other material instrument binding upon the Borrower or any of its Material Subsidiaries or its assets, or give rise to a right thereunder to require any payment to be made by the Borrower or any of its Material Subsidiaries, except, in the case of this clause (iii), for any such violations, defaults or rights that could not reasonably be expected to result in a Material Adverse Effect, (iv) will not violate or result in a default under the Existing Credit Agreement or any Corporate Campus Facility Financing Document, or give rise to a right thereunder to require any payment to be made by the Borrower or any of its Material Subsidiaries and (v) will not result in the creation or imposition of any Lien on any asset of the Borrower or any of its Material Subsidiaries, other than Liens (if any) permitted by Section 6.02(a) of the Credit Agreement.

SECTION 4. Reference to and Effect on the Credit Agreement.

(a) On and after the effectiveness of this Amendment, each reference in the Credit Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Credit Agreement, and each reference in each Loan Document to "the Credit Agreement", "thereunder", "thereof" or words of like import referring to the Credit Agreement, shall mean and be a reference to the Credit Agreement, as amended by this Amendment. On and after the effectiveness of this Amendment, this Amendment shall for all purposes constitute a Loan Document.

(b) The Credit Agreement, as specifically amended by this Amendment, and the other Loan Documents are and shall continue to be in full force and effect and are hereby in all respects ratified and confirmed.

(c) The execution, delivery and effectiveness of this Amendment shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of any Lender or the Administrative Agent under the Credit Agreement or any other Loan Document, nor constitute a waiver of any provision of the Credit Agreement or any other Loan Document.

SECTION 5. Costs and Expenses. The Borrower agrees to pay on demand all reasonable and documented out-of-pocket expenses of the Administrative Agent in connection with the preparation, execution,

delivery and administration of this Amendment (including, without limitation, the reasonable and documented fees and expenses of a single firm as primary counsel, along with such specialist counsel as may reasonably be required by the Administrative Agent, and, to the extent reasonably necessary, a single firm of local counsel in each applicable jurisdiction, for the Administrative Agent) in accordance with the terms of Section 9.03 of the Credit Agreement.

SECTION 6. Execution in Counterparts. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute but one and the same agreement. Delivery of an executed counterpart of a signature page to this Amendment by telecopy, e-mailed .pdf or any other electronic means that reproduces an image of the actual executed signature page shall be effective as delivery of a manually executed counterpart of this Amendment. The words "execution," "signed," "signature," and words of like import in this Amendment shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act; provided that, without limiting the foregoing, upon the request of the Administrative Agent, any electronic signature shall be promptly followed by such manually executed counterpart.

SECTION 7. **GOVERNING LAW; WAIVER OF JURY TRIAL; JURISDICTION. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK. THE PROVISIONS OF SECTIONS 9.09 AND 9.10 OF THE CREDIT AGREEMENT ARE INCORPORATED HEREIN BY REFERENCE*, MUTATIS MUTANDIS*.**

SECTION 8. Headings. Section headings are included for convenience of reference only and shall not affect the interpretation of this Amendment.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective officers thereunto duly authorized, as of the date first above written.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Robert E. Landry
Name: Robert E. Landry
Title: Executive Vice President, Finance and
Chief Financial Officer

GOLDMAN SACHS BANK USA, as Lender and Administrative Agent

By: /s/ Robert Ehudin
Name: Robert Ehudin
Title: Authorized Signatory

Exhibit 10.3

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

THIRD AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

THIS THIRD AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT (this "Third Amendment"), dated as of April 5, 2020 (the "Execution Date"), and effective as of April 1, 2020 (the "Transition Date"), is by and between Sanofi Biotechnology SAS, a sociéte par actions simplifiée, organized under the laws of France, as successor in interest to Aventis Pharmaceuticals Inc., having a principal place of business at 54, rue La Boétie, 75008 Paris, France ("Sanofi"), Sanofi, a société anonyme organized under the laws of the French Republic with its principal headquarters at 54, rue La Boétie, 75008 Paris, France ("Sanofi Parent"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of the state of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties").

RECITALS

WHEREAS, Regeneron, Sanofi and Sanofi Parent are parties to that certain Amended and Restated License and Collaboration Agreement dated as of November 10, 2009, as amended as of May 1, 2013 and July 1, 2015 (the "LCA") for the Development, Manufacture and Commercialization of Licensed Products (as such terms are defined therein);

WHEREAS, simultaneously herewith, the Parties are entering into the Praluent Agreement (as defined below), pursuant to which the Parties set forth their rights and obligations with respect to the development, manufacture and commercialization of the Praluent License Agreement Products (as defined below) from and after the Transition Date (as defined below); and

WHEREAS, in connection with entering into the Praluent Agreement, the Parties desire to amend the LCA to, except as expressly set forth in this Third Amendment, remove the Praluent LCA Products from the LCA effective from and after the Transition Date.

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. **Effectiveness.** This Third Amendment is entered into as of the Execution Date but shall be effective as of and after the Transition Date.

2. **Definitions.**

2.1. Unless otherwise specifically provided herein, capitalized terms used, but not otherwise defined, herein shall have the meanings ascribed thereto in the LCA.

2.2. Additional Definitions. Article I of the LCA is hereby amended by adding the following definitions:

(a) "Praluent Agreement" shall mean that certain Praluent Cross License & Commercialization Agreement between Sanofi and Regeneron, dated as of the Execution Date, and effective as of the Transition Date, as such agreement may be amended from time to time pursuant to its terms.

(b) "Praluent LCA Product" shall mean any Licensed Product that contains alirocumab.

(c) "Praluent License Agreement Product" shall mean any "Praluent Product" as defined in the Praluent Agreement.

(d) "ROW Profit Split Sales" shall mean the aggregate Net Sales of all Licensed Products and Praluent License Agreement Products in the ROW. For the purpose of this definition of "ROW Profit Split Sales", from and after the Transition Date, "Licensed Product" as used in the definition of Net Sales and First Commercial Sale shall also include the Praluent License Agreement Products (without double counting); provided that with respect to any Praluent License Agreement Product that is a Combination Product (as defined in the Praluent Agreement), any adjustment to the Net Sales of such Praluent License Agreement Product due to the fact that such Praluent License Agreement Product is such a Combination Product shall be as set forth in the definition of "Net Sales" in the Praluent Agreement.

2.3. Amended Definitions. The following definitions in the LCA are hereby amended as follows:

(a) The definition of "Licensed Products" is hereby amended by adding the following as a new sentence at the end of such definition:

"Notwithstanding the foregoing, the Licensed Products shall, from and after the Transition Date, exclude the Praluent LCA Products."

(b) The definition of "New Information" is hereby amended by adding the following as a new sentence at the end of such definition:

"Any ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public that arose or were conceived or developed by either Party or its Affiliates, or by the Parties or their Affiliates jointly, pursuant to this Agreement prior to the Transition Date shall, as from and after the Transition Date, be excluded from New Information and shall be governed by the terms of the Praluent Agreement to the extent specifically related to a Praluent License Agreement Product or a Praluent LCA Product."

(c) The definition of "Party Information" is hereby amended by adding the following as a new sentence at the end of such definition:

"Any trade secrets or other proprietary information other than New Information that were disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement prior to the Transition Date to the extent specifically related to a Praluent License Agreement Product or a Praluent LCA Product shall, from and after the Transition Date, be excluded from Party Information and shall be governed by the terms of the Praluent Agreement."

(d) The definition of "Product Trademark" is hereby amended by adding the following as a new sentence at the end of such definition:

"Notwithstanding the foregoing, Product Trademarks shall, from and after the Transition Date, exclude all Praluent Product Trademarks (as defined in the Praluent Agreement)."

3. Acknowledgements and Agreements. The Parties acknowledge and agree that:

3.1. From and after the Transition Date, (i) each Party's rights and obligations with respect to the Praluent LCA Products shall be as set forth in the Praluent Agreement (including, without limitation, the Tech Transfer Plans (as defined in the Praluent Agreement)), except to the extent expressly set forth in the LCA (including as amended by this Third Amendment); and (ii) the Praluent LCA Products shall not be Licensed Products. Notwithstanding anything herein or in the LCA to the contrary, the LCA shall continue to govern any existing or future disputes in respect of any payments made, owed or alleged to be owed, in each case, by either Party under the LCA with respect to the Praluent LCA Products.

3.2. From and after the Transition Date, [* * *] for purposes of the definition of "Competing Product."

3.3. From and after the Transition Date, no Committee shall have jurisdiction with respect to the Praluent LCA Products.

3.4. All licenses granted under Sections 4.1, 4.2, 11.5 and 11.6 of the LCA with respect to the Praluent LCA Products shall terminate as of the Transition Date and from and after the Transition Date licenses with respect to the Praluent LCA Products shall be governed by the Praluent Agreement.

3.5. No costs, expenses or taxes incurred by either Party from and after the Transition Date with respect to a Praluent LCA Product will be included in, or otherwise taken into account in, the definitions of "Clinical Supply Cost", "Commercial Overhead Charge", "Commercial Supply Cost", "Development Balance", "Development Cost", "Medical Post-Approval Costs", "Other Shared Expenses", "Regeneron Reimbursement Amount", "Sales Force Costs", "Shared Commercial Expenses" or "Shared Phase 3 Trial Costs" under the LCA. However, for avoidance of doubt, this provision shall not affect any portion of the Development Balance based on amounts incurred prior to the Transition Date, whether or not with respect to Praluent LCA Products.

3.6. From and after the Transition Date, there are no Country/Region Commercialization Budgets, Country/Region Commercialization Plans, Development Plans, Initial Development Plans, Manufacturing Plans, Global Commercialization Budgets, Global Commercialization Plans, Global Development Budgets, Global Development Plans, interim budgets, budgets or Plans under the LCA for the Praluent LCA Products.

3.7. From and after the Transition Date, the Parties rights and obligations for manufacturing and supplying the Praluent LCA Products shall be as set forth in the Praluent Agreement and any supply agreements entered into in connection therewith.

3.8. From and after the Transition Date:

(a) Regeneron Know-How excludes any Know-How owned by, licensed to or otherwise held by Regeneron or any of its Affiliates with the right to sublicense the same that relates to a Praluent LCA Product and does not relate to a Licensed Product (taking into account the exclusion of Praluent LCA Products from the definition of Licensed Products) in the Field.

(b) Regeneron Patent Rights exclude any Patent Rights owned by, licensed to or otherwise held by Regeneron or any of its Affiliates with the right to sublicense the same that include at least one Valid Claim that would be infringed by the Development, Manufacture or Commercialization of a Praluent LCA Product and would not be infringed by the Development, Manufacture or Commercialization of a Licensed Product (taking into account the exclusion of Praluent LCA Products from the definition of Licensed Products) in the Field.

(c) Sanofi Know-How excludes any Know-How owned by, licensed to or otherwise held by Sanofi or any of its Affiliates with the right to sublicense the same that relates to a Praluent LCA Product and does not relate to a Licensed Product (taking into account the exclusion of Praluent LCA Products from the definition of Licensed Products) in the Field.

(d) Sanofi Patent Rights exclude any Patent Rights owned by, licensed to or otherwise held by Sanofi or any of its Affiliates with the right to sublicense the same that include at least one Valid Claim that would be infringed by the Development, Manufacture or Commercialization of a Praluent LCA Product and would not be infringed by the Development, Manufacture or Commercialization of a Licensed Product (taking into account the exclusion of Praluent LCA Products from the definition of Licensed Products) in the Field.

(e) Any Patent Rights that exist as of the Transition Date, cover a Joint Invention and are related to a Praluent LCA Product and are not related to a Licensed Product (taking into account the exclusion of Praluent LCA Products from the definition of Licensed Products) shall be excluded from Joint Patent Rights and shall be governed by the terms of the Praluent Agreement.

(f) Each Party's rights under Section 12.1(f) of the LCA with respect to Joint Inventions that are Covered (as defined in the Praluent Agreement) by a Joint Patent (as defined in the Praluent Agreement) shall be subject to the licenses granted by the Parties under Sections 2.1 and 2.2 of the Praluent Agreement.

3.9. The Praluent LCA Products are not Terminated Licensed Products and the provisions of Section 19.2, Section 19.7, Section 19.8 and Schedules 4 and 5 of the LCA shall not apply with respect to Praluent LCA Products.

4. Amendments to Certain Provisions of the LCA.

4.1. Amendment to Section 9.5(c). Section 9.5(c) of the LCA is hereby amended to read in its entirety as follows:

"Within forty-five (45) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, Sanofi shall deliver electronically to Regeneron a written report setting forth, on a country-by-country basis in the Territory for such Quarter the Net Sales of (i) each Licensed Product and (ii) from and after the Transition Date, each Praluent License Agreement Product, in each case ((i) and (ii)), in local currency and in United States Dollars;"

4.2. Amendment to Section 9.14. Section 9.14 of the LCA is hereby amended to read in its entirety as follows:

"No Double Counting. Any specific cost or expense paid or reimbursed under this Agreement, the Praluent Agreement or any Ancillary Collaboration Agreements shall be paid or reimbursed only once so as to avoid any "double counting," regardless of whether such cost or expense is reflected in more than one plan or budget under this Agreement, the Praluent Agreement or the Ancillary Collaboration Agreements."

4.3. Amendment to Section 12.1(b). Section 12.1(b) of the LCA is hereby amended by adding the following sentence after the last sentence of Section 12.1(b) of the LCA:

"From and after the Transition Date, Joint Inventions discovered, invented, authored or otherwise created under the Collaboration prior to the Transition Date that relate to a Praluent LCA Product and are not related to a Licensed Product (taking into account the exclusion of Praluent LCA Products from the definition of Licensed Products) shall be excluded from Joint Inventions hereunder and shall be governed by the Praluent Agreement."

4.4. Addition of Section 14.4. New Section 14.4 of the LCA is hereby added after Section 14.3 of the LCA and shall provide as follows:

"Praluent LCA Products. The provisions of Section 14.1 and Section 14.2 shall continue to apply with respect to books and records regarding sales of, or costs and expenses incurred with respect to, Praluent LCA Products prior to the Transition Date."

4.5. Amendment to Section 15.4. Section 15.4 of the LCA is hereby amended by adding the following sentence after the first sentence of Section 15.4 of the LCA:

"FROM AND AFTER THE TRANSITION DATE, THE FOREGOING DISCLAIMER CONTINUES TO APPLY WITH RESPECT TO PRALUENT LCA PRODUCTS PRIOR TO THE TRANSITION DATE."

4.6. Amendment to Section 16.1. Section 16.1 of the LCA is hereby amended by adding the following sentence after the last sentence of Section 16.1 of the LCA:

"Notwithstanding the foregoing, nothing herein will prohibit either Party from using any Know-How that is (x) related to any Praluent License Agreement Product and (y) included in the definition of (1) Party Information or (2) New Information, in each case ((x) and (y)) in connection with the Praluent License Agreement Products pursuant to the Praluent Agreement as if such Know-How were Party Information (as defined in the Praluent Agreement) (in the case of clause (y)(1)) or Existing Joint Know-How (as defined in the Praluent Agreement) (in the case of clause (y)(2))."

4.7. Amendment to Section 16.4. Section 16.4 of the LCA is hereby amended by adding the following sentence after the last sentence of Section 16.4 of the LCA:

"Notwithstanding the foregoing, the obligations and restrictions imposed upon the Parties by this Section 16.4 shall not apply with respect to any press release relating to the restructuring of this Agreement in connection with the Praluent Agreement, which press release shall be governed by the Praluent Agreement."

4.8. Amendment to Section 17.1. Section 17.1 of the LCA is hereby amended by adding the following clause after clause (f) of Section 17.1 of the LCA:

"(g)

(i) From and after the Transition Date, (A) all Third Party claims relating to Praluent LCA Products that (1) are due to or based upon any act or occurrence on or after the Transition Date or (2) are Special Claims (as defined in the Praluent Agreement), in each case ((1) and (2)), shall be governed by the Praluent Agreement (which agreement, with respect to certain Special Claims, allocates applicable Damages (other than Litigation Costs (as defined below)) as they would have been shared under this Agreement as in effect immediately prior to the Transition Date) and (B) other than Special Claims (which are governed by the applicable provisions of the Praluent Agreement), all claims relating to Praluent LCA Products that are due to or based upon any act or occurrence prior to the Transition Date shall be governed by the terms of this Agreement as in effect immediately prior to the Transition Date.

(ii)If any Third Party claim that is not a Special Claim relates to a Praluent LCA Product and is due to acts or occurrences both prior to and on or after the Transition Date and would therefore be subject to indemnity under both this Agreement and the Praluent Agreement, the provisions of Section 17.2 of this Agreement and Section 14.2 of the Praluent Agreement shall not apply with respect to the defense of such claim and:

(A) the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending such claim, provided that Sanofi shall have final decision-making authority with respect to any such claim relating to Praluent LCA Products in the Sanofi Territory (as defined in the Praluent Agreement), and Regeneron shall have final decision-making authority with respect to any such claim relating to Praluent LCA Products in the Regeneron Territory (as defined in the Praluent Agreement), provided that neither Party shall settle any such claim without the other Party's consent, not to be unreasonably withheld, conditioned or delayed;

(B) (1) if such claim relates to Praluent LCA Products in the Sanofi Territory, then Sanofi shall be solely responsible for the administrative defense costs and expenses (e.g., attorneys' fees, experts' fees and court costs) ("Litigation Costs") with respect thereto and shall reimburse Regeneron for Regeneron's Litigation Costs for such defense or (2) if such claim relates to Praluent LCA Products in the Regeneron Territory, then Regeneron shall be solely responsible for the Litigation Costs with respect thereto and shall reimburse Sanofi for Sanofi's Litigation Costs for such defense;

(C) with respect to any Damages (other than Litigation Costs) from such claim allocable to acts or occurrences prior to the Transition Date, the Parties shall share such Damages as they would have been shared under this Agreement as in effect immediately prior to the Transition Date; and

(D) with respect to any Damages (other than Litigation Costs) from such claim allocable to acts or occurrences on or after the Transition Date, each Party's responsibility for such Damages shall be as set forth in the Praluent Agreement."

4.9. Amendment to Section 20.4. Section 20.4 of the LCA is hereby amended to read in its entirety as follows:

"This Agreement, together with the Discovery Agreement, the Praluent Agreement, the Praluent Transition Services Agreement (as defined in the Praluent Agreement) and the Ancillary Agreements, contains the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof, provided that the last sentence of Section 14.4 of the Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the Discovery Agreement. In the event of any conflict between this Agreement and the Praluent Agreement, the Praluent Agreement shall control. Any variation

between a provision of this Agreement and a corresponding or similar provision of the IO License and Collaboration Agreement, the IO Discovery Agreement or the Praluent Agreement shall not be considered in the interpretation of this Agreement, the IO License and Collaboration Agreement, the IO Discovery Agreement or the Praluent Agreement."

4.10. Amendment to Schedule 2, Part I. The definition of "U.S. Profits" is hereby amended to read in its entirety as follows:

""U.S. Profits" in a Quarter shall mean aggregate Net Sales of all Licensed Products in the U.S. in the Quarter less the sum of (a) aggregate COGS in the U.S. in the Quarter, (b) aggregate Shared Commercial Expenses incurred by both Parties and allocable to the U.S. in the Quarter, and (c) aggregate Other Shared Expenses incurred by both Parties and allocable to, the U.S. in the Quarter; provided, that with respect to the Quarter ending March 31, 2020, provisions or reserves for Praluent LCA Products shall be taken into account for purposes of calculating U.S. Profits for such Quarter [* * *]."

4.11. Amendment to Schedule 2, Part II. Part II of Schedule 2 of the LCA is hereby amended to read in its entirety as follows:

"II. REST OF WORLD PROFIT SPLIT

The Parties intend to share ROW Profits (as defined below) in each Contract Year (the "Rest of World Profit Split," defined below) based on the aggregate amount of ROW Profit Split Sales in accordance with the Target ROW Profit Split (defined below). Since the full calculation cannot be done until ROW Profits and ROW Profit Split Sales for the full Contract Year are known, each Quarter, the Parties will calculate an estimated profit split for the Quarter based on ROW Profits and ROW Profit Split Sales for the Quarter and the Applicable ROW Percentages (defined below). Following the end of each Contract Year, the Parties will true-up the quarterly estimates of the Rest of World Profit Split to the Target ROW Profit Split through the ROW Profit Split Annual True-Up calculation (defined below).

The following definitions shall apply to the determination of the Target ROW Profit Split for any Contract Year:

"Tier" means each of Tier 1, Tier 2 or Tier 3, as applicable.

"Tier 1" means, for a Contract Year, up to $[* * *] of ROW Profit Split Sales in such Contract Year.

"Tier 2" means, for a Contract Year, from $[* * *] up to $[* * *] of ROW Profit Split Sales in such Contract Year.

"Tier 3" means, for a Contract Year, greater than $[* * *] of ROW Profit Split Sales in such Contract Year.

"Tier Fraction" means, with respect to a Contract Year and a Tier, a fraction, (a) the numerator of which is the amount of ROW Profit Split Sales in such Tier in such Contract

Year (e.g., [* * *]) and (b) the denominator of which is the aggregate amount of ROW Profit Split Sales in such Contract Year (e.g., [* * *]).

The "Target ROW Profit Split" for any Contract Year shall mean a profit split whereby (a) an amount equal to the ROW Profits for such Contract Year multiplied by the Tier Fraction for Tier 1 for such Contract Year is split [* * *]% Sanofi/[* * *]% Regeneron, (b) an amount equal to the ROW Profits for such Contract Year multiplied by the Tier Fraction for Tier 2 for such Contract Year is split [* * *]% Sanofi/[* * *]% Regeneron, and (c) an amount equal to the ROW Profits for such Contract Year multiplied by the Tier Fraction for Tier 3 for such Contract Year is split [* * *]% Sanofi/[* * *]% Regeneron.

An example of the calculation of the Target ROW Profit Split is set forth below for illustrative purposes only. If there is a conflict between the operative language and the example, the operative language shall govern.

Example Target ROW Profit Split calculation:

[* * *]

The "Rest of World Profit Split" (or "ROW Profit Split") for a Quarter shall mean [* * *].

The "Applicable ROW Percentages" for the Quarter for each of Sanofi and Regeneron shall mean the percentages to be used to calculate each Party's Rest of World Profit Split for the Quarter, as illustrated in the example set forth on Schedule 2A. At the end of each Contract Year, as part of the calculation of the fourth Quarter Rest of World Profit Split, a "ROW Profit Split Annual True-Up" shall also be calculated to make each Party's Rest of World Profit Split for the Contract Year equal to the Target ROW Profit Split. Calculation of the Applicable ROW Percentages and Rest of World Profit Splits for a Quarter and ROW Profit Split Annual True-Up for a Contract Year are illustrated in the example set forth on Schedule 2A.

Notwithstanding the method of calculation shown on Schedule 2A, in any Quarter (or for any full Contract Year) in which the ROW Profits are negative, the Applicable ROW Percentages for such Quarter (or for such Contract Year after calculation of the ROW Profit Split Annual True-Up) shall be [* * *] percent ([* * *]%) for Sanofi and [* * *] percent ([* * *]%) for Regeneron.

An example of a calculation of the Rest of World Profit Split in a Quarter would be: [* * *]

4.12. Schedule 2A. Promptly after the Execution Date, the Parties shall in good faith agree upon an amendment to add a Schedule 2A to the LCA that contains an example Rest of World Profit Split calculation based on the revised provisions of Part II of Schedule 2 as set forth in this Third Amendment. Such example shall be based on the Rest of World Profit Split Example included in Part II of Schedule 2 to the LCA but shall implement the following changes: [* * *].

4.13. Amendment to Schedule 3. Schedule 3 of the LCA is hereby amended to read in its entirety as follows:

Sales Milestones

Aggregate annual ROW Profit Split Sales	Sales Milestone
US$[* * *]	US$[* * *]
US$[* * *]	US$[* * *]
US$[* * *]	US$[* * *]
US$[* * *]	US$[* * *]
US$[* * *]	US$[* * *]

For purposes of clarification, each of the foregoing milestone payments shall be made only once and only upon the first occurrence of each milestone. Aggregate annual ROW Profit Split Sales shall be determined based on the aggregate ROW Profit Split Sales in any rolling twelve (12) month period.

