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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 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 October 23, 2020:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,848,970
Common Stock, $.001 par value	104,857,294

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,573.0	$ 1,617.8
Marketable securities	1,452.9	1,596.5
Accounts receivable - trade, net	3,092.5	2,100.0
Accounts receivable - Sanofi	460.8	260.6
Accounts receivable - other	486.2	425.0
Inventories	1,801.6	1,415.5
Prepaid expenses and other current assets	230.6	273.7
Total current assets	9,097.6	7,689.1
Marketable securities	2,875.1	3,256.8
Property, plant, and equipment, net	3,138.3	2,890.4
Deferred tax assets	804.2	824.2
Other noncurrent assets	168.8	144.7
Total assets	$ 16,084.0	$ 14,805.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 443.1	$ 418.1
Accrued expenses and other current liabilities	1,303.0	1,211.4
Deferred revenue - Sanofi	409.3	310.5
Deferred revenue - other	85.5	71.6
Other liabilities - Sanofi	96.9	85.0
Total current liabilities	2,337.8	2,096.6
Long-term debt	1,978.3	—
Finance lease liabilities	716.5	713.9
Deferred revenue - Sanofi	37.9	27.7
Deferred revenue - other	67.0	77.6
Other liabilities - Sanofi	367.0	482.0
Other noncurrent liabilities	454.0	317.7
Total liabilities	5,958.5	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 - 120,516,837 in 2020 and 113,288,103 in 2019	0.1	0.1
Additional paid-in capital	6,592.8	4,428.6
Retained earnings	9,743.8	7,379.8
Accumulated other comprehensive income	30.8	21.1
Treasury Stock, at cost; 15,741,824 shares in 2020 and 4,860,123 shares in 2019	(6,242.0)	(739.9)
Total stockholders' equity	10,125.5	11,089.7
Total liabilities and stockholders' equity	$ 16,084.0	$ 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Statements of Operations				
Revenues:				
Net product sales	$ 1,482.2	$ 1,238.3	$ 3,945.8	$ 3,548.0
Sanofi collaboration revenue	353.3	175.0	869.3	232.8
Bayer collaboration revenue	299.9	293.6	825.5	834.8
Other revenue	158.6	36.8	433.6	78.5
	2,294.0	1,743.7	6,074.2	4,694.1
Expenses:				
Research and development	684.6	526.0	1,990.5	1,897.6
Selling, general, and administrative	326.9	304.4	1,042.5	890.1
Cost of goods sold	131.0	115.9	312.3	253.8
Cost of collaboration and contract manufacturing	143.0	109.6	454.5	289.6
Other operating (income) expense, net	(44.6)	(50.7)	(135.2)	(171.1)
	1,240.9	1,005.2	3,664.6	3,160.0
Income from operations	1,053.1	738.5	2,409.6	1,534.1
Other income (expense):				
Other (expense) income, net	(28.5)	37.8	218.3	28.7
Interest expense	(26.3)	(7.8)	(42.1)	(23.5)
	(54.8)	30.0	176.2	5.2
Income before income taxes	998.3	768.5	2,585.8	1,539.3
Income tax expense	156.2	98.9	221.8	215.5
Net income	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
Net income per share - basic	$ 7.98	$ 6.12	$ 21.83	$ 12.12
Net income per share - diluted	$ 7.39	$ 5.86	$ 20.36	$ 11.54
Weighted average shares outstanding - basic	105.5	109.4	108.3	109.2
Weighted average shares outstanding - diluted	113.9	114.2	116.1	114.7
Statements of Comprehensive Income				
Net income	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
Other comprehensive income