5. Clean Slate. Sanofi, Sanofi Parent and Regeneron, each on their own behalf, and on behalf of each of their respective subsidiaries, affiliates, partners, parent entities, members, managers, shareholders, directors, officers, and employees, and the respective heirs, executors, administrators, predecessors, agents, successors and permitted assigns of each of the foregoing (collectively, "Released Entities") , hereby irrevocably forever relieves, releases and discharges the other party and its Released Entities, from and against any and all claims related [* * *]. Notwithstanding the foregoing, the Parties shall maintain their audit rights under Section 14.2 of the LCA and any under- or over-payment disclosed by such audit shall be paid by the Party owing such money in accordance with Section 14.2(c) of the LCA.

6. Miscellaneous Provisions

6.1. Due Organization, Valid Existence and Due Authorization. Each Party represents and warrants to the other Party, as of the Transition Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into this Third Amendment; (c) the execution of this Third Amendment will not constitute a breach of, or conflict with, its organizational documents or any other agreement by which it is bound or requirement of applicable Laws or regulations; and (d) this Third Amendment is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium).

6.2. Miscellaneous. The provisions of Sections 20.1, 20.3, 20.5, 20.7, 20.6, 20.8, 20.12 and 20.17 of the LCA shall apply *mutatis mutandis* to this Third Amendment as though set out in full in this Third Amendment.

6.3. No Other Amendments. Except as expressly amended hereby, all of the terms and conditions of the LCA shall remain in full force and effect.

[Signature Page Follows]

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Third Amendment to be executed by their duly authorized representatives as of the Execution Date.

SANOFI BIOTECHNOLOGY SAS

By /s/ Benedicte Bonny
Name: Benedicte Bonny
Title: President

SANOFI

By /s/ Karen Linehan
Name: Karen Linehan
Title: EVP & General Counsel

REGENERON PHARMACEUTICALS, INC.

By /s/ Robert E. Landry
Name: Robert E. Landry
Title: Executive Vice President, Finance and Chief Financial Officer

Exhibit 10.4

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

PRALUENT CROSS License & COMMERCIALIZATION AGREEMENT

By and Between

SANOFI BIOTECHNOLOGY SAS

and

REGENERON PHARMACEUTICALS, INC.

Dated as of April 5, 2020

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SCHEDULES

EXHIBITS

Praluent CROSS LICENSE &
commercialization AGREEMENT

THIS PRALUENT CROSS LICENSE & COMMERCIALIZATION AGREEMENT (this "Agreement"), dated as of April 5, 2020 (the "Execution Date"), and effective as of April 1, 2020 (the "Transition Date"), by and between SANOFI BIOTECHNOLOGY SAS, a société par actions simplifiée organized under the laws of France and having a principal place of business at 54 rue La Boétie, 75008 Paris, France ("Sanofi"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Regeneron and Sanofi (as successor in interest to Aventis Pharmaceuticals Inc. and Sanofi-Aventis Amerique Du Nord) are parties to an Amended and Restated License and Collaboration Agreement dated as of November 10, 2009, as amended as of May 1, 2013, July 1, 2015, and the date hereof (the "LCA") for the Development, Manufacture and Commercialization of certain Licensed Products (as such term is defined therein), including the antibody Praluent® (alirocumab); and

WHEREAS, pursuant to the terms and conditions of an amendment to the LCA of same date as the Execution Date (the "LCA Amendment"), the Parties have agreed to remove, effective as of the Transition Date (as defined below), the Praluent Products (as defined below) from the scope of the LCA and desire to have the Development, Manufacture and Commercialization thereof be governed by the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Accounting Standards" shall mean, GAAP with respect to Regeneron or IAS/IFRS with respect to Sanofi, as generally and consistently applied throughout the applicable Party's organization.

1.2 "Acting Party" shall have the meaning set forth in Section 11.5(a).

1.3 "Affiliate" shall mean, with respect to any Person, any other Person that controls, is controlled by or is under common control with such first Person. A Person shall be deemed to control another Person if such first Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such first Person, whether through the ownership of voting

securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates of Sanofi or any of its Affiliates.

1.4 "Agreement" shall have the meaning set forth in the introductory paragraph and shall include all Schedules and Exhibits attached hereto.

1.5 "Alliance Manager" shall have the meaning set forth in Section 3.1.

1.6 [* * *].

1.7 "Ancillary Agreements" shall mean the Praluent Supply Agreements, the Praluent Transition Services Agreement, the Praluent Pharmacovigilance Transition Services Agreement, the Praluent Services Agreements, the Praluent Bill of Sale, the Praluent Domain Name Assignment and the Praluent Trademark Assignment.

1.8 "Ancillary Services Agreements" shall mean the Praluent Supply Agreements, the Praluent Transition Services Agreement, the Praluent Pharmacovigilance Transition Services Agreement and the Praluent Services Agreements.

1.9 "Approval" shall mean any approval, registration, license or authorization from any Regulatory Authority required for the testing, Manufacture, Development, Commercialization, sale, storage or transport of, or expanded labeling for, a Praluent Product in any country, and shall include an approval, registration, license or authorization granted in connection with any IND, BLA or equivalent application in any country.

1.10 "Assay Services" shall have the meaning set forth in Section 4.7.

1.11 "Back-Up Request" shall have the meaning set forth in Section 7.6.

1.12 "BLA" shall mean a biologics license application filed with respect to a Praluent Product, as described in the FDA regulations, including all amendments and supplements to the application.

1.13 "Breaching Party" shall have the meaning set forth in Section 16.2.

1.14 “Business Day” shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.

1.15 “Calendar Quarter” shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.16 “Calendar Year” shall mean each successive period of twelve (12) calendar months commencing on January 1, except that the first Calendar Year shall commence on the Transition Date and shall end on December 31, 2020.

1.17 “CMC” shall mean chemistry, manufacturing and control.

1.18 “Code” shall mean the U.S. Internal Revenue Code of 1986, as amended.

1.19 “Combination Product” shall have the meaning set forth in the definition of “Net Sales”.

1.20 “Commercialize” or “Commercialization” shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, offering for sale, having sold or selling any Praluent Product or biosimilar thereof (as the case may be), including obtaining and maintaining NDCs and Pricing Approvals therefor.

1.21 “Control” shall mean, with respect to any item of Know-How, material, regulatory documentation, Patents or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license (other than by operation of a license or other rights granted by one Party to the other Party hereunder) or otherwise, to assign, or grant a license, sublicense, right of reference or other right to or under such Know-How, material, regulatory documentation, Patents or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.22 “Controlling Party” shall have the meaning set forth in Section 11.3(b).

1.23 “Copyright” shall mean all copyrights and all rights in any copyrightable works, in all forms and media, including any copyrightable elements in any html and web content, and any copyright registrations or applications therefor and all extensions, restorations, reversions and renewals of any of the foregoing.

1.24 “Cover”, “Covered” or “Covering” shall mean, with respect to an invention or activity and the relevant Patent, that, but for a license granted under such Patent or ownership of such Patent, the practice of such invention or the conduct of such activity would infringe an issued claim in such Patent or, in the case of a Patent that is a patent application, would infringe a pending claim in such patent application if such patent application were to issue as a patent.

1.25 “Damages” shall have the meaning set forth in Section 14.1(a).

1.26 “Default Interest Rate” shall have the meaning set forth in Section 8.9.

1.27 “Defending Party” shall have the meaning set forth in Section 11.4(b).

1.28 “Develop” or “Development” shall mean activities performed by or on behalf of either Party relating to research, pre-clinical drug development or clinical drug development with respect to any Praluent Product or biosimilar thereof (as the case may be), including test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation and submission of Regulatory Filings, and any other research and development activities, including the discovery of biomarkers and activities supporting new formulations, delivery technologies or new indications.

1.29 “Directing Party” shall have the meaning set forth in Section 11.5(a).

1.30 “Discovery Agreement” shall mean the Amended and Restated Discovery and Preclinical Development Agreement, between Sanofi, as successor-in-interest to Aventis Pharmaceuticals, Inc., and Regeneron Pharmaceuticals, Inc., dated as of November 10, 2009, as amended as of May 1, 2013 and July 1, 2015.

1.31 “Domain Name” shall mean any domain names (including both gTLDs and ccTLDs), URLs and social media names, tags or handles or similar identifiers.

1.32 “Drug Substance Tech Transfer Plan” shall have the meaning set forth in Section 7.3(a).

1.33 “EMA” shall mean the European Medicines Agency or any successor agency thereto.

1.34 “Enforcing Party” shall have the meaning set forth in Section 11.1(b).

1.35 “Europe” means the countries comprising the European Economic Area as of the Transition Date.

1.36 “Execution Date” shall have the meaning set forth in the introductory paragraph.

1.37 “Executive Officers” shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi, or their respective designees with equivalent decision-making authority with respect to the matters under this Agreement.

1.38 “Existing European Opposition” shall have the meaning set forth in Section 11.5(b).

1.39 “Existing Indication” shall mean, with respect to an Existing Praluent Product, any indication and therapeutic regimen (i.e., standalone therapy or use with one (1) or more other products) for such indication for which such Existing Praluent Product (a) has received Marketing Approval as of the Transition Date or (b) was being, or has been, clinically Developed under the LCA as of the Transition Date, including under any Existing Trials.

1.40 "Existing Joint Know-How" shall mean (a) any and all Know-How existing as of the Transition Date that arose from the Parties' and their Affiliates' performance under the LCA, to the extent specifically related to the Praluent Compound or any Praluent Product, excluding Regeneron Manufacturing Know-How and Sanofi Manufacturing Know-How and (b) Existing Trials Information whether created before or after the Transition Date.

1.41 "Existing Praluent Product" shall mean the Praluent Compound or a Praluent Product (including any delivery devices, e.g., an autoinjector), in either case, (a) that has received Marketing Approval as of the Transition Date or (b) that was being, or has been, clinically Developed (or, with respect to such delivery devices, Developed) under the LCA as of the Transition Date, including under the Existing Trials.

1.42 "Existing Sole Oppositions" shall have the meaning set forth in Section 11.5(a).

1.43 "Existing Trials" shall mean any clinical trial that was initiated under the LCA prior to the Transition Date in respect of the Praluent Products, including investigator-initiated clinical trials. For clarity, the Existing Trials include the Global Clinical Trials and the Other Existing Trials.

1.44 "Existing Trials Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, that arise or are conceived or developed by or on behalf of either Party or its Affiliates, or by or on behalf of the Parties or their Affiliates jointly, or are otherwise Controlled by either Party or its Affiliates, in each case in connection with any Existing Trials.

1.45 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.46 "Finished Clinical Product" shall mean either (a) a Praluent Product, containing as its only active ingredient Formulated Drug Substance, or (b) placebo, in each case (a) and (b) in its finished (e.g., in an autoinjector), labeled and packaged form, ready for use in clinical trials.

1.47 "Finished Product" shall mean a Praluent Product, containing as its only active ingredient the Formulated Drug Substance, in its finished (i.e., in a DAI autoinjector as such DAI autoinjector exists and is Commercialized as of the Transition Date or, subject to the terms and conditions of Article 5 of the Finished Product Supply Agreement, the [* * *] delivery device), labeled and packaged form, ready for sale to the market, as the case may be.

1.48 "Finished Product Supply Agreement" shall have the meaning set forth in Section 7.5(b).

1.49 [* * *].

1.50 "Force Majeure" shall have the meaning set forth in Article 15.

1.51 "Formulated Drug Substance" shall mean a Praluent Product containing as its only active ingredient the Praluent Compound formulated into solution, ready for storage or shipment to a Manufacturing facility, to allow processing into finished, labeled and packaged form.

1.52 "FTE" shall mean a full time equivalent employee or contract personnel (i.e., one fully-committed or multiple partially-committed employees or contract personnel aggregating to one full-time employee or contract personnel) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee or contract personnel performing such work on a full-time basis, which for purposes hereof shall be [* * *] hours per year. For purposes of the definition of FTE, "contract personnel" refers to personnel (other than employees) who are engaged by a Party on an individual basis and who are not accounted for as Out-of-Pocket Costs and does not include Third Party entities to which activities under this Agreement have been outsourced, such as contract manufacturers, contract research organizations or other external service providers such as consulting firms.

1.53 "FTE Rate" shall mean US$[* * *] per FTE, with respect to employees, and US$[* * *] per FTE, with respect to contract personnel, in the Calendar Year ending December 31, 2020, such amounts to be adjusted as of January 1, 2021 and annually thereafter by the sum of (a) the average of the percentage increases or decreases, if any, in the [* * *] and the [* * *] for the twelve (12) months ending June 30 of the Calendar Year prior to the Calendar Year for which the adjustment is being made plus (b) [* * *] percent ([* * *]%) to reflect [* * *] for each Calendar Year. Upon a variance of more than [* * *] percent ([* * *]%) in the [* * *] since the Transition Date as calculated pursuant to Section 8.8, the Parties shall meet to consider a revision to the FTE Rate.

1.54 "GAAP" shall mean generally accepted accounting principles in the United States.

1.55 "Global Clinical Trials" shall have the meaning set forth in Section 4.2(a).

1.56 "Global Trial Cost Report" shall have the meaning set forth in Section 4.2(b).

1.57 "Global Trial Costs" shall have the meaning set forth on Schedule 1.57.

1.58 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMA, ICH or other country regulatory agencies, as applicable.

1.59 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.60 "Grantee" shall have the meaning set forth in Section 2.3(c).

1.61 "Grantor" shall have the meaning set forth in Section 2.3(c).

1.62 "Human Biological Materials" shall have the meaning set forth in Section 4.6.

1.63 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.64 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Requirements for Registration of Pharmaceuticals for Human Use.

1.65 "IND" shall mean an Investigational New Drug Application filed with the FDA, as described in the FDA regulations, including all amendments and supplements to the application.

1.66 "Indemnified Party" shall have the meaning set forth in Section 14.2(a).

1.67 "Indemnifying Party" shall have the meaning set forth in Section 14.2(a).

1.68 "Inventory Payment" shall have the meaning set forth in Section 8.5.

1.69 "Joint Information" shall mean (a) any Existing Joint Know-How and (b) any Know-How included in the Joint Inventions under this Agreement.

1.70 "Joint Intellectual Property" shall mean Joint Patents and Joint Information.

1.71 "Joint Inventions" shall have the meaning set forth in Section 10.1(b).

1.72 "Joint Patents" shall mean (a) Patents in the Joint Inventions or that Cover a Joint Invention and (b) Joint Patent Rights (as defined in the LCA) that exist as of the Transition Date and are related to the Praluent Compound or the Praluent Products. The Joint Patents that exist as of the Transition Date are set forth on Schedule 1.72.

1.73 "Joint Praluent Committee" or "JPC" shall have the meaning set forth in Section 3.2.

1.74 "Know-How" shall mean any and all proprietary technical or scientific information, know-how, data, materials, protocols, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, improvements and other information, including marketing or supply information and data, and information and data included or referenced in the Regulatory Filings made or Approvals, whether or not patentable or otherwise protected by trade secret Law, in each case that are not claimed or disclosed in any published Patents.

1.75 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions or ordinances of any Governmental Authority in the Territory.

1.76 "LCA" shall have the meaning set forth in the recitals hereto.

1.77 "LCA Amendment" shall have the meaning set forth in the recitals hereto.

1.78 "Lead Defense Party" shall have the meaning set forth in Section 11.4(b).

1.79 "Lead Enforcement Party" shall have the meaning set forth in Section 11.1(b).

1.80 "Litigation Costs" shall have the meaning set forth in Section 14.1(c)(i)(A).

1.81 "Manufacture" or "Manufacturing" shall mean all activities related to the production, manufacture, making, processing, filling, finishing, packaging, labeling, analytical testing, inspection,

receiving, holding and shipping of any Praluent Product or biosimilar thereof, as the case may be, or any constituents (including the Formulated Drug Substance), placebo or a comparator agent, as the case may be or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, release, testing, quality assurance and quality control. When used as a verb, "Manufacture" shall mean to engage in Manufacturing, and when used as a noun, "Manufacturer" shall mean a Person engaged in Manufacturing.

1.82 "Manufacturing Party" shall have the meaning set forth in Section 6.3(b).

1.83 "Manufacturing Transition Team" shall have the meaning set forth in Section 7.9(a).

1.84 "Marketing Approval" shall mean an Approval required for the marketing and sale of a Praluent Product in a country in the Territory.

1.85 "Modified Clause" shall have the meaning set forth in Section 18.8.

1.86 "NDC" shall mean the "National Drug Code" registered by a company with the FDA with respect to a pharmaceutical product.

1.87 "Net Sales" shall mean, with respect to a Praluent Royalty Product for any Calendar Quarter, the gross amount billed or invoiced by Sanofi, its Affiliates or its or their Sublicensees for the sale of such Praluent Royalty Product to Third Parties, less the following deductions determined in accordance with applicable Accounting Standards from such gross amounts which are actually incurred, allowed, accrued or specifically allocated to the Praluent Royalty Product:

(a) discounts, including cash, trade and quantity discounts inclusive of free goods, price reduction programs (including co-pay assistance, compulsory refunds or any other patient assistance programs), retroactive price adjustments with respect to sales of a Praluent Royalty Product, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments (or their respective agencies, purchasers and reimbursors) or to trade customers, including wholesalers and chain and pharmacy buying groups;

(b) amounts repaid or credited by reason of defects, damaged Praluent Royalty Products, expired dating, rejections, recalls, refunds, returns, rebates and billing errors;

(c) freight, postage, shipping and insurance charges actually allowed or paid for delivery of a Praluent Royalty Product, which are separately identified on the invoice or other documentation;

(d) [* * *]

(e) customs, taxes, duties or other governmental charges incurred in connection with, levied on, absorbed or otherwise imposed on sale, exportation or importation of Praluent Royalty Product, including value-added taxes, or other governmental charges otherwise measured by the billing amount, when

included in billing, as adjusted for rebates and refunds, but specifically excluding taxes based on net income of the seller, which are separately identified on the invoice or other documentation;

(f) [* * *]

(g) rebates, credits, compulsory refunds and similar payments made with respect to sales paid for by any governmental or regulatory authority under any governmental program similar or equivalent to Medicaid, Medicare outside the United States;

(h) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to the Praluent Royalty Product; and

(i) any other similar and customary deductions that are consistent with Accounting Standards as determined from the books and records of Sanofi, its Affiliates or its or their (sub)licensees, as the case may be, maintained in accordance with Sanofi's, its Affiliates' or its or their (sub)licensees' normal practices.

Any of the deductions listed above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. Any of the deductions listed above that involves a payment by Sanofi, its Affiliates or its or their Sublicensees shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Praluent Royalty Product shall be deemed to be sold when it has met the applicable Accounting Standards' revenue recognition criteria. Net Sales shall not include transfers or dispositions of such Praluent Royalty Product for pre-clinical or clinical purposes, compassionate use or as samples, in each case, without charge. Sanofi's, its Affiliates' or its or their Sublicensees' transfer of the Praluent Royalty Product to an Affiliate or Sublicensee shall not result in any Net Sales unless the transferee is an end user.

In the event that a Praluent Royalty Product is sold in any country in the form of a combination product containing both the Praluent Compound or, where applicable, biosimilar thereof and one or more other active ingredients ("Other Ingredients") (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average net invoice price in such country of the Praluent

Royalty Product that contains the Praluent Compound or, where applicable, biosimilar thereof as its sole active ingredient, if sold separately in such country, and B is the average net invoice price in such country of, as applicable, each product that contains such Other Ingredient(s) as its sole active ingredient(s) if sold separately in such country; provided that the invoice price in a country for Praluent Royalty Product that contains the Praluent Compound or, where applicable, biosimilar thereof as its sole active ingredient and such product that contains such Other Ingredient(s) as its sole active ingredient(s) shall to the extent feasible be for quantities comparable to those used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable. If either such Praluent Royalty Product that contains the Praluent Compound or, where applicable, biosimilar thereof as its sole active ingredient or any such product that contains such Other Ingredient(s) as its sole active ingredient(s) is not sold separately in a particular country, then the adjustment to Net Sales shall be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of such Praluent Royalty Product that contains the Praluent Compound or, where applicable, biosimilar thereof as its sole active ingredient to the total fair market value of such Combination Product.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Sanofi's, its Affiliates' or its or their Sublicensees' existing allocation method; *provided* that any such allocation shall be done in accordance with applicable Law, including any price reporting laws, rules and regulations.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Sanofi, its Affiliates or its or their Sublicensees, which shall be in accordance with applicable Accounting Standards.

1.88 "New Regeneron License" shall mean any license entered into by Regeneron (or any of its Affiliate(s)) with a Third Party after the Transition Date, required for the U.S. Praluent Product Business.

1.89 "New Sanofi License" shall mean any license entered into by Sanofi (or any of its Affiliate(s)) with a Third Party after the Transition Date, required for the ROW Praluent Product Business.

1.90 "Non-Manufacturing Party" shall have the meaning set forth in Section 6.3(b).

1.91 "Other Existing Trial" shall mean any Existing Trial other than a Global Clinical Trial.

1.92 "Other Ingredients" shall have the meaning set forth in the definition of "Net Sales".

1.93 "Out-of-Pocket Costs" shall mean documented costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with applicable Accounting Standards) by either Party or its Affiliates, excluding any such costs and expenses in respect of "contract personnel" that are accounted for on an FTE basis in accordance with the definition of FTE. For the avoidance of doubt, in no case shall any particular cost or expense be accounted for hereunder both as an Out-of-Pocket Cost and as an FTE-based cost.

1.94 "Owed Party" shall have the meaning set forth in Section 8.7.

1.95 "Owing Party" shall have the meaning set forth in Section 8.7.

1.96 "Party" or "Parties" shall have the meaning set forth in the introductory paragraph.

1.97 "Party Information" shall mean any and all trade secrets or other proprietary information, including any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party's or its Affiliates' technology, products, business or objectives, in each case that (a) were disclosed under the LCA prior to the Transition Date to the extent specifically related to the Praluent Products or (b) are disclosed or made available by or on behalf of a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement or any Ancillary Services Agreement. Notwithstanding the foregoing, (i) (A) the Regeneron Background Know-How, (B) the Regeneron Core Know-How and (C) the Transferred Product Records, in each case ((A) - (C)) shall be deemed to be the Party Information of Regeneron and not of Sanofi, (ii) the Sanofi Background Know-How and the Sanofi Core Know-How shall be deemed to be the Party Information of Sanofi and not of Regeneron and (iii) "Party Information" shall in all cases be deemed to exclude the Joint Information.

1.98 "[* * *]" shall have the meaning set forth in Section 10.2(c).

1.99 "Patent Infringement" shall have the meaning set forth in Section 11.1(a).

1.100 "Patents" shall mean (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.101 "Person" shall mean and include an individual, a partnership, a joint venture, a limited liability company, a corporation, a firm, a trust, an unincorporated organization and a government or other department or agency thereof.

1.102 “PMDA” shall mean the Pharmaceutical and Medical Devices Agency and any successor agency thereto.

1.103 “Praluent Bill of Sale” shall mean that certain Praluent Bill of Sale and Assignment and Assumption Agreement, by and between the Parties, entered into as of the Execution Date and effective as of the Transition Date.

1.104 “Praluent Compound” shall mean the biological compound alirocumab.

1.105 “Praluent Domain Name Assignment” shall mean that certain Praluent Domain Name Assignment Agreement, by and among Regeneron, Sanofi and Sanofi Parent, entered into as of the Execution Date and effective as of the Transition Date.

1.106 “Praluent Master Cell Bank” shall mean the master cell bank used by Regeneron or any of its Affiliates to Manufacture Formulated Drug Substance as of the Transition Date.

1.107 “Praluent Pharmacovigilance Transition Services Agreement” shall mean that certain Praluent Pharmacovigilance Transition Services Agreement, by and between the Parties, entered into as of the Execution Date and effective as of the Transition Date.

1.108 “Praluent Product” shall mean any product that is comprised of or contains the Praluent Compound as an active ingredient, whether alone or in fixed dose combination with one or more additional active ingredients.

1.109 “Praluent Product Domain Names” shall mean the Praluent Product ROW Domain Names or the Praluent Product U.S. Domain Names, as applicable.

1.110 “Praluent Product Regeneron Copyrights” shall mean all Copyright(s) owned or Controlled by Regeneron or its Affiliates or its or their Sublicensees as of the Transition Date that are used in connection with, or are otherwise necessary or useful for, the ROW Praluent Product Business.

1.111 “Praluent Product ROW Domain Names” shall mean any Domain Name(s) owned or Controlled by Sanofi or its Affiliates or its or their Sublicensees and used or to be used by Sanofi or its Affiliates or its or their Sublicensees for the Commercialization of Praluent Products in the Sanofi Territory.

1.112 “Praluent Product ROW Trademarks” shall mean any Trademark(s) owned or Controlled by Sanofi or its Affiliates or its or their Sublicensees and used or to be used by Sanofi or its Affiliates or its or their Sublicensees for the Commercialization of Praluent Products in the Sanofi Territory and any registrations thereof or any pending applications relating thereto in the Sanofi Territory (excluding, in any event, the corporate name or logo of either Party or its Affiliates or its or their (sub)licensees).

1.113 “Praluent Product Sanofi Copyrights” shall mean all Copyright(s) owned or Controlled by Sanofi or its Affiliates or its or their Sublicensees as of the Transition Date that are used in connection with, or are otherwise necessary or useful for, the conduct of the U.S. Praluent Product Business.

1.114 “Praluent Product Trademarks” shall mean the Praluent Product ROW Trademarks or the Praluent Product U.S. Trademarks, as applicable.

1.115 “Praluent Product U.S. Domain Names” shall mean any Domain Name(s) owned or Controlled by Regeneron or its Affiliates or its or their Sublicensees and used or to be used by Regeneron or its Affiliates or its or their Sublicensees for the Commercialization of Praluent Products in the Regeneron Territory, including the Transferred Product Domain Names.

1.116 “Praluent Product U.S. Trademarks” shall mean any Trademark(s) owned or Controlled by Regeneron or its Affiliates or its or their Sublicensees and used or to be used by Regeneron or its Affiliates or its or their Sublicensees for the Commercialization of Praluent Products in the Regeneron Territory and any registrations thereof or any pending applications relating thereto in the United States (excluding, in any event, the corporate name or logo of either Party or its Affiliates or its or their (sub)licensees), including the Transferred Product Trademarks.

1.117 “Praluent Royalty Product” shall mean any Praluent Product [* * *] developed by or on behalf of Sanofi or any of its Affiliates or its or their Sublicensees, but, with respect to any country in the Sanofi Territory other than [* * *], excluding [* * *].

1.118 “Praluent Services Agreement” shall have the meaning set forth in Section 2.8.

1.119 “Praluent Substance Supply Agreement” shall have the meaning set forth in Section 7.5(a).

1.120 “Praluent Supply Agreements” shall mean the Praluent Substance Supply Agreement and the Finished Product Supply Agreement and any related quality agreements.

1.121 “Praluent Trademark Assignment” shall mean that certain Praluent Trademark Assignment Agreement, by and between the Parties, entered into as of the Execution Date and effective as of the Transition Date.

1.122 “Praluent Transition Services Agreement” shall mean that certain Praluent Transition Services Agreement, by and between Regeneron Healthcare Solutions, Inc. and Sanofi-Aventis U.S. LLC., entered into as of the Execution Date and effective as of the Transition Date.

1.123 “Praluent Working Cell Bank” shall mean working cell bank generated from the Praluent Master Cell Bank.

1.124 “Pricing Approval” shall mean any Approval, or any agreement, determination or governmental decision, establishing prices for a Praluent Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.125 “Promotional Materials” shall mean promotional, advertising, communication and educational materials relating to any Praluent Product for use in connection with the marketing,

promotion and sale of, or educational activities with respect to, the Praluent Product, and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.126 "Publishing Party" shall have the meaning set forth in Section 13.5.

1.127 "Recall Cost" shall mean, with respect to a recall, market suspension or market withdrawal, the product of (a) the number of FTEs used to carry out such recall, market suspension or market withdrawal and (b) the applicable FTE Rate(s), plus any Out-of-Pocket Costs incurred by the applicable Party or its Affiliates in respect of such recall, market suspension or market withdrawal.

1.128 "Regeneron" shall have the meaning set forth in the introductory paragraph.

1.129 "Regeneron Background Intellectual Property" shall mean the Regeneron Background Patents and the Regeneron Background Know-How.

1.130 "Regeneron Background Know-How" shall mean any and all Know-How Controlled by Regeneron or any of its Affiliates as of or after the Transition Date that is necessary or useful for the Development, Manufacturing or Commercialization of any Existing Praluent Product for any Existing Indication, excluding the Regeneron Core Know-How and the Joint Information.

1.131 "Regeneron Background Patents" shall mean any and all Patents Controlled by Regeneron or any of its Affiliates as of or after the Transition Date to the extent Covering the use, making, sale, offer for sale or import of any Existing Praluent Product for any Existing Indication, excluding the Regeneron Core Patents and the Joint Patents.

1.132 "Regeneron Cell Media" shall mean any cell culture media that is proprietary to Regeneron and used by Regeneron or any of its Affiliates to Manufacture Formulated Drug Substance as of the Transition Date.

1.133 "Regeneron Core Intellectual Property" shall mean the Regeneron Core Patents and the Regeneron Core Know-How.

1.134 "Regeneron Core Know-How" shall mean any and all Know-How Controlled by Regeneron or any of its Affiliates as of the Transition Date that was conceived or developed by Regeneron or any of its Affiliates under the LCA or the Discovery Agreement and that is related to any Praluent Product, including, for clarity, any Know-How Controlled by Regeneron or any of its Affiliates as of the Transition Date that is contained or referenced in the Transferred Approvals, Transferred Regulatory Documentation or other Transferred U.S. Assets, but excluding any Regeneron Manufacturing Know-How or Joint Information.

1.135 "Regeneron Core Patents" shall mean those Patents Controlled by Regeneron or any of its Affiliates as of or after the Transition Date that contain composition of matter, method of use or formulation claims for any Existing Praluent Product for any Existing Indication, including the Patents listed on Schedule 1.135.

1.136 "Regeneron Indemnitees" shall have the meaning set forth in Section 14.1(a).

1.137 “Regeneron Managed Patents” shall have the meaning set forth in Section 10.2(a).

1.138 “Regeneron Manufacturing Know-How” shall mean any and all Know-How Controlled by Regeneron or any of its Affiliates as of or after the Transition Date that is related to the Manufacture of the Praluent Compound or any Praluent Product, including all CMC data for the Praluent Compound that is included or referenced in, or that otherwise supports, an Approval.

1.139 “Regeneron Manufacturing Site Notice” shall have the meaning set forth in Section 7.2(a).

1.140 “Regeneron Sole Inventions” shall have the meaning set forth in Section 10.1(a).

1.141 “Regeneron Territory” shall mean the United States.

1.142 “Regulatory Authority” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the Development, Manufacture and Commercialization of any Praluent Product in a country in the Territory, including the FDA in the United States, the EMA in Europe and the PMDA in Japan.

1.143 “Regulatory Filing” shall mean the application to the relevant Regulatory Authority for any Approval, and shall include any testing, marketing authorization application, marketing authorization renewal application, Annual Product Quality review application, device application, supplementary application or variation thereof.

1.144 “ROW CPI” shall mean the Harmonized Index of Consumer Prices, overall for working days as seasonally adjusted, referenced as ICP.M.U2.Y.000000.3.INX (or its successor equivalent index), which is published monthly and available via the European Central Bank internet site.

1.145 “ROW Praluent Product Business” shall mean the Development or Manufacture of the Praluent Products (including the Praluent Compound) anywhere in the Territory for the Sanofi Territory, or the Commercialization of the Praluent Products in the Sanofi Territory.

1.146 “Royalty Report” shall have the meaning set forth in Section 8.3.

1.147 “Royalty Term” shall have the meaning set forth in Section 8.1(b).

1.148 “Safety Data Exchange Agreement” shall have the meaning set forth in Section 6.4.

1.149 “Sales Deduction Costs” shall mean, with respect to any period, items deducted from gross sales, solely attributable to Praluent Products, but excluding the cost of recalls (such costs are allocated between the Parties in accordance with Section 6.6). As an example, Sales Deduction Costs include the types of deductions taken in the determination of Net Sales (excluding recalls), including the costs of returns, cash discounts, contracted discounts, rebates, chargebacks or wholesaler fees incurred by a Party or any of its Affiliates (whether paid out-of-pocket or taken as deductions from invoices collected by such Party during such period).

1.150 “Sanofi” shall have the meaning set forth in the introductory paragraph.

1.151 “Sanofi Background Intellectual Property” shall mean the Sanofi Background Patents and the Sanofi Background Know-How.

1.152 “Sanofi Background Know-How” shall mean any and all Know-How Controlled by Sanofi or any of its Affiliates as of or after the Transition Date that is necessary or useful for the Development, Manufacturing or Commercialization of any Existing Praluent Product for any Existing Indication, excluding the Sanofi Core Know-How and the Joint Information.

1.153 “Sanofi Background Patents” shall mean any and all Patents Controlled by Sanofi or any of its Affiliates as of or after the Transition Date to the extent Covering the use, making, sale, offer for sale or import of any Existing Praluent Product for any Existing Indication, excluding the Sanofi Core Patents and the Joint Patents.

1.154 “Sanofi Core Intellectual Property” shall mean the Sanofi Core Patents and Sanofi Core Know-How.

1.155 “Sanofi Core Know-How” shall mean any and all Know-How Controlled by Sanofi or any of its Affiliates as of the Transition Date that was conceived or developed by Sanofi or any of its Affiliates under the LCA or the Discovery Agreement and that is related to any Praluent Product, including, for clarity, any Know-How Controlled by Sanofi or any of its Affiliates as of the Transition Date that is contained or referenced in the Transferred Approvals, Transferred Regulatory Documentation or other Transferred U.S. Assets, but excluding any Sanofi Manufacturing Know-How or Joint Information.

1.156 “Sanofi Core Patents” shall mean those Patents Controlled by Sanofi or any of its Affiliates as of or after the Transition Date that contain composition of matter, method of use or formulation claims for any Existing Praluent Product for any Existing Indication, including the Patents listed on Schedule 1.156.

1.157 “Sanofi Indemnitees” shall have the meaning set forth in Section 14.1(b).

1.158 “Sanofi Managed Patents” shall have the meaning set forth in Section 10.2(b).

1.159 “Sanofi Manufacturing Know-How” shall mean any and all Know-How Controlled by Sanofi or any of its Affiliates as of or after the Transition Date that is related to Manufacture of the Praluent Compound or any Praluent Product.

1.160 “Sanofi Parent” shall mean Sanofi, a société anonyme organized under the laws of France and having a registered office at 54 rue La Boétie, 75008 Paris, France.

1.161 “Sanofi ROR Authorization” shall mean any letter of authorization from a Third Party that permits Sanofi or any of its Affiliates to reference any regulatory documentation, data or information of such Third Party with respect to any Existing Praluent Product in any Existing Indication.

1.162 “Sanofi Samples” shall have the meaning set forth in Section 4.7.

1.163 “Sanofi Sole Inventions” shall have the meaning set forth in Section 10.1(a).

1.164 “Sanofi Territory” shall mean all of the countries and territories of the world other than the Regeneron Territory.

1.165 “Selected Recall” shall have the meaning set forth in Section 6.6(a).

1.166 “Sole Inventions” shall have the meaning set forth in Section 10.1(a).

1.167 “Special Claim” shall have the meaning set forth in Section 14.1(c).

1.168 “Sublicensee” shall mean a Third Party to whom a Party or its Affiliate will have granted (a) a license or sublicense to Manufacture, Develop or Commercialize Praluent Royalty Products in the Territory or (b) the right to distribute Praluent Royalty Products whereby such Third Party provides consideration to such Party or its Affiliate for such distribution rights or in connection with the sale of Praluent Royalty Products other than the supply price for Praluent Royalty Products sold to such Third Party by such Party or its Affiliate, irrespective of whether a license or sublicense or further right of reference is granted under Section 2.3. For clarity, “Sublicensee” shall not include any bona fide commercial distributor that pays to such Party or its Affiliate only a supply price for the Praluent Royalty Products ordered from such Party or its Affiliate.

1.169 “Tech Transfer FTE Cost” shall mean, for all activities performed by a Party in accordance with a Tech Transfer Plan, the product of (a) the number of FTEs used to carry out such activities and (b) the applicable FTE Rate(s).

1.170 “Tech Transfer Plan” shall have the meaning set forth in Section 7.4(a).

1.171 “Technology Transfer Cost Report” shall have the meaning set forth in Section 7.4(c).

1.172 “Terminating Party” shall have the meaning set forth in Section 16.2.

1.173 “Territory” shall mean either Sanofi Territory or Regeneron Territory or, as applicable, both of Sanofi Territory and Regeneron Territory.

1.174 “Third Party” shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.175 “Third Party Claim” shall have the meaning set forth in Section 14.1(a).

1.176 “Third Party Invalidity Assertion” shall have the meaning set forth in Section 11.4(a).

1.177 “Trademark” shall mean any trademark, service mark, trade name, trade dress, logo, slogan, design or other designation that functions as an identifier of source, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor and renewals thereof, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.178 “Transferee” shall have the meaning set forth in Section 7.4(a).

1.179 “Transferor” shall have the meaning set forth in Section 7.4(a).

1.180 “Transferred Approvals” shall mean the Approvals set forth on Schedule 1.180. For clarity, the term “Transferred Approvals” shall only refer to the approvals, registrations, licenses or authorizations granted by the applicable Regulatory Authority and expressly excludes any Sanofi Core Know-How or any of Sanofi’s rights in or to the Existing Joint Know-How included or referenced therein, which shall be subject to the license grants in Section 2.2. The transfer to Regeneron of the Transferred Approvals under Section 2.6 shall not operate to vest or result in any assignment or transfer of any rights, title or interest in and to such Know-How.

1.181 “Transferred Inventory” means all inventories of Finished Product intended for sale or distribution in the Regeneron Territory, including samples intended for distribution in the Regeneron Territory, that are held by Sanofi or any of its Affiliates and unsold (or, with respect to samples, undistributed) as of the Transition Date.

1.182 “Transferred Product Contracts” shall mean all rights and interests of Sanofi or its Affiliates under the contracts set forth on Schedule 1.182.

1.183 “Transferred Product Domain Names” shall mean the Domain Names set forth on Schedule 1.183 and all subdomains thereof.

1.184 “Transferred Product Records” shall mean all books and records (other than the Transferred Regulatory Documentation and any contracts or agreements) solely related to the Commercialization of Praluent Products in the Regeneron Territory, including all books and records that correspond to the items listed on Schedule 1.184 and that are solely related to the Commercialization of Praluent Products in the Regeneron Territory, owned by Sanofi or its Affiliates as of the Transition Date or during the Distribution Service Period (as defined in the Praluent Transition Services Agreement), including all information provided to Regeneron pursuant to the Schedules (as defined in the Praluent Transition Services Agreement).

1.185 “Transferred Product Trademarks” shall mean the Trademarks set forth on Schedule 1.185.

1.186 “Transferred Product Trademarks Documentation” shall mean all trademark registration certificates and maintenance documents (Declaration of Use) and, as the case may be, prosecution files and trademark clearance search results, in each case, that may be in the possession or Control of Sanofi or its Affiliates or its or their outside Trademark counsel as of the Transition Date relating to the Transferred Product Trademarks.

1.187 “Transferred Promotional Materials” shall mean all Promotional Materials to the extent used or intended for use by either Party or its Affiliates for the Commercialization of the Existing Praluent Products in the Regeneron Territory and in the possession of Sanofi or its Affiliates as of the Transition Date.

1.188 “Transferred Regulatory Documentation” shall mean (a) all documentation comprising the Transferred Approvals, and all reports, regulatory applications, submissions and filings

in connection therewith and (b) all correspondence and reports submitted to or received from Governmental Authorities in the Regeneron Territory to the extent related to any such Approvals or to the Commercialization of any Existing Praluent Product for any Existing Indication in the Regeneron Territory, and all relevant supporting documents with respect thereto, in each case ((a) and (b)), in the possession or Control of Sanofi or any of its Affiliates as of the Transition Date. For clarity, the term "Transferred Regulatory Documentation" shall only refer to the embodiments of such documentation, reports, applications, submissions, filings or correspondence and expressly excludes any Sanofi Core Know-How or any of Sanofi's rights in or to the Existing Joint Know-How included or referenced therein, which shall be subject to the license grants in Section 2.2. The transfer to Regeneron of the Transferred Regulatory Documentation under Section 2.6 shall not operate to vest or result in any assignment or transfer of any rights, title or interest in and to such Know-How. For the avoidance of doubt, the term "Transferred Regulatory Documentation" shall not include any Trademark or Domain Name registration documentation, prosecution or enforcement files or Trademark clearance searches or conflict or opposition records and files.

1.189 "Transferred U.S. Assets" shall mean the following rights and assets: (a) the Transferred Approvals, (b) Transferred Inventory, (c) the Transferred Product Contracts, (d) the Transferred Product Domain Names, (e) the Transferred Product Records, (f) the Transferred Product Trademarks, (g) the Transferred Promotional Materials, (h) the Transferred Regulatory Documentation, and (i) Transferred Product Trademarks Documentation.

1.190 "Transition Date" shall have the meaning set forth in the recitals hereto.

1.191 "Triggering Event" shall mean, (a) with respect to any Third Party Claim alleging [* * *] or (b) with respect to any [* * *] Third Party Claim alleging [* * *].

1.192 "United States" or "U.S." shall mean the United States of America (including its territories and possessions and its military bases and commissaries, and any other federal government purchasers, wherever located in the Territory) and Puerto Rico.

1.193 "U.S. CPI" shall mean the Consumer Price Index – All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.194 "U.S. Praluent Product Business" shall mean the Development or Manufacture of the Praluent Products (including the Praluent Compound) anywhere in the Territory for the Regeneron Territory, or the Commercialization of the Praluent Products in the Regeneron Territory.

1.195 "U.S.-Related Praluent Agreements" shall mean the agreements, including all amendments thereto existing as of the Transition Date to which Sanofi or its Affiliates are a party that relate to the Commercialization of any Existing Praluent Product for any Existing Indication in the Regeneron Territory, excluding the Transferred Product Contracts.

ARTICLE 2
LICENSE GRANTS; LIMITED ASSET TRANSFER; TRANSITION COSTS

2.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement, Regeneron (on behalf of itself and its Affiliates) hereby grants to Sanofi and its Affiliates:

(a) an exclusive (including with regard to Regeneron and its Affiliates), royalty-bearing, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10) right and license under the Regeneron Core Intellectual Property, the Regeneron Background Intellectual Property and Regeneron's interest in the Joint Intellectual Property to Commercialize the Praluent Royalty Products in the Sanofi Territory;

(b) a co-exclusive, royalty-bearing, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10) right and license under the Regeneron Core Intellectual Property, the Regeneron Background Intellectual Property, and Regeneron's interest in the Joint Intellectual Property to use (other than to Commercialize), Develop and Manufacture the Praluent Royalty Products (including the Praluent Compound) anywhere in the Territory, solely to support Commercialization of the Praluent Royalty Products in the Sanofi Territory;

(c) a co-exclusive, royalty-free, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10) right and license to reproduce, modify, distribute, create derivative works based on, including translations of, publicly perform, publicly display, publish and otherwise use the Praluent Product Regeneron Copyrights, in all forms and media, now known or hereafter invented, solely to support the ROW Praluent Product Business;

(d) subject to Section 9.3(b), a co-exclusive, royalty-free, fully paid-up, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10) license to use the Praluent Product U.S. Trademarks to Develop and Manufacture the Praluent Products in the Regeneron Territory solely to support the ROW Praluent Product Business; and

(e) subject to Section 9.4(b), the right, free of charge, to use the name or logo of Regeneron or its Affiliate (i) on product labels, package inserts, packaging, trade packaging, samples and all Promotional Materials that are being used for the Commercialization of the Praluent Products in the Sanofi Territory as of the Transition Date, only for the time period (which in any case may not exceed [* * *] years after the Transition Date or such other maximum period as may be agreed by the Parties) and solely to the extent necessary to exhaust the inventory of such product labels, package inserts, packaging, trade packaging, samples and Promotional Materials, in each case existing as of the Transition Date and containing such name or logo or (ii) as necessary to identify, to the extent required under any applicable Law, Regeneron (or its Affiliate) as the Manufacturer of Formulated Drug Substance on any product labels, package inserts, packaging, trade packaging or samples of Praluent Products to be used by Sanofi or its Affiliates or its or their Sublicensees in the ROW Praluent Product Business that incorporate Formulated Drug Substance Manufactured by Regeneron (or its Affiliate).

2.2 Sanofi License Grants. Subject to the terms and conditions of this Agreement, Sanofi (on behalf of itself and its Affiliates) hereby grants to Regeneron and its Affiliates:

(a) an exclusive (including with regard to Sanofi and its Affiliates), fully paid-up, royalty-free, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10)

right and license under the Sanofi Core Intellectual Property, the Sanofi Background Intellectual Property and Sanofi's interest in the Joint Intellectual Property to Commercialize the Praluent Products or any biosimilar thereof in the Regeneron Territory;

(b) a co-exclusive, fully paid-up, royalty-free, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10) right and license under the Sanofi Core Intellectual Property, the Sanofi Background Intellectual Property and Sanofi's interest in the Joint Intellectual Property to use (other than to Commercialize), Develop and Manufacture the Praluent Products (including the Praluent Compound) or any biosimilar thereof anywhere in the Territory, solely to support Commercialization of the Praluent Products or any biosimilar thereof in the Regeneron Territory;

(c) a co-exclusive, royalty-free, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10) right and license to reproduce, modify, distribute, create derivative works based on, including translations of, publicly perform, publicly display, publish and otherwise use the Praluent Product Sanofi Copyrights, in all forms and media, now known or hereafter invented, solely to support the U.S. Praluent Product Business;

(d) subject to Section 9.3(b), a co-exclusive, royalty-free, fully paid-up, sublicensable (pursuant to Section 2.3), transferable (pursuant to Section 18.10), license to use the Praluent Product ROW Trademarks to Develop and Manufacture the Praluent Products in the Sanofi Territory solely to support the U.S. Praluent Product Business; and

(e) subject to Section 9.4(b), the right, free of charge, to use the name or logo of Sanofi or its Affiliate (i) on product labels, package inserts, packaging, trade packaging, samples and all Transferred Promotional Materials, only for the time period (which in any case may not exceed [* * *] years after the Transition Date or such other maximum period as may be agreed by the Parties) and solely to the extent necessary to exhaust the inventory of such product labels, package inserts, packaging, trade packaging, samples and Promotional Materials existing as of the expiration of the Distribution Service Period (as defined in the Praluent Transition Services Agreement) and containing such name or logo or (ii) as necessary to identify, to the extent required under any applicable Law, Sanofi (or its Affiliate) as the Manufacturer of Finished Product on any product labels, package inserts, packaging, trade packaging or samples of Praluent Products to be used by Regeneron or its Affiliates or its or their Sublicensees in the U.S. Praluent Product Business that incorporate Finished Product Manufactured by Sanofi (or its Affiliate).

2.3 Sublicensing and Subcontracting.

(a) Subject to Section 2.3(c), (i) the licenses granted by Regeneron to Sanofi in Section 2.1 and the rights of reference granted by Regeneron to Sanofi in Section 6.2(a) may be freely sublicensed, or further rights of reference may be granted, by Sanofi or its Affiliates to Third Parties through one or multiple tiers and (ii) the licenses granted by Sanofi to Regeneron in Section 2.2 and the rights of reference granted by Sanofi to Regeneron in Section 6.2(b) and Section 6.2(c) may be freely sublicensed, or further rights of reference may be granted, by Regeneron or its Affiliates to Third Parties through one or multiple tiers.

(b) Subject to Section 2.3(c), either Party may, as such Party deems appropriate, delegate any of its obligations hereunder or subcontract the performance of all or part of such Party's activities with respect to the U.S. Praluent Product Business, in the case of Regeneron, or the ROW Praluent Product Business, in the case of Sanofi, in each case to its Affiliates or Third Parties.

(c) Sublicensing or subcontracting by either Party or its Affiliates (the "Grantee") of any Manufacturing rights granted by the other Party (the "Grantor") hereunder (or any agreement under which any Third Party will Manufacture Praluent Compound or Praluent Products on behalf of the Grantee) (i) shall require the Grantor's consent, not to be unreasonably withheld, conditioned or delayed and (ii) without limiting clause (i), shall [* * *]. Each Party acknowledges and agrees that it would be reasonable for the other Party to [* * *]. For the avoidance of doubt, [* * *].

(d) A sublicensing, subcontracting or delegating Party shall ensure that its sublicensees (including Sublicensees), subcontractors and delegatees are bound by terms and conditions that are consistent with the applicable terms and conditions of this Agreement, including the confidentiality and non-use obligations set forth in Article 13, and such terms and conditions must include, with respect to a Sublicensee of Sanofi or its Affiliate, an obligation of the Sublicensee to account for and report its sales of Praluent Products to Sanofi or such Affiliate on the same basis as if such sales were Net Sales by Sanofi or its Affiliate. For the avoidance of doubt, Regeneron shall be entitled to receive royalties under this Agreement based on Net Sales of Praluent Products sold by Sanofi's or its Affiliates' Sublicensees. Each Party shall notify the other Party within thirty (30) days of the grant of any sublicense or the appointment of any Sublicensee by such Party or its Affiliates or its or their Sublicensees pursuant to this Section 2.3. Each Party shall remain liable for any action or failure to act by its Affiliates, sublicensees (including Sublicensees), subcontractors or delegatees to whom such Party's rights and obligations under this Agreement have been delegated, subcontracted or sublicensed and which action or failure to act would constitute a breach of this Agreement if such action or failure to act were committed by such Party.

(e) For clarity, each Party may freely (sub)license any of its retained rights under Section 2.5 through one or multiple tiers.

2.4 Limitations.

(a) No Implied License. Except as expressly provided herein, neither Party will be deemed by this Agreement to have been granted any license or other rights in or to the other Party's Patents, Know-How, Party Information or the other Party's interest in the Joint Intellectual Property either expressly or by implication, estoppel or otherwise.

(b) No Sequencing or Reverse Engineering. Sanofi shall not, and shall ensure that its Affiliates and its and their Sublicensees do not, reverse engineer any cell lines, media or feeds or any other proprietary materials in the Regeneron Manufacturing Know-How, including Regeneron Cell Media, Praluent Working Cell Bank or Praluent Master Cell Bank.

2.5 Retained Rights.

(a) For the avoidance of doubt, Regeneron expressly reserves for itself and its Affiliates and its and their Third Party (sub)licensees under the Regeneron Core Intellectual Property, the Regeneron Background Intellectual Property and Regeneron's interest in the Joint Intellectual Property the right to (i) fulfill its Manufacturing obligations under the Praluent Supply Agreements and (ii) Develop and Commercialize any product that is owned or controlled by Regeneron or any of its Affiliates for use with Praluent Products in the Sanofi Territory. For the further avoidance of doubt, Regeneron retains all rights in Regeneron Core Intellectual Property, Regeneron Background Intellectual Property and Regeneron's interest in the Joint Intellectual Property not expressly licensed hereunder.

(b) For the avoidance of doubt, Sanofi expressly reserves for itself and its Affiliates and its and their Third Party (sub)licensees under the Sanofi Core Intellectual Property, the Sanofi Background Intellectual Property and Sanofi's interest in the Joint Intellectual Property the right to (i) fulfill its Manufacturing obligations under the Praluent Supply Agreements and (ii) Develop and Commercialize any product that is owned or controlled by Sanofi or any of its Affiliates for use with Praluent Products in the Regeneron Territory. For the further avoidance of doubt, Sanofi retains all rights in Sanofi Core Intellectual Property, Sanofi Background Intellectual Property and Sanofi's interest in the Joint Intellectual Property not expressly licensed hereunder.

2.6 Limited Asset Transfer.

(a) Sanofi shall, and shall cause its Affiliates to, and does hereby, assign to Regeneron all of its right, title and interest in and to, and transfer to Regeneron (or its designee), the Transferred U.S. Assets free and clear of any encumbrance, lien or claim of ownership of any Third Party. Without limiting the foregoing, the Parties shall commence the transfer of all Transferred U.S. Assets to Regeneron immediately after the Transition Date or such other time as may be specified in the schedules to the Praluent Transition Services Agreement or as the Parties may otherwise agree in writing with respect to certain Transferred U.S. Assets. For clarity, other than in respect of the Transferred Product Trademarks, this Agreement shall not vest in Regeneron ownership of, or result in any assignment or transfer by Sanofi or its Affiliates to Regeneron of, any rights, title or interest in and to any Patents, Know-How or other intellectual property rights owned or controlled by Sanofi or its Affiliates as of the Transition Date in respect of any Praluent Product, including the Sanofi Background Intellectual Property, Sanofi Core Intellectual Property and any interest of Sanofi in the Joint Intellectual Property, other than pursuant to the Sanofi license grants under Section 2.2 or the rights of reference granted by Sanofi under Section 6.2.

(b) Further Assurances. From time to time after the transfer of the Transferred U.S. Assets to Regeneron in accordance with Section 2.6(a), and for no further consideration except as otherwise provided in the Praluent Transition Services Agreement, Sanofi shall, and shall (i) cause its Affiliates and (ii) use commercially reasonable efforts to cause applicable Third Parties to, execute, acknowledge and deliver such assignments, transfers, consents, assumptions and other documents and instruments and take such other actions as may

reasonably be requested by Regeneron to more effectively assign, convey or transfer to or vest in Regeneron and its designee(s), all right, title and interest in and to the Transferred U.S. Assets.

(c) Maintenance of Transferred U.S. Assets Prior to Transfer.

(i) Except as may be required or prohibited by applicable Law or as may be required under any Ancillary Agreement, prior to the transfer of the applicable Transferred U.S. Asset to Regeneron, Sanofi shall, and shall cause its Affiliates and shall use commercially reasonable efforts to cause applicable Third Parties to:

(A) maintain each Transferred U.S. Asset until such time as such Transferred U.S. Asset is transferred to Regeneron pursuant to this Section 2.6, in each case, in substantially the same manner as maintained by or on behalf of Sanofi immediately prior to the Transition Date;

(B) not take or omit to take any action that would reasonably be expected to have a materially adverse effect on any Transferred Approvals or any Regulatory Filings in the Transferred Regulatory Documentation;

(C) not commence, compromise or settle any action, claim, action, suit, audit, assessment, arbitration or proceeding related to the Transferred U.S. Assets; and

(D) not enter into any agreements, make any commitments or make any offer (in writing or otherwise) to take any of the actions described in this Section 2.6(c), except as may be agreed to in writing by the Parties.

(ii) Notwithstanding anything to the contrary in Section 2.6(c)(i), Sanofi may, and may cause its Affiliates and applicable Third Parties to, take reasonable actions in compliance with applicable Laws or, to the extent consistent with Sanofi's actions in respect of its business generally, as necessary to respond to operational emergencies (including any measures in response to any Force Majeure event) or immediate and material threats to the health or safety of natural Persons or the overall economic stability of the businesses of Sanofi, its Affiliates or such applicable Third Parties, as the case may be, provided that such actions taken in respect of such emergencies, events or threats shall not relieve Sanofi of its obligations under Section 2.6(c)(i) for any longer time than is necessary in light of such emergencies, events or threats.

(d) Wrong Pockets. If either Regeneron or Sanofi becomes aware that (i) any of the Transferred U.S. Assets has not been transferred to Regeneron or (ii) any right, record or other asset owned by Sanofi or any of its Affiliates, including any contract, Trademark, Approval, Domain Name, physical inventory, or Regulatory Filing (for clarity, other than any Patents, Know-How or Copyrights) that (A) exclusively relates to the Existing Praluent Product in the Regeneron Territory, (B) is not contained in the Transferred U.S. Assets and (C) is not otherwise transferred hereunder or under any Ancillary Agreements, in each case ((i) and (ii)) it shall promptly notify the other Party in writing and the Parties shall, as soon as reasonably

practicable, take all actions reasonably necessary to ensure that such right, asset or record is assigned and transferred, with any reasonably necessary prior Third Party consent or approval, to Regeneron. Without limiting the foregoing, if either Regeneron or Sanofi becomes aware that any right, record or other asset owned or Controlled by Sanofi or any of its Affiliates that relates (but does not exclusively relate) to the Existing Praluent Product in the Regeneron Territory and has not otherwise been transferred or made available to Regeneron, it shall notify the other Party in writing and the Parties shall take all actions reasonably necessary to provide Regeneron with the benefit of such right, record or other asset to the extent necessary for the U.S. Praluent Product Business and Sanofi shall provide Regeneron a copy of such record, which may be redacted as necessary to remove information that does not relate to the Existing Praluent Product in the Regeneron Territory. Notwithstanding anything to the contrary in this Agreement, this Section 2.6(d) sets forth Regeneron's sole and exclusive remedy for Sanofi's inadvertent failure to identify or transfer any Transferred U.S. Asset to Regeneron under this Section 2.6.

2.7 Transition Costs. Except as expressly set forth in the Praluent Transition Services Agreement, each Party shall bear its own costs and expenses incurred in connection with its or its vendors' and collaborators' transition of activities (including any necessary termination of any agreement between such Party or any of its Affiliates and a Third Party relating to the Commercialization of the Praluent Products in the Regeneron Territory) and responsibilities pursuant to this Agreement and the schedules to the Praluent Transition Services Agreement.

2.8 Certain Contract Services. On the request of either Party, the Parties shall negotiate in good faith the terms of one or more commercial services agreements (each, a "Praluent Services Agreement") pursuant to which a Party may, to the extent provided for under this Agreement, perform certain services for the other Party with respect to the Praluent Products, including Regeneron providing the bioanalytical testing services contemplated in Section 4.7 or a Party conducting certain Other Existing Trials for the other Party. The Parties' FTE-based costs and Out-of-Pocket Costs in connection with any such services shall be [* * *].

ARTICLE 3
ALLIANCE MANAGEMENT AND JOINT PRALUENT COMMITTEE

3.1 Alliance Management. Each of the Parties shall appoint a single individual to act as a single point of contact between the Parties for matters requiring coordination under this Agreement (each, an "Alliance Manager") during the Royalty Term. The Alliance Managers: (a) will be the point of first referral in all matters of conflict resolution with respect to this Agreement; (b) will identify and bring issues and potential disputes to the attention of the Parties' in a timely manner; (c) will work together to manage and facilitate communication between the Parties under this Agreement; and (d) shall have such other responsibilities as the Parties may agree in writing. A Party may replace the individual serving as its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

3.2 Joint Praluent Committee. Within thirty (30) days after the Execution Date, the Parties shall establish a joint Praluent committee (the "Joint Praluent Committee" or "JPC"), which shall have the following responsibilities:

(a) overseeing the performance of the Global Clinical Trials and serving as a forum for the Parties to discuss matters with respect thereto;

(b) serving as a forum for the Parties to exchange and discuss Existing Trials Information;

(c) serving as a forum for the Parties to provide the clinical trial and Commercialization updates contemplated by Section 4.8 and Section 5.3, respectively; and

(d) performing such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

3.3 Composition; Meetings; Disbandment; Limitations on Authority.

(a) Composition. The JPC shall be comprised of three (3) representatives from each of Sanofi and Regeneron or such other number of representatives from each Party as the Parties may agree from time to time, provided that the Parties shall provide an equal number of representatives. A Party may change any of its representatives at any time by giving written notice to the other Party.

(b) Meetings. The JPC shall meet whenever any Alliance Manager shall make such a request in writing to the other Party; provided, however, that the JPC shall in no event meet less frequently than (i) once every [* * *] while any of the Global Clinical Trials is ongoing or (ii) thereafter, once per Calendar Year or with such other frequency as may be agreed by the Parties. Each Party shall be responsible for all of its own costs and expenses of participating in the JPC. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member of the JPC to attend meetings where appropriate (e.g., representatives of industrial affairs, regulatory affairs or outside consultants). The Alliance Managers shall (A) set meeting agendas, provided that the agenda shall include any matter reasonably requested by either Party, (B) call emergency meetings of the JPC at the request of a Party and (C) be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JPC meetings.

(c) Disbandment. Upon completion of all activities in connection with Global Clinical Trials, either Party shall have the right to request that the other Party consent to the disbandment of the JPC, such consent not to be unreasonably withheld, conditioned or delayed. Following disbandment of the JPC, any coordination activities or updates between the Parties will be supervised and handled through the Alliance Managers through appropriate written reports or other materials.

(d) Limitations on Authority. The JPC shall be a consultative body and shall not have any independent decision-making authority. Without limiting the generality of the foregoing, the JPC shall not have any authority to: (i) amend, modify, or waive compliance with this Agreement or any Ancillary Agreements, any of which shall require mutual written agreement of the Parties; (ii) interpret this Agreement or any Ancillary Agreement, or determine whether or not a Party has met its obligations under this Agreement or any Ancillary Agreement

or whether or not a breach of this Agreement or any Ancillary Agreement has occurred; or (iii) require either Party to pay, or otherwise expend resources on any Development, Manufacturing or Commercialization activities.

3.4 Cooperation Generally. As long as a Party, its Affiliates or its or their Sublicensees Develop, Manufacture or Commercialize the Praluent Compound or any Praluent Product, such Party shall cooperate in good faith and timely answer any reasonable request for information, or reasonable solicitation, by the other Party in connection with such first Party's Development, Manufacturing or Commercialization activities, either through or outside the Joint Praluent Committee, including after the disbandment thereof, to the extent that such request or solicitation reasonably relates to (a) if the requesting Party is Regeneron, the U.S. Praluent Product Business or (b) if the requesting Party is Sanofi, the ROW Praluent Product Business.

ARTICLE 4
DEVELOPMENT

4.1 Development of Praluent Products. Subject to the terms and conditions of this Agreement and the Praluent Transition Services Agreement and the Praluent Pharmacovigilance Transition Services Agreement, other than the Global Clinical Trials or as set forth for the Other Existing Trials on Schedule 4.3, each Party shall be solely responsible and have decision-making authority for all aspects of the Development of the Praluent Products undertaken in connection with (a) if such Party is Regeneron, the U.S. Praluent Product Business or (b) if such Party is Sanofi, the ROW Praluent Product Business, and shall bear all costs and expenses related thereto. Without limiting either Party's obligations under any Safety Data Exchange Agreement contemplated by Section 6.4 that is then in effect, and other than with respect to Global Clinical Trials pursuant to Section 4.2, neither Party shall have the obligation to pursue the Development of any Praluent Product in its Territory and may discontinue such Development at its sole discretion.

4.2 Global Clinical Trials.

(a) Schedule 4.2(a) lists the global clinical trials ongoing as of the Transition Date that the Parties shall jointly complete (the "Global Clinical Trials") in accordance with any applicable Global Development Plans (as defined under the LCA) in effect under the LCA immediately prior to the Transition Date. Each Party shall use commercially reasonable efforts to carry out the Development activities assigned to it under such Global Development Plans in connection with such Global Clinical Trials in a timely manner and conduct all such activities in compliance with applicable Laws, including Good Practices, and applicable protocols and budgets for such Global Clinical Trials as in effect as of immediately prior to the Transition Date. Amendments to any such Global Development Plan or Global Clinical Trial protocol or budget shall [* * *].

(b) The Parties agree to share Global Trial Costs incurred by or on behalf of either Party in connection with the Global Clinical Trials after the Transition Date on a [* * *] basis such that the owing Party will pay such amounts to the other Party so that, after such payment, each Party has incurred its share of the Global Trial Costs for the considered period. Within twenty (20) days following the end of each Calendar Quarter during which a Party incurs

any Global Trial Costs in connection with a Global Clinical Trial, such Party shall deliver to the other Party an estimate of such Global Trial Costs. Within thirty (30) days following the end of each Calendar Quarter during which a Party incurs any Global Trial Costs in connection with a Global Clinical Trial, such Party shall deliver to the other Party a report providing detail in respect of such Global Trial Costs sufficient to enable the other Party to verify the amount of such Global Trial Costs (a "Global Trial Cost Report").

(c) Based on the applicable Global Trial Cost Report, the Party having a credit over the other Party shall submit an invoice to such other Party for the total amount that such other Party is obligated, pursuant to Section 4.2(b), to pay to such Party in respect of the Global Trial Costs reflected in such Global Trial Cost Report, and such other Party shall pay such invoice no later than forty-five (45) days after receipt thereof. Each such payment shall be subject to the provisions of Section 8.7 through Section 8.12.

4.3 Other Existing Trials. Schedule 4.3 sets forth, for each Other Existing Trial that is active as of the Transition Date, (a) whether such Other Existing Trial shall be continued following the Transition Date or wound-down, (b) which Party shall have the right or responsibility to continue or wind-down, as applicable, such Other Existing Trial, (c) the allocation between the Parties of any costs and expenses with respect to the activities described in clause (b) and (d) whether sponsorship of such Other Existing Trial will be transferred from one Party to the other Party. Each Party shall conduct its activities, if any, with respect to each Other Existing Trial set forth in Schedule 4.3 in accordance with applicable Law and, in the case of any Other Existing Trial that is to be wound-down, with due regard for patient safety and the rights of any subjects that are participants in such Other Existing Trial. Except as otherwise set forth on Schedule 4.3 with respect to allocation of applicable costs and expenses, for any Other Existing Trial in respect of which a Party continues to perform activities on behalf of the other Party after the Transition Date, the terms and conditions set forth in Sections 4.2(b) and 4.2(c) shall apply *mutatis mutandis* to the reporting and payment of FTE-based costs by one Party to the other Party in respect of such Other Existing Trial. For any Other Existing Trial for which sponsorship is, as set forth in Schedule 4.3, to be transferred from one Party to the other Party, each Party shall, at its own cost and expense, reasonably cooperate with the other Party in order to effect such transfer, including to notify the relevant hospital authority that such sponsorship has changed.

4.4 Supply for Certain Investigator-Initiated Studies. Regeneron shall be responsible for the Manufacture and supply of Finished Clinical Product for use as clinical trial material in the Other Existing Trials listed on Schedule 4.4 consistent with the practices observed by Regeneron immediately prior to the Transition Date and in accordance with the terms and conditions applicable to the supply of such Finished Product prior to the Transition Date.

4.5 Development Records. Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner in accordance with its internal practices and standard operating procedures, complete and accurate Development records with respect to activities initiated under the LCA in respect of the Praluent Compound or the Praluent Products, including with respect to the Existing Trials; provided that neither Party shall be deemed to have breached its obligations under this Section 4.5 with respect to periods prior to the Transition Date to the extent that such obligations would not have applied to such Party under the LCA. Such records shall (a) include

sufficient detail to verify compliance with such Party's obligations under this Agreement or the LCA, as applicable, (b) be appropriate for patent and regulatory purposes, (c) be in compliance with applicable Law, (d) properly reflect all work done and results achieved in the performance of such Development activities and (e) in the case of such records as relate to a clinical trial, record only activities relating to such clinical trial and not include or be commingled with records of activities outside the scope of such clinical trial. Either Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such records maintained pursuant to this Section 4.5 to the extent that such review is consistent with the licenses and rights of reference granted to such Party under Section 2.1, Section 2.2 or Section 6.2, as applicable; provided, however, that such Party shall maintain such records so disclosed in confidence in accordance with Article 13. Without limiting the foregoing, upon a Party's reasonable request for the other Party to provide copies of any particular items within such records, such other Party shall provide such copies to such first Party to the extent that doing so is consistent with the licenses and rights of reference granted to such Party under Section 2.1, Section 2.2 or Section 6.2, as applicable; provided, however, that such Party shall maintain such copies so disclosed in confidence in accordance with Article 13. If either Party desires to no longer maintain any such records in such Party's custody, then such Party shall notify the other Party of such desire, and such other Party shall have thirty (30) days after receipt of such notice to take custody of any such records at such other Party's sole cost and expense. If such other Party does not take custody of such records within such thirty (30)-day period, then such first Party shall have the right to destroy such records.

4.6 Human Biological Materials. Promptly following the Transition Date, the Parties shall discuss in good faith procedures and allocation of Out-of-Pocket Costs for the storage, and provision by one Party to the other Party, of any biological materials of human origin in the custody of such first Party that were collected or otherwise obtained in connection with (a) any clinical activities with respect to any Praluent Product conducted under the LCA prior to the Transition Date or (b) any Existing Trials (whether prior to or on or after the Transition Date) ("Human Biological Materials"). Each Party shall, upon the other Party's reasonable request and to the extent not prohibited by any applicable informed consent form or Law, make available to the requesting Party a reasonable quantity (which shall be determined based on the Parties' needs with respect to such materials), of any Human Biological Materials in the custody of such Party. The Party making such a request to receive Human Biological Materials shall pay any and all Out-of-Pocket Costs to be incurred by the shipping Party or its Affiliates in connection with the shipment of the Human Biological Materials, based on a quote for such shipping services provided by the shipping Party to the requesting Party. Each Party agrees that it shall use the Human Biological Materials in compliance with applicable Law and any applicable informed consent form. If either Party desires to no longer maintain any Human Biological Materials in such Party's custody, then, subject to applicable Law and any applicable informed consent form, such Party shall notify the other Party of such desire, and such other Party shall have sixty (60) days after receipt of such notice, or such longer period agreed between the Parties, to notify such Party that such other Party desires to take custody of such Human Biological Materials. If such other Party provides such notice within such period, then the Parties shall, subject to applicable Law and any applicable informed consent form, cooperate in good faith to transfer such Human Biological Materials into such other Party's custody at such other Party's sole cost and expense. If such other Party does not provide such notice within such sixty (60) day period (or such longer period as may be agreed by the Parties), the first Party shall from and after the end of such period have the right, subject to applicable Law and any applicable informed consent form, to destroy such Human Biological Materials.

4.7 Bioanalytical Testing of Sanofi Samples. Notwithstanding anything to the contrary in this Agreement (including Section 4.1(b)), as between the Parties, [* * *].

4.8 Clinical Trial Updates and Notices. Each Party will, in connection with meetings of the JPC, provide updates on any Existing Trials and notice, to the extent not previously provided, of any clinical trials in respect of the Praluent Compound or Praluent Products expected to be initiated by it and its Affiliates during the following [* * *] period in the Territory. Each such update shall also contain information regarding (a) the status of Marketing Approvals of each Existing Praluent Product in the Territory and (b) the results of any Existing Trial not previously exchanged between the Parties.

ARTICLE 5
COMMERCIALIZATION

5.1 Commercialization of Praluent Products. Subject to the terms and conditions of this Agreement, each Party shall have the sole responsibility and decision-making authority with respect to the Commercialization of the Praluent Products in such Party's Territory, at such Party's sole cost and expense. For clarity, neither Party shall have an obligation to Commercialize any Praluent Product anywhere in the Territory and neither Party shall be obligated to participate in any joint or global Commercialization activities for any Praluent Product. Each Party shall retain the right to attend any medical congress or similar events in the other Party's Territory and nothing herein shall be construed to prohibit either Party from attending any such medical congress or similar event anywhere in the Territory.

5.2 Booking of Sales and Praluent Product Distribution. As of the Transition Date, subject to the Praluent Transition Services Agreement, (a) each Party, its Affiliates and its and their Sublicensees shall invoice and book, and appropriately record, all sales of Praluent Products in such Party's Territory and (b) each Party (or its Affiliate) shall also be responsible for (i) the distribution of Praluent Products in its Territory and for paying Medicaid (if applicable) and any and all other governmental rebates that are due and owing with respect to the Praluent Products distributed by or on behalf of such Party, its Affiliates or its or their Sublicensees in its Territory, (ii) handling all other rebates, returns or chargebacks of Praluent Product sold under this Agreement in its Territory and (iii) handling all aspects of ordering, processing, invoicing, collection, receivables and returns with respect to Praluent Product in its Territory.

5.3 Commercialization Updates. Each Party will, in connection with meetings of the JPC, provide updates on any Commercialization activities undertaken by or on behalf of such Party with respect to the Praluent Products in [* * *] since the preceding meeting (or, in the case of the first meeting of the JPC, since the Transition Date) that such Party reasonably determines could have a material impact on the other Party's Development or Commercialization of any Praluent Product or on any Marketing Approvals in such other Party's Territory. Without limiting the foregoing, if a Party plans to withdraw a Marketing Approval for a Praluent Product in the Regeneron Territory, in the case of Regeneron, or in [* * *], in the case of Sanofi, such Party shall provide prior written notice of such withdrawal to the other Party at least [* * *] days in advance of such withdrawal. For the avoidance of doubt, the updates and notices provided pursuant to this Section 5.3 are for informational purposes only and do not grant the receiving Party the right to comment on, approve or object to the update or notice

provided by the other Party. A Party's inadvertent failure to provide to the other Party any update or notice described in this Section 5.3 shall not be grounds for termination by such other Party.

5.4 Medical and Consumer Inquiries. Subject to the Praluent Transition Services Agreement or Praluent Pharmacovigilance Transition Services Agreement, and except to the extent related to Development responsibilities allocated to a Party pursuant to Article 4, each Party shall have sole responsibility for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Praluent Products in such Party's Territory. Subject to the Praluent Pharmacovigilance Transition Services Agreement or Praluent Transition Services Agreement, each Party shall refer to the other Party all such questions or inquiries that it receives about any Praluent Product pertaining to the other Party's Territory (other than with respect to the Development responsibilities allocated to such first Party pursuant to Article 4) or relating to Development responsibilities allocated to such other Party pursuant to Article 4.

5.5 Market Exclusivity Extensions. Each Party shall have the exclusive right but not the obligation to maintain, and, to the extent available, legally extend, the period of time during which, in any country in such Party's Territory, (a) such Party, or any of its Affiliates or its or their Sublicensees, has the exclusive legal right, whether by means of a Patent or through other rights granted by a Governmental Authority in such country, to Commercialize the Praluent Products in such country, and (b) no generic equivalent of any Praluent Product is marketed in such country.

5.6 Promotional Materials.

(a) Without limiting Section 2.1 or Section 2.2, each Party shall have the right to use any Promotional Materials in such Party's possession as of the Transition Date (or, in the case of Regeneron, that are transferred to Regeneron as part of the Transferred U.S. Assets) solely for the purpose of Commercializing the Praluent Products in such Party's Territory.

(b) Except with respect to any Transferred Promotional Materials, each Party shall be responsible, at its sole cost and expense, for preparing and producing Promotional Materials for use in its Territory and such Promotional Materials shall bear the corporate name and logo of the promoting Party only.

(c) For clarity, neither Party shall have any right or obligation to review Promotional Materials of the other Party and neither Party shall be entitled to reproduce, distribute, create derivative works based on (including translations thereof), publicly perform, publicly display or otherwise use any Promotional Materials, educational or training materials or other materials relating to the Commercialization of the Praluent Products that are created by or on behalf of the other Party after the Transition Date.

5.7 Market Access; Pricing Approvals; Re-Sale Price. Each Party shall be solely responsible for market access activities and shall be free to file for NDCs and Pricing Approvals and determine the price(s) at which Praluent Products shall be sold in such Party's Territory, subject to any NDCs, Pricing Approvals or other requirements imposed by any applicable Law.

5.8 Cross-Territory Sales. During the Royalty Term:

(a) Each Party undertakes and covenants, for itself, its Affiliates, (sub)licensees and distributors not to directly solicit, advertise, sell, distribute, consign for sale, or otherwise promote the Praluent Products outside its Territory.

(b) Each Party shall use commercially reasonable efforts to ensure that the quantities of Praluent Product sold in its Territory are not exported outside its Territory.

(c) Without limiting the generality of the foregoing, neither Party shall sell any quantity of Praluent Product to a distributor if it knows, or has reason to believe, that such distributor intends to export such Praluent Product into the other Party's Territory or otherwise intends to facilitate the use of such Praluent Product outside its Territory.

(d) In the event that Regeneron, its Affiliates or its or their Sublicensees [* * *]. For clarity, this Section 5.8(d) does not grant Regeneron, its Affiliates and its and their Sublicensees any license rights under the Sanofi Background Intellectual Property, the Sanofi Core Intellectual Property or Sanofi's interest in the Joint Intellectual Property in the Sanofi Territory beyond the license grants expressly set forth in Section 2.2. [* * *]. For clarity, this Section 5.8(d) does not grant Sanofi, its Affiliates and its and their Sublicensees any license rights under the Regeneron Background Intellectual Property, the Regeneron Core Intellectual Property or Regeneron's interest in the Joint Intellectual Property in the Regeneron Territory beyond the license grants expressly set forth in Section 2.1.

ARTICLE 6
REGULATORY AFFAIRS

6.1 Ownership of Approvals and Regulatory Filings. Except to the extent prohibited by applicable Law or as provided in any Praluent Supply Agreement, as between the Parties, each Party shall own all Approvals and Regulatory Filings with respect to its Manufacture, Development or Commercialization of Praluent Products (including the Praluent Compound) conducted in accordance with the terms and conditions of this Agreement (including the licenses and other rights granted to such Party).

6.2 Rights of Reference; Sanofi ROR Authorizations; DAI Design History File; Separate INDs.

(a) Sanofi and its Affiliates shall have, and Regeneron (on behalf of itself and its Affiliates) hereby grants to Sanofi and its Affiliates, the right to access and reference (with the right to grant further rights of reference pursuant to Section 2.3) all regulatory documentation (including all Regulatory Filings and Approvals) Controlled by Regeneron (or its Affiliates) that is related to any Existing Praluent Product for any Existing Indication solely as necessary to exercise Sanofi's rights under the license grants set forth in Section 2.1 or necessary or useful to obtain Approval for any of Sanofi's or its Affiliates' products for use in combination with any Existing Praluent Product. Promptly upon the request of Sanofi, Regeneron or its Affiliate shall, to the extent such request is consistent with the foregoing rights to access and reference, submit a letter of authorization to the applicable Regulatory Authority (and take such actions or make such other filings) in order to permit any such regulatory documentation (including all

Regulatory Filings and Approvals) to be incorporated by reference by Sanofi, its Affiliates or its or their Sublicensees in their Regulatory Filings.

(b) Regeneron and its Affiliates shall have, and Sanofi (on behalf of itself and its Affiliates) hereby grants to Regeneron and its Affiliates, the right to access and reference (with the right to grant further rights of reference pursuant to Section 2.3) all regulatory documentation (including all Regulatory Filings and Approvals) Controlled by Sanofi (or its Affiliates) that is related to any Existing Praluent Product for any Existing Indication solely as necessary to exercise Regeneron's rights under the license grants set forth in Section 2.2 or necessary or useful to obtain Approval for any of Regeneron's or its Affiliates' products for use in combination with any Existing Praluent Product. Promptly upon the request of Regeneron, Sanofi or its Affiliate shall, to the extent such request is consistent with the foregoing rights to access and reference, submit a letter of authorization to the applicable Regulatory Authority (and take such actions or make such other filings) in order to permit any such regulatory documentation (including all Regulatory Filings and Approvals) to be incorporated by reference by Regeneron, its Affiliates or its or their Sublicensees in their Regulatory Filings.

(c) Sanofi ROR Authorizations; DAI Design History File.

(i) With respect to each Sanofi ROR Authorization on which the BLA relies that is not partially assignable or transferable to Regeneron for use in connection with the U.S. Praluent Product Business (or entirely to the extent exclusively relating to the U.S. Praluent Product Business) without the consent of a Third Party, Sanofi shall use diligent efforts to facilitate Regeneron obtaining a corresponding right to access and reference directly from the applicable Third Party.

(ii) Without limiting Section 6.2(c)(i), if any Sanofi ROR Authorization that is necessary or useful for the Manufacture or use of [* * *]. Promptly upon the request of Regeneron, Sanofi or its Affiliate shall, to the extent such request is consistent with the foregoing rights to access and reference, submit a letter of authorization to the applicable Regulatory Authority (and take such actions or make such other filings) as necessary in order to permit any such regulatory documentation to be incorporated by reference by Regeneron, its Affiliates or its or their Sublicensees in their Regulatory Filings.

(iii) For the avoidance of doubt, nothing in this Section 6.2(c) shall be construed to require Sanofi to transfer to Regeneron [* * *].

(d) Subject to the rights of reference granted under this Section 6.2, each Party shall be solely responsible for obtaining and maintaining any IND or other Approval required for such Party to conduct any Development activities performed by such Party, including with respect to any Development activities permitted to be conducted in the other Party's Territory, it being understood, however, that Regeneron shall be responsible for maintaining the IND or any other Transferred Approvals required for either Party to conduct Development activities relating to or in connection with the Existing Trials.

6.3 Regulatory Activities.

(a) Subject to the remainder of this Section 6.3 and Section 13.3(c) and subject to the Praluent Transition Services Agreement and the Praluent Pharmacovigilance Transition Services Agreement, each Party shall be solely responsible for, and shall have sole decision-making authority with respect to, all regulatory strategy and actions, including preparing communications and filings with and submissions (including supplements and amendments thereto) to, and attending meetings with, the applicable Regulatory Authority(ies), in each case with respect to such Party's Development and Commercialization activities conducted in accordance with the terms and conditions of this Agreement (including the licenses and other rights granted to such Party), provided that Regeneron may not, until the [* * *] anniversary of the Transition Date, [* * *]. Each Party shall provide the other Party (i) copies of all material submissions with respect to any Praluent Product to the FDA, in respect of Regeneron's submissions, and the EMA or PMDA, in respect of Sanofi's submissions, in each case reasonably in advance of such Party's submission thereof and (ii) copies of all material correspondence with respect to any Praluent Product received from such Regulatory Authorities promptly following receipt of such correspondence. If a Party becomes aware that a copy of any such submission or correspondence has not been provided in accordance with the foregoing sentence, it shall promptly notify the other Party in writing and the applicable Party shall, as soon as reasonably practicable, provide such copy to the Party to whom such copy is owed. Notwithstanding anything to the contrary in this Agreement, the immediately preceding sentence sets forth each Party's sole and exclusive remedy for the other Party's inadvertent failure to provide such copies. With respect to any filing, correspondence or communications by a Party with a Regulatory Authority anywhere in the Territory, including submission of additional data regarding a Praluent Product, that would reasonably be expected to materially impact (i) if the other Party is Regeneron, the U.S. Praluent Product Business or (ii) if the other Party is Sanofi, the ROW Praluent Product Business, in either case ((i) or (ii)), the Parties shall cooperate in good faith to coordinate with each other to ensure consistent messaging with respect thereto.

(b) Subject to the remainder of this Section 6.3(b) and Section 13.3(c) and subject to any applicable Praluent Supply Agreement, each Party shall be solely responsible for, and shall have sole decision-making authority with respect to, all regulatory strategy and actions, including preparing communications and filings with and submissions (including supplements and amendments thereto) to, and attending meetings with, the applicable Regulatory Authority(ies) anywhere in the Territory, in each case, with respect to such Party's Manufacturing activities with respect to any Praluent Compound or Praluent Product. For purposes of this Section 6.3(b), "Manufacturing Party" shall mean, (i) Regeneron for so long as Regeneron is Manufacturing and supplying Formulated Drug Substance to Sanofi pursuant to the Praluent Substance Supply Agreement and (ii) Sanofi for so long as Sanofi is Manufacturing and supplying Finished Product to Regeneron pursuant to the Finished Product Supply Agreement. Notwithstanding the foregoing, with respect to each Manufacturing Party, for so long as such Manufacturing Party is a Manufacturing Party, the other Party (the "Non-Manufacturing Party") shall consult with the Manufacturing Party with respect to any portion of any Regulatory Filing, submission or other communication (including any response to a question from a Regulatory Authority) anywhere in the Territory by or on behalf of the Non-Manufacturing Party relating to the Manufacturing Party's Manufacture of, with respect to Regeneron as the Manufacturing Party, Formulated Drug Substance pursuant to the Praluent Substance Supply Agreement, and

with respect to Sanofi as the Manufacturing Party, Finished Product pursuant to the Finished Product Supply Agreement and shall provide a draft thereof to the Manufacturing Party (including an English translation if such draft is not in English) at least thirty (30) days (or, with respect to a submission or communication other than a Regulatory Filing, ten (10) days or such shorter period as may be required with respect to any question from a Regulatory Authority) prior to the date that such submission or communication is required to be made to the applicable Regulatory Authority for the Manufacturing Party's review and comment and shall consider in good faith any comments timely provided by the Manufacturing Party to the Non-Manufacturing Party in respect of such draft.

6.4 Pharmacovigilance and Safety Data Exchange. To ensure continuity in the exchange of necessary safety and pharmacovigilance information regarding the Praluent Products Developed and Commercialized under this Agreement and prompt communication of notifications and compliance with reporting obligations to Regulatory Authorities, the Parties have entered, on the Execution Date, into the Praluent Pharmacovigilance Transition Services Agreement and the new Safety Data Exchange Agreement in the form attached hereto as Exhibit 6.4 (the "Safety Data Exchange Agreement"). Subject to the terms and conditions of the Praluent Pharmacovigilance Transition Services Agreement, the Parties shall comply with their respective obligations and responsibilities assigned under the Safety Data Exchange Agreement.

6.5 Regulatory Inspection or Audit. Each Party shall cooperate with the other Party and any Regulatory Authority in the Territory during an inspection or audit to the extent relating to (a) any of the Existing Trials or (b) any other clinical Development under the LCA in respect of the Praluent Compound or the Praluent Products, in each case including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the receiving Party will immediately provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses that concern the Praluent Products, provided that the other Party shall have the right to review and comment on such responses, except to the extent such responses contain information for which the Party in receipt of the observation owes an obligation of confidentiality to a Third Party, and such Party shall consider in good faith the comments made by such other Party. In the event that the Parties disagree concerning the form or content of a response, the Party that received the observations shall decide the appropriate form and content of the response. Regulatory inspections and audits pertaining to either Party's Manufacturing facilities shall be governed by the Praluent Substance Supply Agreement or the Finished Product Supply Agreement, as applicable. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall, for so long as Manufacture under an applicable Praluent Supply Agreement is ongoing, notify the other Party within twenty-four (24) hours after receipt of notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities being used or proposed to be used for the Manufacture of Praluent Product by or on behalf of such Party for such other Party under such Praluent Supply Agreement.

6.6 Recalls and Other Corrective Actions.

(a) Notice. Each Party shall notify the other Party promptly (but in no event later than forty-eight (48) hours) following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of any Praluent Product in such Party's Territory that (i) would reasonably be expected to materially impact (A) if such other Party is Regeneron, the U.S. Praluent Product Business or (B) if such other Party is Sanofi, the ROW Praluent Product Business, (ii) relates to Praluent Product sold before the Transition Date or (iii) (A) if such other Party is Regeneron, is being implemented with respect to Formulated Drug Substance supplied by Regeneron to Sanofi under the Praluent Substance Supply Agreement or (B) if such other Party is Sanofi, is being implemented with respect to Finished Product supplied by Sanofi to Regeneron under the Finished Product Supply Agreement (any recall, market suspension or market withdrawal described in clauses (i), (ii) or (iii), a "Selected Recall"), and, in any case ((i), (ii) or (iii)), shall include in such notice the reasoning behind such determination and any supporting facts.

(b) Implementation. As between the Parties, a Party shall have the right to make the final determination whether to voluntarily implement, and shall have operational responsibility for implementation of, any recall, market suspension or market withdrawal of Praluent Product in its Territory; provided that operational responsibility for implementation of any recall, market suspension or market withdrawal of any Praluent Product in the Regeneron Territory bearing Sanofi's NDC shall be governed by the Praluent Transition Services Agreement or the Praluent Pharmacovigilance Transition Services Agreement; provided further that, prior to any implementation of a Selected Recall, such Party shall consult with the other Party and shall consider the other Party's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in a Party's Territory, as between the Parties, such Party shall have the right to make the final determination to implement such recall, market suspension or market withdrawal.

(c) Costs. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 6.6, (i) to the extent such recall, market suspension or market withdrawal is attributable to conduct occurring prior to the Transition Date, the Recall Costs of any recall, market suspension or market withdrawal will be shared in the same proportions as if such Recall Costs were Other Shared Expenses (as defined in the LCA) under the LCA as of immediately prior to the Transition Date and (ii) subject to any further allocation under any applicable Praluent Supply Agreement, to the extent such recall, market suspension or market withdrawal is attributable to conduct occurring after the Transition Date and to the extent not constituting Third Party Claims covered by Section 14.1, the Recall Costs of any recall, market suspension or market withdrawal will be borne [* * *]. The payment of such Recall Costs shall be subject to the provisions of Section 8.7 through Section 8.12, except to the extent addressed in the Praluent Transition Services Agreement or the Praluent Pharmacovigilance Transition Services Agreement, in which case it shall be subject to the applicable provisions thereof.

(d) Correspondence or Public Announcements. Notwithstanding the provisions of this Article 6 or Article 13, each Party shall provide the other Party with copies of any proposed correspondence with Regulatory Authorities or any proposed public announcement, in each case, related to any voluntary or mandated recall, market suspension or

market withdrawal of any Praluent Product in such Party's Territory for the other Party's review and comment prior to such Party making or disclosing any such correspondence or public announcement if such recall, market suspension or market withdrawal constitutes a Selected Recall. Without limiting the foregoing, each Party shall provide the other Party with copies of any correspondence sent to or received from Regulatory Authorities or any issued public announcement, in each case, related to any Selected Recall.

(e) Miscellaneous. Each Party shall consider any comments made by the other Party pursuant to this Section 6.6 in good faith. Notwithstanding anything herein to the contrary, in the event of any inconsistency between this Section 6.6 and the terms and conditions of any applicable quality agreement that is an exhibit to any Praluent Supply Agreement or the Safety Data Exchange Agreement, the terms of such quality agreement or Safety Data Exchange Agreement, as applicable, shall control.

ARTICLE 7
TECHNOLOGY TRANSFER - MANUFACTURING AND SUPPLY

7.1 Manufacturing Generally. Notwithstanding the terms and conditions of the Praluent Supply Agreements, it is the Parties' intention to transfer responsibility for the Manufacture of all forms of Praluent Products (and of the constituents thereof) to (a) Sanofi for all clinical and commercial requirements of Praluent Products with respect to Development and Commercialization activities of Sanofi, its Affiliates and its and their Sublicensees and (b) Regeneron for all clinical and commercial requirements of Praluent Products with respect to Development and Commercialization by Regeneron, its Affiliates and its and their Sublicensees, in each case ((a) and (b)) pursuant to the terms and conditions of this Agreement. The Parties shall cooperate diligently toward that goal in accordance with the terms and conditions of [* * *] the Drug Substance Tech Transfer Plan referred to in Section 7.3.

7.2 [* * *].

(a) [* * *]. Each Party shall appoint a technology transfer coordinator to serve as a single point of contact with respect to the Parties' activities [* * *]. No later than [* * *] prior to the date on which Regeneron desires to initiate the Finished Product technology transfer, Regeneron shall notify Sanofi in writing regarding Regeneron's choice of Manufacturing site or contract manufacturing organization for the Manufacture by or on behalf of Regeneron of Finished Product from Formulated Drug Substance ("Regeneron Manufacturing Site Notice"). Within [* * *] days following Sanofi's receipt of the Regeneron Manufacturing Site Notice, the Parties shall [* * *]. Each Party shall use commercially reasonable efforts to perform its activities [* * *] within the anticipated timelines, and Regeneron shall use commercially reasonable efforts to enable it to accept the Finished Product technology transfer, including obtaining and making available such information, personnel, products, materials, services, facilities and other resources as reasonably necessary to implement such technology transfer. Provided that Sanofi has complied with its obligations under this Section 7.2(a) [* * *], Sanofi shall not be liable to Regeneron for Regeneron's inability to Manufacture Finished Product from Formulated Drug Substance [* * *]. Except to the extent specifically set forth in [* * *], the Praluent Transition Services Agreement, the Praluent Pharmacovigilance Transition Services Agreement or this Section 7.2(a), Sanofi shall have no obligation to provide transition

or other support with respect to the transfer of Finished Product Manufacture (from Formulated Drug Substance) from Sanofi to Regeneron or its designee.

(b) [* * *], upon Regeneron's request, Sanofi shall use commercially reasonable efforts to facilitate an introduction and an initial discussion between Regeneron and any Third Party with which Sanofi or its Affiliate has a material Third Party supplier relationship that pertains to the Finished Product (including any delivery devices, e.g., an autoinjector).

7.3 Drug Substance Tech Transfer Plan.

(a) The Parties acknowledge that the activities necessary to enable Sanofi to Manufacture or have Manufactured Formulated Drug Substance have been substantially advanced by the Parties as of the Transition Date and, except for the activities set forth in the Drug Substance Tech Transfer Plan, Sanofi has received the Formulated Drug Substance technology transfer as of the Transition Date. Schedule 7.3(a) is the Manufacturing technology transfer plan setting forth a high-level summary of the Parties' remaining activities necessary for Sanofi to Manufacture or have Manufactured Formulated Drug Substance, as well as the anticipated starting date and timelines for the completion of such activities (the "Drug Substance Tech Transfer Plan"). Each Party shall appoint a technology transfer coordinator to serve as a single point of contact with respect to the Parties' activities under the Drug Substance Tech Transfer Plan. Each Party shall use commercially reasonable efforts to perform its activities under the Drug Substance Tech Transfer Plan within the anticipated timelines, and Sanofi shall use commercially reasonable efforts to enable it to accept the remainder of the Formulated Drug Substance technology transfer, including obtaining and making available such information, personnel, products, materials, services, facilities and other resources as reasonably necessary to implement such technology transfer. Provided that Regeneron has complied with its obligations under this Section 7.3(a) and the Drug Substance Tech Transfer Plan, Regeneron shall not be liable to Sanofi for Sanofi's inability to Manufacture Formulated Drug Substance following completion of the activities contemplated under the Drug Substance Tech Transfer Plan. Except to the extent specifically set forth in the Drug Substance Tech Transfer Plan, the Praluent Transition Services Agreement, the Praluent Pharmacovigilance Transition Services Agreement or this Section 7.3, Regeneron shall have no obligation to provide transition or other support with respect to the transfer of Formulated Drug Substance Manufacture to Sanofi.

(b) As part of the Drug Substance Tech Transfer Plan, upon Sanofi's request, Regeneron shall use commercially reasonable efforts to facilitate an introduction and an initial discussion between Sanofi and any Third Party with which Regeneron or its Affiliate has a material Third Party supplier relationship that pertains to the Formulated Drug Substance.

7.4 Technology Transfer Costs.

(a) Subject to Section 7.4(b), each Party shall bear all of its and its Affiliates' costs and expenses incurred in connection with its assigned activities under [* * *] the Drug Substance Tech Transfer Plan (each, a "Tech Transfer Plan" where each Party transferring the Manufacturing process under a Tech Transfer Plan shall be a "Transferor" and each Party implementing such Manufacturing process under a Tech Transfer Plan shall be a "Transferee").

(b) With respect to each Tech Transfer Plan, the Transferee shall, pursuant to Section 7.4(d), reimburse to the Transferor (i) [* * *] percent ([* * *]%) of the Transferor's Out-of-Pocket Costs incurred by the Transferor and its Affiliates in connection with the Transferor's assigned activities under such Tech Transfer Plan and (ii) (A) [* * *] percent ([* * *]%) of the Transferor's Tech Transfer FTE Costs incurred by the Transferor and its Affiliates in connection with the Transferor's assigned activities under such Tech Transfer Plan during [* * *] and (B) thereafter, [* * *] percent ([* * *]%) of the Transferor's Tech Transfer FTE Costs incurred by the Transferor and its Affiliates in connection with the Transferor's assigned activities under such Tech Transfer Plan.

(c) Within ten (10) days following the end of each Calendar Quarter during which the Transferor or any of its Affiliates incurs any Out-of-Pocket Costs or Tech Transfer FTE Costs in connection with a Tech Transfer Plan for which the Transferee has an obligation to reimburse the Transferor pursuant to Section 7.4(b), the Transferor shall deliver to the Transferee an estimate of such Out-of-Pocket Costs or Tech Transfer FTE Costs. Within thirty (30) days following the end of each Calendar Quarter during which the Transferor or any of its Affiliates incurs any Out-of-Pocket Costs or Tech Transfer FTE Costs in connection with a Tech Transfer Plan for which the Transferee has an obligation to reimburse the Transferor pursuant to Section 7.4(b), the Transferor shall deliver to the Transferee a report providing detail in respect of such Out-of-Pocket Costs or Tech Transfer FTE Costs sufficient to enable the Transferee to verify the amount of such Out-of-Pocket Costs or Tech Transfer FTE Costs (a "Technology Transfer Cost Report").

(d) Simultaneous with the delivery of a Technology Transfer Costs Report by the Transferor to the Transferee, the Transferor shall submit an invoice to the Transferee for the total amount that the Transferee is obligated, per Section 7.4(b), to reimburse to the Transferor in respect of the Out-of-Pocket Costs and Tech Transfer FTE Costs reflected in such Technology Transfer Costs Report, and the Transferee shall pay such invoice no later than forty-five (45) days after receipt thereof. Each such payment shall be subject to the provisions of Section 8.7 through Section 8.12.

(e) For the avoidance of doubt, any Out-of-Pocket Costs referred to in this Section 7.4 will be [* * *].

7.5 Praluent Supply Agreements. Simultaneously with the execution of this Agreement, the Parties (or their Affiliates) have entered into supply agreements, under which:

(a) Sanofi or its Affiliates shall procure Formulated Drug Substance from Regeneron or its Affiliates (the "Praluent Substance Supply Agreement"); and

(b) Subject to Section 4.4, Regeneron or its Affiliates shall procure Finished Product from Sanofi or its Affiliates (the "Finished Product Supply Agreement").

7.6 Back-up Supply. The Parties acknowledge that the Praluent Substance Supply Agreement will address the Parties' rights and obligations in respect of back-up supply of Formulated Drug Substance by Regeneron to Sanofi during the term of the Praluent Substance Supply Agreement.

If after the term of the Praluent Substance Supply Agreement, (a) Sanofi experiences [* * *], (b) Sanofi is [* * *] and (c) Regeneron is [* * *], then, upon Sanofi's reasonable request (which request shall include Sanofi's requested quantities of, and delivery dates for, Formulated Drug Substance manufactured [* * *], "Back-Up Request"), Regeneron shall consider Sanofi's Back-Up Request and within [* * *] Business Days of receiving such request, Regeneron shall [* * *], and (x) if Regeneron [* * *] and (y) if Regeneron [* * *].

7.7 Regeneron Cell Media.

(a) As long as Sanofi is complying with its obligations under Section 2.4(b) and Section 13.3(c), Regeneron hereby grants Sanofi the rights [* * *].

(b) Sanofi shall not, and shall cause its Affiliates not to, (i) use Regeneron Cell Media for any purpose other than to Manufacture the Formulated Drug Substance for purposes of Commercializing Praluent Products in the Sanofi Territory (including any Development in support of such Commercialization) or (ii) transfer Regeneron Cell Media to any Third Party other than a Third Party contract manufacturer approved by Regeneron pursuant to Section 2.3(c).

7.8 Cell Banks.

(a) The Parties acknowledge that the transfer of any vials of Praluent Master Cell Bank or Praluent Working Cell Bank from Regeneron to Sanofi will be carried out as and to the extent set forth in the Drug Substance Tech Transfer Plan and, notwithstanding anything herein to the contrary, at [* * *].

(b) Sanofi shall not, and shall cause its Affiliates not to, (i) use any Praluent Working Cell Bank or Praluent Master Cell Bank (or any component thereof) for any purpose other than to Manufacture the Formulated Drug Substance for purposes of Commercializing Praluent Products in the Sanofi Territory (including any Development in support of such Commercialization) or (ii) transfer any Praluent Working Cell Bank or Praluent Master Cell Bank to any Third Party other than a Third Party contract manufacturer approved by Regeneron pursuant to Section 2.3(c).

(c) If Regeneron desires to no longer maintain the Praluent Master Cell Bank, then Regeneron shall notify Sanofi of such desire, and Sanofi shall have thirty (30) days after receipt of such notice to take custody of the Praluent Master Cell Bank at its sole cost and expense. If Sanofi does not take custody of the Praluent Master Cell Bank within such thirty (30) day period, then Regeneron shall have the right to destroy it.

7.9 Manufacturing Transition Team.

(a) Formation and Responsibilities. Within thirty (30) days after the Execution Date, the Parties shall establish a Manufacturing transition team (the "Manufacturing Transition Team"), which shall have the following responsibilities: (i) overseeing forecasting, ordering and order fulfilment under the Praluent Supply Agreements and serving as a forum for

the Parties to discuss matters with respect thereto; (ii) overseeing the performance of the Tech Transfer Plans; and (iii) serving as a forum for the Parties to discuss other Manufacturing-related topics, such as and not limited to manufacturing changes or new product launches for Praluent Products.

(b) Composition; Meetings; Disbandment; Limitations on Authority.

(i) Composition. The Manufacturing Transition Team shall be comprised of such number of representatives from each Party as the Parties may agree from time to time, provided that the Parties shall provide an equal number of representatives. A Party may change any of its representatives at any time by giving written notice to the other Party.

(ii) Meetings. The Manufacturing Transition Team shall adopt such standing rules regarding its meetings (including regarding the frequency of such meetings) as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement.

(iii) Disbandment. Upon completion of all activities in connection with the Praluent Supply Agreements and the Tech Transfer Plans, either Party shall have the right to request that the other Party consent to the disbandment of the Manufacturing Transition Team, such consent not to be unreasonably withheld, conditioned or delayed. The Manufacturing Transition Team will in any case be disbanded on the [* * *] anniversary of the Transition Date.

(iv) Limitations on Authority. The Manufacturing Transition Team shall be a consultative body and shall not have any independent decision-making authority.

ARTICLE 8
PAYMENTS; BOOKS & RECORDS; AUDITS

8.1 Royalties to Regeneron.

(a) Royalties Generally. In consideration of the licenses granted by Regeneron to Sanofi pursuant to Article 2 of this Agreement, Sanofi shall pay to Regeneron a five percent (5%) royalty on Net Sales of the Praluent Royalty Products in the Sanofi Territory, paid on a Calendar Quarter basis.

Any payments made under this Agreement are exclusive of VAT, GST, sales and use tax, or similar tax, which shall be added thereon as applicable.

(b) Royalty Payment Term. The above royalties shall be payable from the Transition Date until the [* * *] anniversary of the Transition Date (the "Royalty Term"), irrespective of [* * *]. By way of illustration, [* * *].

(c) Royalty Deductions. During the Royalty Term, Sanofi shall have the right to deduct from any royalty payment made to Regeneron pursuant to Section 8.1(a) with respect to a country in the Sanofi Territory in any given Calendar Quarter [* * *] percent ([* * *]%) of

any payments in respect of the Praluent Compound that are owed by Sanofi [* * *]; provided, however, that the foregoing shall not apply to any payments owed by Sanofi [* * *] with respect to which Regeneron has already borne or reimbursed [* * *] percent ([* * *]%) under Section 14.1(c)(i)(B) of this Agreement. Subject to Section 14.1(c), Sanofi shall bear [* * *] percent ([* * *]%) of any other payment owed by Sanofi, its Affiliates or its or their Sublicensees [* * *] under any New Sanofi License, or any other license or settlement, entered into by Sanofi, its Affiliates or its or their Sublicensees in connection with their Development, Manufacture or Commercialization of any Praluent Royalty Product under this Agreement or otherwise.

(d) Royalty Floor. Notwithstanding Section 8.1(c), no reduction in, or deduction from royalties hereunder shall cause the royalty payable by Sanofi hereunder for a given Calendar Quarter for a given country to be less than [* * *] percent ([* * *]%) of the royalty payment that would otherwise be payable under Section 8.1(a) for such Calendar Quarter and such country absent such deductions, provided that if any portion of any such reductions or deductions are not, due to the operation of this Section 8.1(d), fully applied in any particular Calendar Quarter, such portion may be used in subsequent Calendar Quarters for such country until exhausted.

(e) Blended Royalty. Sanofi acknowledges that (a) the Regeneron Manufacturing Know-How and the Know-How included in the Regeneron Core Intellectual Property, Joint Intellectual Property and the Regeneron Background Intellectual Property licensed to Sanofi are proprietary and valuable and that without such Know-How, Sanofi would not be able to obtain and maintain Approvals with respect to the Praluent Royalty Products in the Sanofi Territory, (b) such Approvals may allow Sanofi to obtain and maintain regulatory exclusivity with respect to the Praluent Royalty Products in the Sanofi Territory, (c) access to such Know-How has provided Sanofi with a competitive advantage in the marketplace beyond the exclusivity afforded by the Patents licensed to Sanofi pursuant to Section 2.1 and (d) the royalty set forth in Section 8.1(a) is, in part, intended to compensate Regeneron for such competitive advantage. The Parties agree that the royalty rate set forth in Section 8.1(a) reflects an efficient and reasonable blended allocation of the value provided by Regeneron to Sanofi.

8.2 No Royalty to Sanofi. No royalties shall be payable by Regeneron to Sanofi on Net Sales of Praluent Royalty Product by Regeneron, its Affiliates and its and their Sublicensees in the Regeneron Territory. Regeneron shall bear one hundred percent (100%) of any payment owed by Regeneron, its Affiliates or its or their Sublicensees to Third Parties under any New Regeneron License, or any other license or settlement, entered into by Regeneron, its Affiliates or its or their Sublicensees in connection with any Development, Manufacture or Commercialization of any Praluent Royalty Product by Regeneron, its Affiliates or its or their Sublicensees that occurs on or after the Transition Date under this Agreement.

8.3 Reporting. During the Royalty Term, Sanofi shall prepare and deliver electronically to Regeneron the periodic reports specified below:

(a) Within [* * *] days following the end of each Calendar Quarter, Sanofi shall deliver to Regeneron a non-binding estimate of aggregate Net Sales for all Praluent Royalty Products for such Calendar Quarter; and

(b) Within [* * *] days following the end of each Calendar Quarter, Sanofi shall prepare and deliver to Regeneron a written report setting forth, on a country-by-country basis in the Sanofi Territory for such Calendar Quarter, (i) the Net Sales of each Praluent Royalty Product, (ii) royalties payable in respect of Praluent Royalty Product and (iii) where applicable, any royalty deductions in respect of Praluent Royalty Product under Section 8.1(c) (such report, a "Royalty Report").

Unless otherwise agreed by Regeneron, the financial data in the reports will include calculations in local currency and United States Dollars.

8.4 Royalty Payments. Following delivery of a Royalty Report for a particular Calendar Quarter, Regeneron shall submit an invoice to Sanofi for the amount of royalties thereunder as per the directions set forth in Schedule 8.4 and Sanofi shall pay all royalties due to Regeneron hereunder in respect of such Calendar Quarter no later than thirty (30) days after the receipt of Regeneron's invoice therefor.

8.5 Transferred Inventory. In consideration of the transfer by Sanofi to Regeneron of the Transferred Inventory, Regeneron shall pay to Sanofi the corresponding price(s) per unit set forth on Schedule 8.5 (the "Inventory Payment"). Simultaneous with the transfer by Sanofi to Regeneron of the Transferred Inventory pursuant to Section 2.6, Sanofi shall send Regeneron an invoice for the amount of the Inventory Payment, and Regeneron shall pay Sanofi the Inventory Payment no later than fifteen (15) days after receipt of such invoice. The payment of the Inventory Payment shall be subject to the provisions of Section 8.7 through Section 8.12.

8.6 Allocation of Sales Deduction Costs. Liability with respect to any Sales Deduction Costs (including, for clarity, with respect to any pre-Transition Date sales) incurred by either Party or any of its Affiliates after the Transition Date with respect to the Regeneron Territory shall be allocated between the Parties pursuant to the Praluent Transition Services Agreement. Sanofi shall be solely responsible for any Sales Deduction Costs (including, for clarity, with respect to any pre-Transition Date sales) incurred by Sanofi or any of its Affiliates after the Transition Date with respect to the Sanofi Territory; provided that Sanofi shall have the sole benefit of the provisions or reserves established by Sanofi with respect thereto under the LCA.

8.7 Reimbursement. For all amounts for which a Party (the "Owing Party") is obligated to reimburse or pay the other Party or its designated Affiliate (the "Owed Party") pursuant to this Agreement for which no specific provision is made hereunder for such payment, the Owed Party shall send to the Owing Party an invoice for such amount within [* * *] days after the Owed Party's determination that such amount is payable by the Owing Party, which invoice shall include a reference to the section of this Agreement under which the Owed Party is requesting reimbursement or payment and be accompanied by reasonable documentation of the incurrence or accrual of the costs to be reimbursed. Payment with respect to each such invoice shall be due within [* * *] days after receipt by the Owing Party thereof and shall be made in accordance with Section 8.8; provided, however, that if the Owing Party in good faith disputes any portion of any such invoice, it shall pay the undisputed portion and shall provide the Owed Party with written notice of the disputed portion and its reasons therefor, and the Owing Party shall not be obligated to pay such disputed portion unless and until such dispute is

resolved in favor of the Owed Party. The Parties shall use good faith efforts to resolve any such disputes promptly.

8.8 Payment Method and Currency. Payments under this Agreement shall be made by bank wire transfer in immediately available funds to a bank account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars (a) in respect of any payment by Regeneron, using the average of the daily buying and selling exchange rates for conversion of the applicable foreign currency into Dollars, using the spot rates (the "Mid Price Close" found on Bloomberg, or any other source as agreed to by the Parties) for each day of the period to which the payment relates, and (b) in respect of any payment by Sanofi, using the average of the Reuters mid-market spot rate snapshots at 3.30 pm Paris time for each day of the period to which the payment relates.

8.9 Late Payments. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to one (1) month London Inter-Bank Offering Rate (LIBOR) Dollars, as quoted on Bloomberg (or any other source agreed to by the Parties) effective for the date on which the payment was due, plus [* * *] percent ([* * *]%) (such sum being referred to as the "Default Interest Rate"). Notwithstanding the foregoing, if the London Inter-Bank Offering Rate ceases to be available, the Default Interest Rate shall be the Secured Overnight Financing Rate (SOFR), as quoted by the Federal Reserve Bank of New York (or a successor administrator) on the Federal Reserve Bank of New York's Website, plus [* * *] percent ([* * *]%).

8.10 Taxes.

(a) Each Party shall be responsible for any taxes imposed on or measured by net income or gross income (including branch profits), gross receipts, capital, ability or right to do business, property and franchise or similar taxes pursuant to applicable Law. Any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and timely paid to the appropriate tax authority; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence or other reasonable documentation of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.

(b) To the extent applicable and reasonably requested by Regeneron, Sanofi shall use commercially reasonable efforts to provide Regeneron with any documentation or other certifications required pursuant to Section 250(b) of the Code and any regulations or other guidance promulgated thereunder necessary for any payments made to Regeneron pursuant to

this Agreement to qualify as "foreign-derived deduction eligible income" within the meaning of Section 250(b)(4) of the Code. Regeneron shall reimburse Sanofi for all reasonable Out-of-Pocket Costs incurred by Sanofi in connection with providing such documentation or other certification to Regeneron.

8.11 Sanofi Records; Audits by Regeneron. Sanofi shall, and shall cause its Affiliates and its and their Sublicensees to, maintain complete and accurate books and records in accordance with applicable Accounting Standards in sufficient detail to permit Regeneron to confirm the actual number of FTEs allocated to activities for which reimbursement is sought from Regeneron and the accuracy of royalty payments and any other compensation or reimbursement payable under this Agreement for a period of two (2) years from the creation of individual records or any longer period required by applicable Law. Regeneron shall have the right (at its own cost), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as Regeneron shall request, not more than once during any consecutive twelve (12) month period, to have such books and records of Sanofi and its Affiliates and its and their Sublicensees for the preceding two (2) years available for review at a single location in France by an independent "Big Four" (or equivalent) accounting firm of its choosing under confidentiality and non-use obligations no less stringent than those set forth in Article 13, for the sole purpose of verifying the accuracy of all financial reports furnished, and payments made, by Sanofi pursuant to this Agreement; provided that no period may be subjected to audit by Regeneron more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found. Any such auditor shall not disclose any confidential information of Sanofi to Regeneron, except to the extent such disclosure is necessary to verify the accuracy of such reports or payments. The results of any such audit shall be delivered in writing to each Party and shall, absent manifest error, be final and binding upon the Parties. Any amounts shown by such audit to be owed but unpaid shall be paid within thirty (30) days from the auditor's report, plus interest at the Default Interest Rate from the original due date. Any amounts shown to have been overpaid may be credited by Sanofi against future payments to Regeneron hereunder. No payment to Regeneron shall be reduced by more than [* * *] percent ([* * *]%) as a result of such credit, and Sanofi may carry forward any unused credits to future Calendar Quarters. Regeneron shall bear the full cost of such audit unless such audit reveals a payment or reporting error of more than [* * *] percent ([* * *]%) or more during the applicable audit period, in which case Sanofi shall bear the full cost of such audit.

8.12 Regeneron Records; Audits by Sanofi. Regeneron shall, and shall cause its Affiliates and its and their Sublicensees to, maintain complete and accurate books and records in accordance with applicable Accounting Standards in sufficient detail to permit Sanofi to confirm the actual number of FTEs allocated to activities for which reimbursement is sought from Sanofi and the accuracy of Regeneron's calculations of any reimbursement payments owed by Sanofi hereunder, including pursuant to Section 7.4, or any other payments for which Sanofi is responsible under this Agreement (including in connection with Section 4.7), for a period of two (2) years from the creation of individual records or any longer period required by applicable Law. Sanofi shall have the right (at its own cost), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as Sanofi shall request, not more than once during any consecutive twelve (12) month period, to have such books and records of Regeneron and its Affiliates and its and their Sublicensees for the preceding two (2) years available for review at a single location in the United States by an independent

"Big Four" (or equivalent) accounting firm of its choosing under confidentiality and non-use obligations no less stringent than those set forth in Article 13, for the sole purpose of verifying the accuracy of such calculations; provided that no period may be subjected to audit by Sanofi more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found. Any such auditor shall not disclose any confidential information of Regeneron to Sanofi, except to the extent such disclosure is necessary to verify the accuracy of such calculations. The results of any such audit shall be delivered in writing to each Party and shall, absent manifest error, be final and binding upon the Parties. Any amounts shown by such audit to be owed by Sanofi but unpaid shall be paid within thirty (30) days from the auditor's report, plus interest at the Default Interest Rate from the original due date. Any amounts shown to have been overpaid by Sanofi may be credited by Sanofi against future payments to Regeneron hereunder. Sanofi shall bear the full cost of such audit unless such audit reveals a calculation error of [* * *] percent ([* * *]%) or more during the applicable audit period, in which case Regeneron shall bear the full cost of such audit.

ARTICLE 9
TRADEMARKS, COPYRIGHTS, CORPORATE LOGOS AND DOMAIN NAMES

9.1 Ownership. As between the Parties, (a) Regeneron shall own and retain all right, title and interest in and to (i) the Praluent Product Regeneron Copyrights, (ii) the Praluent Product U.S. Trademark(s), including the goodwill of the business in connection with which the Praluent Product U.S. Trademarks are used and that is symbolized by the Praluent Product U.S. Trademarks and (iii) the Praluent Product U.S. Domain Names and (b) Sanofi shall own and retain all right, title and interest in and to (i) the Praluent Product Sanofi Copyrights, (ii) the Praluent Product ROW Trademark(s), including the goodwill of the business in connection with which the Praluent Product ROW Trademark(s) are used and that is symbolized by the Praluent Product ROW Trademark(s) and (iii) the Praluent Product ROW Domain Names.

9.2 Prosecution, Maintenance, Enforcement, and Defense of Trademarks. Regeneron shall, at its sole cost and expense, have the sole right to register, prosecute, maintain, enforce and defend the Praluent Product U.S. Trademark(s) in the Regeneron Territory and the Praluent Product U.S. Domain Names. Sanofi shall, at its sole cost and expense, have the sole right to register, prosecute, maintain, enforce and defend the Praluent Product ROW Trademark(s) in the Sanofi Territory and the Praluent Product ROW Domain Names. With respect to the Transferred Product Trademarks or Transferred Product Domain Names, Sanofi shall provide to Regeneron all reasonable assistance requested by Regeneron in connection with any Third Party claim or suit asserted against any such Transferred Product Trademarks or Transferred Product Domain Names, at Regeneron's cost and expense, including allowing Regeneron access to Sanofi's personnel who may have possession of relevant information.

9.3 Use of Trademarks and Domain Names.

(a) Except as otherwise expressly provided in this Agreement, each Party, its Affiliates and its and their Sublicensees shall have no rights in or to the other Party's Praluent Product Trademarks or the goodwill pertaining thereto or to the other Party's Praluent Product Domain Names. Each Party agrees that at no time will it or any of its Affiliates or its or their

Sublicensees seek to register or register any Trademark in the other Party's Territory that is confusingly similar to, misleading or deceptive with respect to the Praluent brand name or take any action or do any act that endangers, damages, dilutes, destroys or similarly affects, in any material respect, the other Party's ownership rights in or to the Praluent brand name or the value of the goodwill pertaining thereto or attack, dispute or contest the validity of or ownership of such other Party in or to the Praluent brand name or any registrations or pending registration thereof. Each Party agrees that upon termination of the license granted to it under Section 2.1(d) or Section 2.2(d), as applicable, it will discontinue forthwith all use of the Praluent Product Trademarks of the other Party.

(b) Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, (i) conform to customary industry standards for the protection of, and comply with applicable Law with respect to the use of, the other Party's Praluent Product Trademarks and (ii) adhere to and maintain the highest quality standards of the other Party with respect to goods sold and services provided under the other Party's Praluent Product Trademarks in the applicable country of such other Party's Territory.

9.4 Use of Corporate Names and Logos.

(a) Subject to Section 2.1(e) or Section 2.2(e), as applicable, neither Party shall use the other Party's or the other Party's Affiliates' corporate names or logos on any product labels, package inserts, packaging, trade packaging, samples or Promotional Materials (including any website or social media content) related to any Praluent Product (including in congress booths or Promotional Materials used or distributed in connection with the applicable Praluent Product); provided, however, that such Party shall be permitted to identify the other Party (or its Affiliate) as the Manufacturer of Finished Product or Formulated Drug Substance, as applicable, in any such materials to the extent required under any applicable Law and for so long as the other Party or its Affiliate is supplying Finished Product or Formulated Drug Substance, as applicable, to such Party or its Affiliates under a Praluent Supply Agreement. Neither Party shall, and shall not permit its Affiliates or its or their Sublicensees or distributors to, with respect to its activities under this Agreement, take any action or do any act that endangers, damages, destroys or similarly affects, in any material respect, the other Party's or the other Party's Affiliates' corporate names or logos or the value of goodwill pertaining thereto.

(b) Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, (i) conform to customary industry standards for the protection of, and comply with applicable Law with respect to the use of, the other Party's corporate names and logos and (ii) adhere to and maintain the highest quality standards of the other Party with respect to goods sold and services provided under the other Party's corporate names or logos in the applicable country of such other Party's Territory.

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 Ownership of Intellectual Property.

(a) Subject to Section 10.1(b)(ii), each Party shall exclusively own all right, title and interest in and to any and all intellectual property (including Know-How, Patents and Copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement solely by or on behalf of such Party, its Affiliates or its or their Sublicensees (other than the other Party or its Affiliates) ("Sole Inventions"). Sole Inventions made solely by or on behalf of Sanofi, its Affiliates or its or their Sublicensees (other than Regeneron and its Affiliates) are referred to herein as "Sanofi Sole Inventions." Sole Inventions made solely by or on behalf of Regeneron, its Affiliates or its or their Sublicensees (other than Sanofi and its Affiliates) are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's intellectual property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's intellectual property, other than the license rights expressly granted hereunder.

(b) The Parties shall each own an equal, undivided interest in any and all intellectual property (including Know-How, Patents and Copyrights) discovered, invented, authored or otherwise created under or in connection with (i) this Agreement jointly by or on behalf of Sanofi, its Affiliates or its or their Sublicensees, on the one hand, and Regeneron, its Affiliates or its or their Sublicensees, on the other hand or (ii) any Existing Trials conducted by or on behalf of a Party or its Affiliates or its or their Sublicensees, including the Existing Trials Information ("Joint Inventions"). Each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their Sublicensees to so disclose, the conception, discovery, invention or reduction to practice of any Joint Invention.

(c) Notwithstanding the foregoing in Section 10.1(a) and Section 10.1(b), except with respect to intellectual property described in clause (ii) of the definition of Joint Inventions, (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of Copyright authorship shall be resolved in accordance with United States Copyright Laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and patentable inventions) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the Laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property vests in a Party, by operation of law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party shall, and hereby does, irrevocably assign, and shall cause its Affiliates and its and their Sublicensees to so assign, to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by the other Party.

(e) Subject to Section 2.1, Section 2.2, Section 2.3 and Section 11.1, as applicable, each Party's interest in the Joint Intellectual Property may be used, practiced, (sub)licensed and enforced, and any ownership rights therein transferred, in whole or in part, by

each Party without consent of the other Party, provided that each Party agrees not to transfer any of its ownership interest in any of the Joint Intellectual Property without securing the transferee's written agreement to be bound by the terms of this Section 10.1(e) and the other terms of this Agreement that relate to the Joint Intellectual Property; provided, further, that nothing in this Article 10 shall relieve a Party or its Affiliates of their obligations under Article 13. Except as otherwise provided in this Agreement with respect to the Praluent Royalty Products, neither Party shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, (sub)license, or other exploitation of such Party's interest in the Joint Intellectual Property.

10.2 Prosecution and Maintenance of Patents.

(a) Subject to Section 10.2(c), Regeneron shall control the preparation, filing, prosecution and maintenance of the Regeneron Core Patents, the Sanofi Core Patents and the Joint Patents, in each case, in the Regeneron Territory (the "Regeneron Managed Patents") [* * *], provided it shall confer with and keep Sanofi reasonably informed regarding the status of such activities.

(b) Subject to Section 10.2(c), Sanofi shall control the preparation, filing, prosecution and maintenance of the Regeneron Core Patents, the Sanofi Core Patents and the Joint Patents, in each case, in the Sanofi Territory (the "Sanofi Managed Patents"), [* * *], provided it shall confer with and keep Regeneron reasonably informed regarding the status of such activities.

(c) Promptly following the Transition Date, the Parties shall [* * *].

(d) Unless otherwise agreed by the Parties, all Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Patents and any extensions thereof shall be [* * *] borne by the Parties according to the cost allocation provided in Section 10.2(a) and Section 10.2(b).

(e) Each Party agrees to cooperate with the other Party with respect to the preparation, filing, prosecution and maintenance of the Regeneron Core Patents, Sanofi Core Patents and Joint Patents pursuant to this Section 10.2, including the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any such preparation, filing, prosecution or maintenance.

(f) Each Party shall reasonably cooperate with the other Party in order to make such transfers of responsibilities, documents, and information as are needed in order to effectuate the allocation of rights and responsibilities provided in this Section 10.2.

10.3 Interference, Opposition and Reissue.

(a) Each Party shall notify the other Party within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition, post-grant review, reissue, reexamination, or other similar proceedings relating to the Patents for which it controls filing, prosecution and maintenance in accordance with Section 10.2. The Parties shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Decisions on whether to initiate such a proceeding and the course of action in such proceeding, including settlement negotiations and terms and selection of counsel, will be made (i) with respect to Regeneron Managed Patents, by Regeneron and (ii) with respect to Sanofi Managed Patents, by Sanofi. For clarity, the provisions of this Section 10.3 (other than the first sentence of Section 10.3(a)) shall apply to any interference, opposition, post-grant review, reissue, reexamination, or other similar proceeding with respect to the Regeneron Core Patents, Sanofi Core Patents or Joint Patents, in each case, that was initiated prior to the Transition Date.

(b) Unless otherwise agreed by the Parties, all Out-of-Pocket Costs incurred in connection with any such interference, opposition, post-grant review, reissue, reexamination or other similar proceeding shall be shared as follows:

(i) If such proceeding relates to Regeneron Managed Patents – [* * *]; and

(ii) If such proceeding relates to Sanofi Managed Patents - [* * *].

(c) Each Party shall reasonably cooperate with the other Party in order to make such transfers of responsibilities, documents, and information as are needed in order to effectuate the allocation of rights and responsibilities provided in this Section 10.3.

10.4 Background Patents. For the avoidance of doubt, as between the Parties, (a) Regeneron has the sole right, but not the obligation, to prepare, file, prosecute and maintain, and defend against interference, opposition, post-grant review, reissue or reexamination proceedings in respect of, the Regeneron Background Patents at its cost and expense and (b) Sanofi has the sole right, but not the obligation, to prepare, file, prosecute and maintain, and defend against interference, opposition, post-grant review, reissue or reexamination proceedings in respect of, the Sanofi Background Patents at its cost and expense.

ARTICLE 11
PATENT LITIGATION

11.1 Enforcement of Patents.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual or suspected infringement or unauthorized use, as applicable, of a Sanofi Core Patent, a Regeneron Core Patent or a Joint Patent, in each case, by a Third Party's activities in the Territory (a "Patent Infringement"), the Party that became aware of the Patent Infringement shall notify the other Party in writing within five (5) Business Days and shall provide such other Party with all available evidence supporting such Patent Infringement. As soon as reasonably

practicable after the receipt of such notice, the Parties shall meet and consider the appropriate course of action with respect to such Patent Infringement.

(b) With respect to any Patent Infringement, (i) Regeneron shall have the first right (and, with respect to the Regeneron Core Patents in the Regeneron Territory, the sole right) to bring and control any action or proceeding (including, subject to Section 11.1(c), any settlement) with respect to Patent Infringement of any Regeneron Managed Patent at Regeneron's costs and expenses, and (ii) Sanofi shall have the first right (and, with respect to the Sanofi Core Patents in the Sanofi Territory, the sole right) to bring and control any action or proceeding (including, subject to Section 11.1(c), any settlement) with respect to Patent Infringement of any Sanofi Managed Patent at Sanofi's costs and expenses (the Party with the first right or the sole right being referred to as the "Lead Enforcement Party"); provided, however, that the Parties shall ensure that there is proper communication and coordination of activities between the Parties. If the Lead Enforcement Party has the first right (but not the sole right) and fails to bring any such action or proceeding with respect to Patent Infringement of the applicable Patent by a Third Party within sixty (60) days following notice of the alleged Patent Infringement (or such other period of time as may be required by applicable Law), the non-Lead Enforcement Party shall have the right to bring and control any such action at its own cost and expense by providing written notice to the other Party (the Party who controls the litigation to be referred to as the "Enforcing Party"). The non-Enforcing Party will provide reasonable assistance to the Enforcing Party in prosecuting any action, and if required by applicable Law, will join in the action at the Enforcing Party's cost and expense. Although the Enforcing Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The non-Enforcing Party shall have the right to join in any litigation using counsel of its choice at its sole discretion and cost and expense, subject to Section 11.1(c). The amount of any recovery from any such Patent Infringement action shall be [* * *].

(c) If the Enforcing Party is the Lead Enforcement Party, then, subject to Section 11.4(c), the Lead Enforcement Party has the right to settle any Patent Infringement suit [* * *]. If the Enforcing Party is not the Lead Enforcement Party, then the Enforcing Party [* * *].

(d) For the avoidance of doubt, as between the Parties, (i) Regeneron has the sole right, but not the obligation, to bring and control at its cost and expense any action or proceeding (including any settlement) with respect to any actual or suspected infringement or unauthorized use of a Regeneron Background Patent by a Third Party's activities in the Territory and (ii) Sanofi has the sole right, but not the obligation, to bring and control at its cost and expense any action or proceeding (including any settlement) with respect to any actual or suspected infringement or unauthorized use of a Sanofi Background Patent by a Third Party's activities in the Territory.

11.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which any Praluent Product is made, offered for sale, sold or imported by or on behalf of such Party, its Affiliates or its or their Sublicensees.

11.3 Third Party Infringement Claims.

(a) If either Party or its Affiliates or its or their Sublicensees becomes aware of a claim or assertion that the Manufacture, Development or Commercialization of any Praluent Product infringes or otherwise violates the intellectual property rights of any Third Party in such Party's Territory, such Party shall notify the other Party in writing of this claim or assertion within five (5) Business Days. As soon as reasonably practicable after the receipt of such notice, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement.

(b) Subject to Section 14.1(c), the Parties shall cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use commercially reasonable efforts to mutually agree upon an appropriate course of action, including, as appropriate, with respect to material court filings and the defense or settlement of any such claim or assertion; provided, however, that a Party (the "Controlling Party") shall have the first right to defend and control the defense of any claimed infringement action commenced by a Third Party naming it as a defendant alleging that the Manufacture, Development or Commercialization of any Praluent Product infringes or otherwise violates the intellectual property rights of such Third Party in the Controlling Party's Territory at its sole cost and expense, using counsel of its own choice even if the other Party is also named as a defendant, to the extent that such claimed infringement or violation solely relates to the Manufacture, Development or Commercialization of the Praluent Products in the Controlling Party's Territory and does not relate to the other Party's Territory or to the manufacture, development or commercialization of other products; provided further that, if the Controlling Party fails to initiate and maintain the defense of any such action that names the other Party as a defendant, then such other Party shall have the right to control the defense of such action at its own cost and expense by providing written notice to the Controlling Party.

(c) Subject to Section 14.1(c), unless otherwise agreed by the Parties, each Party shall bear [* * *] Out-of-Pocket Costs and internal costs (except for the costs and expenses of the non-Controlling Party's cooperation pursuant to Section 11.3(b), if only one Party defends a claim) incurred in connection with any litigation under this Section 11.3.

(d) For the avoidance of doubt, subject to Section 14.1(c), neither Party will enter into any settlement of any suit involving any Praluent Product that [* * *].

11.4 Invalidity or Unenforceability Defenses or Actions.

(a) In the event that a Third Party asserts, as a defense or as a counterclaim in any Patent Infringement action under Section 11.1 or in a declaratory judgment action or similar action or claim filed by such Third Party, that any Regeneron Core Patent, Sanofi Core Patent or Joint Patent is invalid or unenforceable (a "Third Party Invalidity Assertion"), then the Party first becoming aware of such Third Party Invalidity Assertion shall give written notice thereof to the other Party within five (5) Business Days.

(b) With respect to any Third Party Invalidity Assertion, (i) Regeneron shall, at its cost and expense, have the first right (and, with respect to the Regeneron Core Patents in the Regeneron Territory, the sole right) to control the defense of such Third Party Invalidity Assertion (including, subject to Section 11.4(c), any settlement thereof) to the extent that it relates to any Regeneron Managed Patent and (ii) Sanofi shall, at its cost and expense, have the first right (and, with respect to the Sanofi Core Patents in the Sanofi Territory, the sole right) to control the defense of such Third Party Invalidity Assertion (including, subject to Section 11.4(c), any settlement thereof) to the extent that it relates to any Sanofi Managed Patent (the Party with the first right or the sole right being referred to as the "Lead Defense Party"); provided, however, that the Parties shall ensure that there is proper communication and coordination of activities between the Parties. If the Lead Defense Party has the first right (but not the sole right) and fails to initiate and maintain the defense of a Third Party Invalidity Assertion, the non-Lead Defense Party shall have the right to control such defense at its own cost and expense by providing written notice to the other Party (the Party who controls the defense to be referred to as the "Defending Party"). The non-Defending Party will provide reasonable assistance to the Defending Party in the defense of any applicable Third Party Invalidity Assertion, and if required by applicable Law, will join in the applicable action at the Defending Party's cost and expense. Although the Defending Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The non-Defending Party shall have the right to join in any applicable action using counsel of its choice at its sole discretion and cost and expense, subject to Section 11.4(c).

(c) If the Defending Party is the Lead Defense Party, then the Lead Defense Party has the right to settle any Third Party Invalidity Assertion action [* * *]. If the Defending Party is not the Lead Defense Party, then the Defending Party [* * *].

(d) For the avoidance of doubt, as between the Parties, (i) Regeneron has the sole right, but not the obligation, to control the defense (including any settlement thereof) of any assertion by a Third Party (whether as a defense or as a counterclaim in any infringement action or in a declaratory judgment action or similar action or claim filed by such Third Party) that any Regeneron Background Patent is invalid or unenforceable and (ii) Sanofi has the sole right, but not the obligation, to control the defense (including any settlement thereof) of any assertion by a Third Party (whether as a defense or as a counterclaim in any infringement action or in a declaratory judgment action or similar action or claim filed by such Third Party) that any Sanofi Background Patent is invalid or unenforceable.

11.5 Interference, Opposition and Reissue of Third Party Patents.

(a) With respect to each interference, opposition, post-grant review, reissue or reexamination proceeding that is set forth on Schedule 11.5(a) (the "Existing Sole Oppositions"), the Party designated as the "Acting Party" on Schedule 11.5(a) for such Existing Sole Opposition (the "Acting Party") shall consult and cooperate fully with the other Party (the "Directing Party") to determine a course of action with respect to any such proceeding [* * *]. Unless otherwise agreed by the Parties, Out-of-Pocket Costs incurred by the Acting Party after the Transition Date in connection with any Existing Sole Opposition shall be borne [* * *].

(b) With respect to each interference, opposition, post-grant review, reissue or reexamination proceeding that is set forth on Schedule 11.5(b) (each, an "Existing European Opposition"), the Party designated as the "Opposing Party" on Schedule 11.5(b) (the "Opposing Party") shall have the sole right and responsibility, [* * *], to carry out such course of action as the Opposing Party may determine in its sole discretion in respect of such Existing European Opposition, including settlement negotiations and terms.

(c) If either Party or one of its Affiliates or its or their Sublicensees desires to initiate any interference, opposition, post-grant review, reissue or reexamination proceeding relating to a Patent of a Third Party in furtherance of Developing, Manufacturing or Commercializing a Praluent Product in the Territory on or after the Transition Date, then such Party shall notify the other Party in writing of such desire. As soon as reasonably practicable after the receipt of such notice, the Parties shall meet and consider the appropriate course of action with respect to such proposed interference, opposition, post-grant review, reissue or reexamination proceeding.

(d) Except as otherwise provided in this Section 11.5, each Party is responsible for any and all activities in respect of any interference, opposition, post-grant review, reissue or reexamination proceedings relating to a Patent of a Third Party in furtherance of Developing, Manufacturing or Commercializing a Praluent Product in such Party's Territory.

11.6 Transfer of Responsibilities. Each Party shall reasonably cooperate with the other Party in order to make such transfers of responsibilities, documents, and information as are needed in order to effectuate the allocation of rights and responsibilities provided in this Article 11

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Due Organization, Valid Existence and Due Authorization. Each Party represents and warrants to the other Party, as of each of the Execution Date and the Transition Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any encumbrances nor any other material agreement or arrangement, whether written or oral, by which it is bound nor any requirement of applicable Laws; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting the licenses and other rights granted to the other Party hereunder; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.

12.2 Additional Representations and Warranties of the Parties.

(a) Regeneron Representations and Warranties. Regeneron represents that, as of each of the Execution Date and the Transition Date, Regeneron (i) owns or Controls all of the

Patents listed on Schedule 1.135 and has the right to grant the licenses or sublicenses, as the case may be, granted under such Patents under this Agreement and (ii) Regeneron does not own or Control any Regeneron Core Patents existing as of the Transition Date, other than the Patents listed on Schedule 1.135.

(b) Sanofi Representations and Warranties.

(i) Sanofi represents that, as of each of the Execution Date and the Transition Date:

(A) Sanofi owns or Controls all of the Patents listed on Schedule 1.156 and has the right to grant the licenses or sublicenses, as the case may be, granted under such Patents under this Agreement.

(B) Sanofi does not own or Control any Sanofi Core Patents existing as of the Transition Date, other than the Patents listed on Schedule 1.156.

(C) Sanofi has, or its Affiliates have, good title to the entire legal ownership interest of or in, or valid contract rights in or right to transfer, as applicable, the Transferred U.S. Assets.

(D) The Transferred Approvals are in full force and effect.

(ii) Sanofi represents that, as of the Execution Date:

(A) No opposition, cancellation or court proceeding is pending, or to Sanofi's knowledge, threatened in writing; no opposition, cancellation or court proceeding regarding the Transferred Product Trademarks has been settled; and Sanofi has not entered into any co-existence agreements, prior rights agreements, covenants not to sue or settlement or other similar agreements regarding the Transferred Product Trademarks.

(B) No written notice of default or termination has been received or given by Sanofi or any of its Affiliates under any U.S.-Related Praluent Agreement.

(C) No proceeding is pending or, to Sanofi's knowledge, threatened in writing regarding the revocation or termination of any Transferred Approval.

(D) Neither Sanofi nor any of its Affiliate(s) have given or received written notice to or from any Person relating to any alleged breach or default under any Transferred Product Contracts.

(E) Each of the Transferred Product Contracts represents a legal, valid and binding obligation of Sanofi or the Sanofi Affiliate(s) that are party thereto and is enforceable against Sanofi or such Affiliate(s), in accordance with its terms, and is in full force and effect, subject to (A) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of

creditors' rights generally and (B) general equitable principles (whether considered in a proceeding in equity or at Law).

(c) Knowledge of Pending or Threatened Litigation or Adverse Agreements. Except as set forth on Schedule 12.2(c), each Party represents and warrants to the other Party that, as of the Transition Date, there is (i) no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party or any of its Affiliates before or by any governmental entity or arbitrator and (ii) to such Party's knowledge, no agreement entered into by such Party or its Affiliates that, in each case ((i) and (ii)), individually or in the aggregate, could reasonably be expected to (A) materially impair the ability of such Party to perform any of its obligations under this Agreement, (B) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby or (C) have a materially adverse effect on (1) if such other Party is Regeneron, the U.S. Praluent Product Business or (2) if such other Party is Sanofi, the ROW Praluent Product Business.

12.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRALUENT PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

12.4 Mutual Covenants. Each Party hereby covenants to the other Party as of the Transition Date as follows: (a) it will not grant any right or license to any Third Party in the Territory that would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would reasonably be expected to materially conflict with, or have a materially adverse effect on, its obligations to the other Party under this Agreement and (b) in the course of the conduct of any Existing Trial, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE 13
CONFIDENTIALITY

13.1 Confidential Information. Each of Sanofi and Regeneron acknowledges that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement or the LCA, as applicable, is confidential and proprietary to such other Party or its respective Affiliates. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article 13) that all Joint Information is confidential and proprietary to both Parties (and both Parties shall be deemed to be the receiving Party with respect thereto). Subject to the further provisions of this Article 13, each of Sanofi and Regeneron agrees to, (a) maintain the Party Information of the other Party and all Joint Information in confidence until ten (10) years after such other Party and its Affiliates and its and their Sublicensees have

permanently ceased Development and Commercialization of all Praluent Products, provided that (i) Sanofi shall maintain in confidence any Regeneron Manufacturing Know-How that Regeneron maintains as a trade secret for so long as Regeneron continues to maintain the same as a trade secret and (ii) Regeneron shall maintain in confidence any Sanofi Manufacturing Know-How that Sanofi maintains as a trade secret for so long as Sanofi continues to maintain the same as a trade secret and (b) use such Party Information and Joint Information solely for the purpose of exercising its rights and performing its obligations under this Agreement, provided that nothing herein will prohibit either Party from using any Know-How included in clause (a) of the definition of Existing Joint Know-How or clause (a) of the definition of Party Information, in either case, solely to the extent necessary or useful for the development or commercialization of such Licensed Products (as defined in the LCA) pursuant to the LCA, as if such Know-How were Party Information or New Information (each as defined in the LCA), as applicable, under the LCA, only to the extent such use is necessary or useful for such development or commercialization of such Licensed Products. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any Party Information of the other Party or Joint Information to any Third Party except (i) to its employees, agents, consultants or any other Person under its authorization (e.g., collaborators, (sub)licensees or vendors); provided such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (ii) as approved by both Parties hereunder or (iii) as set forth elsewhere in this Agreement. Without limiting the foregoing, Sanofi shall limit access to Regeneron Manufacturing Know-How to only those of Sanofi's employees, agents, consultants or other Persons under its authorization that have a need for such access in order to enable Sanofi to exercise its rights or perform its obligations under this Agreement or any Ancillary Services Agreement.

13.2 Exclusions. Notwithstanding anything provided above, the confidentiality and non-use restrictions provided in this Article 13 shall not apply to Party Information or Joint Information that was or is (and such information shall not be considered confidential or proprietary under this Agreement):

(a) already in the public domain as of the Transition Date or becomes publicly known through no act, omission or fault of the receiving Party or any of its Affiliates or any Person to whom the receiving Party or its Affiliate provided such information;

(b) already in the possession of the receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party; provided, however, that this exception shall not apply with respect to Joint Information;

(c) disclosed to the receiving Party or any of its Affiliates on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any of its Affiliates with respect to such information; or

(d) similar in nature to the Party Information of the other Party or Joint Information but has been independently created outside of this Agreement, as evidenced by written or electronic documentation, without any aid, application or use of such Party Information or Joint Information.

13.3 Permitted Disclosures and Uses.

(a) Each Party may use or disclose Party Information of the other Party and Joint Information to the extent that such use or disclosure is:

(i) necessary to file, prosecute, enforce or defend Patents for which the disclosing Party has the right to assume filing, prosecution, enforcement, defense or maintenance pursuant to this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law;

(ii) subject to Section 13.3(c), required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the receiving Party's (or its parent entity's) securities are traded) or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, and provided further that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information that is required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the receiving Party's (or its parent entity's) securities are traded) or court order to be disclosed;

(iii) to enforce the terms of this Agreement or any Ancillary Agreement if the disclosing Party gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information; or

(iv) to the Regulatory Authorities as required in connection with such Party's regulatory interactions with respect to such Party's Manufacturing, Development or Commercialization activities conducted in accordance with the terms and conditions of this Agreement (including the licenses and other rights granted to such Party); provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law.

(b) Notwithstanding anything else in this Agreement to the contrary, each Party (and each employee, representative, or other agent of such Party) may disclose to any and all Persons without limitation of any kind, the Federal income tax treatment and Federal income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to either Party (or to any employee, representative, or other agent of either Party) relating to such tax treatment or tax structure, provided, however, that this authorization of disclosure shall not apply to disclosures reasonably necessary to comply with applicable securities Laws, which disclosures shall be governed by Section 13.3(a)(ii).

(c) Notwithstanding anything else in this Agreement to the contrary, if either Party or any of its Affiliates receives a request for any Regeneron Manufacturing Know-How, if

such Party is Sanofi, or Sanofi Manufacturing Know-How, if such Party is Regeneron, from any Governmental Authority under any freedom of information Law, including the United States Freedom of Information Act or the State Council Regulations on Open Government Information, then such Party shall (i) notify the other Party of such request within one (1) Business Day, (ii) permit such other Party or any of its Affiliates to oppose such request or to seek other limitations on such request, in each case, to the extent consistent with the applicable Law and (iii) provide such other Party with reasonable assistance in opposing such request or seeking such limitations. Each Party shall not, and shall cause its Affiliates not to, disclose any Regeneron Manufacturing Know-How, if such Party is Sanofi, or Sanofi Manufacturing Know-How, if such Party is Regeneron, to any Governmental Authority in response to a request under any freedom of information Law without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed; provided that such other Party acknowledges and agrees that it would be unreasonable for it to not consent to any disclosure if such lack of disclosure would cause such Party or any of its Affiliates to violate applicable Law.

13.4 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties under this Article 13 are special, unique and of extraordinary character, and that if either Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Article 13, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if either Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Article 13, then, in addition to any other remedy that may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages or inadequacy of monetary damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

13.5 Publication. If either Sanofi or Regeneron (the "Publishing Party") desires to disclose any clinical trial results in respect of any Existing Trials in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall, unless the other Party and its Affiliates and its and their Sublicensees have permanently ceased Development and Commercialization of all Praluent Products, provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to such Development results no later than ten (10) Business Days prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to review and comment on such disclosure or publication and the Publishing Party shall (a) remove any Party Information of the other Party or Joint Information (other than such clinical trial results) that such other Party requests be removed, (b) consider any other comments from the other Party in good faith and (c) if requested by the other Party, shall delay or prevent such disclosure or publication as reasonably proposed by such other Party. In the event of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a Patent application(s) or application(s) for a certificate of invention on the information involved. For clarity, neither Party may disclose the Party Information of the other Party or the Joint Information (other than such clinical trial results) in scientific journals, publications or scientific presentations or other similar disclosures without such other Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

13.6 Other Publications. In the event that Sanofi or Regeneron desires to issue any press releases or public announcements concerning this Agreement or any Ancillary Agreement or any other activities contemplated hereunder or thereunder, including restructuring of the LCA in connection with this Agreement, in each case, to the extent not otherwise addressed in Section 13.5, except as prohibited by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which the issuing Party's (or its parent entity's) securities are traded), such Party agrees, unless the other Party and its Affiliates and its and their Sublicensees have permanently ceased Development and Commercialization of all Praluent Products, to provide to the other Party a copy of any such public announcement, as soon as reasonably practicable (which, except under extraordinary circumstances, shall be at least five (5) Business Days) prior to its scheduled release; provided, however, that, without prior submission to the other Party, either Party may issue press releases or public announcements that incorporate information concerning this Agreement or any Ancillary Agreement or any activities contemplated hereunder or thereunder that was included in a press release or public announcement that was previously approved by the other Party as part of a press release or other public disclosure concerning this Agreement or that contains only non-material factual (non-financial) information regarding this Agreement (e.g., that this Agreement remains in effect). Except as otherwise required by applicable Law, the Party whose press release has been reviewed shall remove any Party Information of the reviewing Party that the reviewing Party requests be removed. Except as required by applicable Law (including the rules and regulations of any stock exchange or trading market on which the issuing Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or its Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Agreement, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse at least equivalent in scope to those included herein with a term of at least five (5) years. Each Party acknowledges that the other Party, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential information, including trade secrets, in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of this Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE 14
INDEMNITY

14.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, (sub)licensees, distributors and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and experts' fees and costs and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a

Third Party's claim, action, suit, judgment or settlement (a "Third Party Claim") against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Sanofi or its Affiliates (or its or their respective agents, contractors, Sublicensees, distributors, representatives or other Persons or entities working on their behalf) in connection with their Development, Commercialization, or Manufacture of any Praluent Product from and after the Transition Date, excluding any actions or omissions by or on behalf of Sanofi for Regeneron in connection with any Ancillary Services Agreement;

(ii) the material breach by Sanofi, any of its Affiliates or its or their Sublicensees of its obligations, covenants or representations and warranties under this Agreement (other than any breach of an obligation, covenant, representation or warranty under any Ancillary Services Agreement);

(iii) the exploitation of any Praluent Product by Sanofi and its Affiliates (or its or their respective agents, contractors (including by or on behalf of Regeneron for Sanofi in connection with any Ancillary Services Agreement), Sublicensees, distributors, representatives or other Persons or entities working on their behalf) from and after the Transition Date and any actions or omissions in connection therewith, excluding any Special Claim or any actions or omissions by or on behalf of Sanofi for Regeneron in connection with any Ancillary Services Agreement; or

(iv) any U.S.-Related Praluent Agreement, except to the extent that the applicable Third Party Claim is due to or based upon any change in the terms of such U.S.-Related Praluent Agreement implemented by Sanofi or any of its Affiliates at Regeneron's direction under the Praluent Transition Services Agreement; provided, however, that Regeneron shall be liable for payments or reimbursement of rebates, fees, chargebacks and other payments to be made pursuant to such U.S.-Related Praluent Agreements in respect of sales of Praluent Products made after the Transition Date subject to and in accordance with the Praluent Transition Services Agreement;

except, in each case ((i), (ii), (iii) and (iv)), to the extent that Damages arise out of (A) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or its Affiliates (or its or their respective agents, contractors, Sublicensees, distributors, representatives or other Persons or entities working on their behalf in connection with this Agreement) or (B) the material breach by Regeneron or its Affiliates or its or their Sublicensees of its obligations, covenants or representations and warranties under this Agreement, the Praluent Transition Services Agreement, the Praluent Pharmacovigilance Transition Services Agreement or any Praluent Services Agreement.

For clarity, Sanofi's liability, other than with respect to Special Claims, for any Damages arising from or occurring as a result of a Third Party Claim against a Regeneron Indemnitee that is due to or based upon (x) any actions or omissions by or on behalf of Sanofi for Regeneron in connection with any Ancillary Services Agreement or (y) any breach by Sanofi, any of its Affiliates or its or their Sublicensees of its obligations, covenants or representations and

warranties under any Ancillary Services Agreement, in each case ((x) and (y)), shall be governed by the applicable Ancillary Services Agreement.

(b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and its and their respective officers, directors, employees, Sublicensees, distributors and agents ("Sanofi Indemnitees") from and against all Damages arising from a Third Party Claim against a Sanofi Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Regeneron or its Affiliates (or its or their respective agents, contractors, Sublicensees, distributors, representatives or other Persons or entities working on their behalf), in connection with their Development, Commercialization, or Manufacture of any Praluent Product from and after the Transition Date, excluding any actions or omissions by or on behalf of Regeneron for Sanofi in connection with any Ancillary Services Agreement;

(ii) the material breach by Regeneron, any of its Affiliates or its or their Sublicensees, of its obligations, covenants or representations and warranties under this Agreement (other than any breach of an obligation, covenant, representation or warranty under any Ancillary Services Agreement); or

(iii) the exploitation of any Praluent Product by Regeneron and its Affiliates (or its or their respective agents, contractors (including by or on behalf of Sanofi for Regeneron in connection with any Ancillary Services Agreement), Sublicensees, distributors, representatives or other Persons or entities working on their behalf) from and after the Transition Date and any actions or omissions in connection therewith, excluding any Special Claim or any actions or omissions by or on behalf of Regeneron for Sanofi in connection with any Ancillary Services Agreement;

except, in each case ((i), (ii) and (iii)), to the extent that Damages arise out of (A) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Sanofi or its Affiliates (or its or their respective agents, contractors, Sublicensees, distributors, representatives or other Persons or entities working on their behalf in connection with this Agreement) or (B) the material breach by Sanofi or its Affiliates or its or their Sublicensees of its obligations, covenants or representations and warranties under this Agreement, the Praluent Transition Services Agreement, Praluent Pharmacovigilance Transition Services Agreement or any Praluent Services Agreement.

For clarity, Regeneron's liability, other than with respect to [* * *], for any Damages arising from or occurring as a result of a Third Party Claim against a Sanofi Indemnitee that is due to or based upon (x) any actions or omissions by or on behalf of Regeneron for Sanofi in connection with any Ancillary Services Agreement or (y) any breach by Regeneron, any of its Affiliates or its or their Sublicensees of its obligations, covenants or representations and warranties under any Ancillary Services Agreement, in each case ((x) and (y)), shall be governed by the applicable Ancillary Services Agreement.

(c) In the event of any (i) Third Party Claim alleging that [* * *] (any such Third Party Claim described in this Section 14.1(c) and subject to the exclusions set forth in this Section 14.1(c), a "Special Claim"), then:

(i) if any such Special Claim is due to or based upon Triggering Events that occur prior to the Transition Date (including Special Claims that are due to or based upon Triggering Event(s) that occur both prior to, and after, the Transition Date), then (subject to Section 14.1(c)(iii)):

(A) the provisions of Section 14.2 shall not apply with respect to the defense of such Special Claim and (1) the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending such Special Claim, provided that, subject to Section 11.3, [* * *];

(B) with respect to any Damages (other than Litigation Costs) from such Special Claim allocable to Triggering Events occurring prior to the Transition Date, the Parties shall share such Damages on a [* * *] basis; and

(C) with respect to any Damages (other than Litigation Costs) from such Special Claim allocable to Triggering Events occurring on or after the Transition Date, [* * *];

(ii) if any such Special Claim is solely due to or based upon Triggering Events occurring on or after the Transition Date (and is not due to or based upon Triggering Events prior to the Transition Date, which shall be governed by Section 14.1(c)(i)), then (subject to Section 14.1(c)(iii)):

(A) the provisions of Section 14.2 shall apply with respect to the defense of such Third Party Claim; and

(B) with respect to any Damages (other than any costs or expenses allocated pursuant to Section 14.2) from such Special Claim, (1) Regeneron shall indemnify, defend and hold harmless the Sanofi Indemnitees, to the extent such Damages are allocable to the Commercialization of any Praluent Product in the Regeneron Territory, or the Development (other than the conduct of any Global Clinical Trials) or Manufacturing (including by Sanofi or any of its Affiliates for Regeneron under the Finished Product Supply Agreement) of any Praluent Product in the Territory in support of Commercialization of such Praluent Product in the Regeneron Territory and (2) Sanofi shall indemnify, defend and hold harmless the Regeneron Indemnitees, to the extent such Damages are allocable to the Commercialization of any Praluent Product in the Sanofi Territory, or the Development (other than the conduct of any Global Clinical Trials) or Manufacturing (including by Regeneron or any of its Affiliates for Sanofi under the Praluent Substance Supply Agreement) of any Praluent Product in the Territory in support of Commercialization of such Praluent Product in the Sanofi Territory; and

(iii) if any Special Claim is allocable to the Global Clinical Trials, then:

(A) the provisions of Section 14.2 shall not apply with respect to the defense of such Special Claim and the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending such Special Claim and shall share the Litigation Costs for such defense [* * *] that are Out-of-Pocket Costs; provided that, subject to Section 11.3, Sanofi shall have final decision-making authority with respect to any such Special Claims in the Sanofi Territory and Regeneron shall have final decision-making authority with respect to any such Special Claims in the Regeneron Territory; provided further that neither Party shall settle any such Special Claim without the other Party's consent, not to be unreasonably withheld, conditioned or delayed; and

(B) the Parties shall share Damages (other than Litigation Costs) from such Special Claim [* * *].

(d) For clarity, other than Special Claims (which are governed by Section 14.1(c)), all Damages that are due to or based upon any act or omission by or on behalf of Regeneron or Sanofi prior to the Transition Date shall be governed by the terms of the LCA as in effect immediately prior to the Transition Date.

(e) For clarity, for purposes of Section 14.1(a), Section 14.1(b), Section 14.1(c) and Section 14.1(d), any reference to Licensed Product (as defined in the LCA) under any applicable section of the LCA shall be deemed to include a reference to Praluent Product.

(f) Each Party shall maintain, at its own cost and expense, liability insurance coverage on, or self-insurance of, its activities performed under this Agreement. Such insurance will be maintained, at a minimum, until five (5) years after such Party and its Affiliates and its and their Sublicensees have permanently ceased Development and Commercialization of all Praluent Products, with a reputable insurance carrier(s) or through self-insurance, and will include Commercial General Liability and Products Liability insurance covering damages arising from bodily injury (including death), property damage and consequential loss, in an amount not less than [* * *] dollars ($[* * *]) per occurrence and in the annual aggregate arising out of Third Party claims made against the Parties in respect of the activities performed under this Agreement. Maintenance of such insurance coverage will not relieve either Party of any responsibility under this Agreement for damage in excess of insurance limits or otherwise. Upon a Party's written request, the other Party will promptly provide it with a certificate from the insurer(s) or the insurer's authorized representative, or in the case of self-insurance, an authorized corporate officer evidencing such insurance coverage.

14.2 Indemnity Procedure.

(a) The Party entitled to indemnification under this Article 14 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of being notified of any claim or claims asserted or threatened against the Indemnified Party that could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party. For the avoidance of

doubt, the indemnification procedures in this Section 14.2 shall not apply to Third Party Claims described in Section 14.1(c)(i), which shall be governed by such section unless specified otherwise in such section.

(i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending a claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (A) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (B) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld, conditioned or delayed unless such compromise or settlement involves (1) any admission of legal wrongdoing by the Indemnified Party, (2) any payment by the Indemnified Party that is not indemnified hereunder or (3) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the cost and expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed), provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

(ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 14.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.

(iii) Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 14.2, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to, reasonably cooperate in the defense or prosecution thereof and, if the Indemnifying Party assumes the defense of any such claim, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals, in each case, as may be reasonably requested in connection therewith. Such cooperation shall include access upon reasonable notice during

normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and to the extent the Indemnified Party is entitled to indemnification pursuant to this Article 14, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable Out-of-Pocket Costs in connection with providing such assistance.

ARTICLE 15
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement or any Ancillary Agreement for failure or delay in fulfilling or performing any term of this Agreement or any Ancillary Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, epidemics, pandemics, quarantines or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement is entered into as of the Execution Date but shall be effective as of the Transition Date and shall, from and after the Transition Date, remain in full force and effect in perpetuity and may not be terminated other than pursuant to the terms and conditions of Section 16.2.

16.2 Termination of Licenses and Certain Contractual Restrictions. Each Party (the "Terminating Party") may terminate (a) the licenses and rights of reference granted to the other Party (the "Breaching Party") hereunder and (b) any restrictions imposed upon the Terminating Party pursuant to Section 5.8 (provided however that the termination of such restrictions shall not be deemed to expand the licenses and rights of reference granted by the Breaching Party to the Terminating Party), in each case ((a) and (b)) upon prior written notice, if the Breaching Party or any of its Affiliates or its or their Sublicensees commits a material breach of its obligations under this Agreement. Any such notice shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions alleged to have been breached), and the termination of the applicable licenses, rights of reference and contractual restrictions shall be effective ninety (90) days after the date such notice is given unless the Breaching Party shall have cured such breach within such ninety (90)-day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90)-day period, such longer period not to exceed one hundred eighty (180) days so long as the Breaching Party is using commercially reasonable efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one

hundred eighty (180)-day period or such time as the Breaching Party ceases to use commercially reasonable efforts to cure such breach).

16.3 Other Effects of Termination. From and after the effective date of any termination pursuant to Section 16.2:

(a) If Regeneron is the Terminating Party, then Sanofi shall have no royalty payment obligations hereunder with respect to Net Sales occurring after such effective date.

(b) All of the Breaching Party's rights and obligations hereunder specifically relating to (i) if the Breaching Party is Regeneron, the U.S. Praluent Product Business or (ii) if the Breaching Party is Sanofi, the ROW Praluent Product Business, in each case ((i) and (ii)) shall immediately terminate (but not, for clarity, any licenses and rights of reference granted by the Breaching Party under Section 2.1, Section 2.2 or Section 6.2, as applicable). For clarity, all of the Breaching Party's rights and obligations under Article 13 and Article 14 shall continue in full force and effect, and all of the Breaching Party's other rights and obligations hereunder, including under any Ancillary Services Agreement, shall continue in full force and effect with respect to Regeneron's conduct of the U.S. Praluent Product Business, if the Terminating Party is Regeneron, or Sanofi's conduct of the ROW Praluent Product Business, if the Terminating Party is Sanofi.

(c) Promptly following such effective date, the Parties shall negotiate in good faith to amend this Agreement as may be needed in order to preserve the Terminating Party's rights relating to the U.S. Praluent Product Business, if the Terminating Party is Regeneron, or to the ROW Praluent Product Business, if the Terminating Party is Sanofi.

ARTICLE 17
DISPUTE RESOLUTION

17.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement. In the event the Parties are unable to resolve any such dispute (other than a dispute in respect of any final and binding results of any audit conducted pursuant to Section 8.11 or Section 8.12) either Party may submit such dispute to the Executive Officers for resolution, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within thirty (30) days of receiving such written notification. Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such dispute, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise. Nothing in this Section 17.1 shall prohibit either Party from seeking immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions of the other Party or any of its Affiliates or its or their Sublicensees.

17.2 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Schedule 18.4 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

ARTICLE 18
MISCELLANEOUS

18.1 Compliance With Law. Both Sanofi and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or that it believes, in good faith, may violate, any applicable Law.

18.2 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use all commercially reasonable efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement and (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement.

18.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

18.4 Notices. All notices or demands required by this Agreement shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 18.4 attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, or (c) sent via a reputable nationwide overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, or one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either Party may change its notice address by giving notice to the other Party in the manner provided above.

18.5 Entire Agreement. This Agreement, together with the LCA, the Discovery Agreement and the Ancillary Agreements, contain the complete understanding of the Parties with

respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof.

18.6 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

18.7 Headings. The descriptive headings of Articles and Sections are inserted solely for convenience of reference and are not intended as complete or accurate descriptions of the content of such Articles or Sections.

18.8 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction, provided, further that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

18.9 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 13.6. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement and shall promptly cooperate to respond to any request for further information therefrom.

18.10 Assignment. Each of Sanofi and Regeneron may, without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of any assignment by Regeneron, assign any of their respective rights and obligations under this Agreement to any of its Affiliates or any Third Party, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement; provided, however, that (i) any such assignment by Sanofi that would entail [* * *] to a Third Party shall be subject to Regeneron's prior written consent (not to be unreasonably withheld, conditioned or delayed) unless such Third Party (A) acquires whether by merger, sale of assets or otherwise all or substantially all of Sanofi's cardio metabolic business, or any successor business unit or division to which this Agreement relates (which business unit or division does not include only Praluent Products) and (B) such Third Party acquirer and agrees in writing to be bound by the terms of this Agreement and (ii) any such assignment by Regeneron that would entail [* * *] to a Third Party shall be subject to Sanofi's prior written consent (not to be unreasonably withheld, conditioned or delayed) unless such Third Party acquires whether by merger, sale of assets or otherwise all or substantially all of Regeneron's cardio metabolic business, or any successor business unit or division to which this Agreement relates (which business unit or division does not include only Praluent Products), and agrees in writing to be bound by the terms of this Agreement.

18.11 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18.12 Affiliates. Each Party may perform its obligations hereunder through one or more of its Affiliates, although each Party shall nonetheless be responsible for the performance of its Affiliates. Neither Party shall permit any of its Affiliates to commit any act (including any act or omission) that such Party is prohibited hereunder from committing directly.

18.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but that together shall constitute one and the same instrument. This Agreement may be executed by exchange between the Parties of electronically transmitted signatures (via facsimile, PDF format via e-mail or other electronic means) and such signatures shall be deemed to bind each Party as if they were original signatures.

18.14 No Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party including any creditor of either Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

18.15 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties or any of their respective Affiliates.

18.16 Limitation of Damages. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES, EXCEPT TO THE EXTENT ANY SUCH DAMAGES (a) ARE PAID BY THE OTHER PARTY TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM THAT IS COVERED BY SUCH PARTY'S INDEMNIFICATION OBLIGATIONS IN ARTICLE 14, (b) RELATE TO A BREACH BY SUCH PARTY OF SECTION 5.8, SECTION 6.3(b), SECTION 18.10 (TO THE EXTENT RELATING TO REGENERON MANUFACTURING KNOW-HOW) OR ARTICLE 13 OR (c) ARISE AS A RESULT OF SUCH PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

18.17 Rejection of Agreement in Bankruptcy. The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by applicable Laws. All rights and licenses granted under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code or in any analogous provisions in any other country or jurisdiction, as applicable, shall be deemed to be "intellectual property" for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction, as applicable. The Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, including the right to obtain the intellectual property from another entity. In the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not subject to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in the non-subject Party's possession, shall be promptly delivered to it upon the non-subject Party's written request (a) upon commencement of a bankruptcy proceeding, unless the Party subject to such proceeding continues to perform all of its obligations under this Agreement or (b) if not delivered pursuant to clause (a) above because the subject Party continues to perform, upon the rejection of this Agreement by or on behalf of the subject Party. Unless and until the subject Party rejects this Agreement, the subject Party shall perform this Agreement or provide the intellectual property (including all embodiments of such intellectual property) to the non-subject Party, and shall not interfere with the rights of the non-subject Party to such intellectual property, including the right to obtain the intellectual property from another entity.

18.18 Construction.

(a) Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The words "will" and "shall" shall have the same meaning and the use of the word "or" is used in the inclusive sense (and/or). The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used with "without limitation" or "without limiting" elsewhere in this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(b) Unless otherwise specified, (i) the references in this Agreement to any Article, Section, Schedule or Exhibit shall mean references to such Article, Section, Schedule or Exhibit of this Agreement, (ii) references in any section to any clause are references to such clause of such section and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, amended, replaced or supplemented from time to time, so varied, amended, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement and notification of such approval or consent is not delivered within

the applicable time limit, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. This Agreement has been prepared jointly and the provisions contained herein shall not be construed or interpreted for or against either Party to this Agreement because such Party drafted or caused such Party's legal representative to draft any provision contained herein.

(d) In the event of any conflict between this Agreement and the Schedules and Appendices hereto, this Agreement shall prevail. In the event of any conflict between this Agreement and a Praluent Supply Agreement, such Praluent Supply Agreement shall control in respect of any supply-related terms, and this Agreement shall control for any other terms.

[SIGNATURE PAGE FOLLOWS.**]**

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

SANOFI BIOTECHNOLOGY SAS

By /s/ Benedicte Bonny

Name: Benedicte Bonny
Title: President

REGENERON PHARMACEUTICALS, INC.

By /s/ Robert E. Landry

Name: Robert E. Landry
Title: Executive Vice President, Finance and Chief Financial Officer

Schedules to the Praluent Cross License & Commercialization Agreement

Schedule 1.57

Global Trial Costs

"Global Trial Costs" shall mean, with respect to a Global Clinical Trial, costs incurred by a Party directly in connection with the conduct of such Global Clinical Trial in accordance with this Agreement and the applicable Global Development Plan (as defined under the LCA) in effect under the LCA immediately prior to the Transition Date and applicable protocol and budget for such Global Clinical Trial as in effect as of immediately prior to the Transition Date, [* * *].

For purposes of this Schedule 1.57:

"Global Trial FTE Cost" shall mean, for all clinical Development activities performed by a Party to conduct any Global Clinical Trials in accordance with Section 4.2(a), excluding regulatory activities in support thereof, the product of (a) the number of FTEs used for such Development activities and (b) the applicable FTE Rate(s).

Schedule 1.72

Joint Patents

[* * *]

Schedule 1.135

Regeneron Core Patents

[* * *]

Schedule 1.156

Sanofi Core Patents

[* * *]

Schedule 1.180

Transferred Approvals

[* * *]

Schedule 1.182

Transferred Product Contracts

[* * *]

Schedule 1.183

Transferred Product Domain Names

[* * *]

Schedule 1.184

Transferred Product Records

[* * *]

Schedule 1.185

Transferred Product Trademarks

[* * *]

Schedule 2.3(c)

Approved Contract Manufacturers

Each of companies listed below shall be deemed to include the listed company (including following any change of name) as well as any of its existing or future affiliates or successors-in-interest by virtue of mergers or similar operations.

For use by Regeneron:

[* * *]

For use by Sanofi:

[* * *]

Schedule 4.2(a)

Global Clinical Trials

[* * *]

Schedule 4.3

Certain Other Existing Trials

[* * *]

Schedule 4.4

Certain Investigator-Initiated Studies

[* * *]

Schedule 4.7

Assay Services

[* * *]

Schedule 7.2(a)

[* * *]

Schedule 7.3(a)

Drug Substance Tech Transfer Plan

[* * *]

Schedule 8.4

Royalty Invoicing Directions

Invoices shall be made out as follows:

[* * *]

And be sent to the following mailing address:

[* * *]

Schedule 8.5

Transferred Inventory Prices

[* * *]

The prices listed above include all tax and duties, such as sales, export, import, value added and excise tax or duty.

Sanofi shall issue invoices for Transferred Inventory under this Agreement consistent with relevant tax requirements.

Schedule 11.5(a)

Existing Sole Oppositions

[* * *]

Schedule 11.5(b)

Existing European Oppositions

[* * *]

Schedule 12.2(c)

Pending or Threatened Litigation or Adverse Agreements

[* * *]

Schedule 18.4

Notice Addresses

If to Sanofi:

[* * *]

Copy (which shall not constitute notice) to:

[* * *]

If to Regeneron:

[* * *]

Exhibit 31.1

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

I, Leonard S. Schleifer, certify that:

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

Date: August 5, 2020

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

Exhibit 31.2

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

I, Robert E. Landry, certify that:

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

Date: August 5, 2020

/s/ Robert E. Landry

Robert E. Landry

Executive Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

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

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

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
August 5, 2020

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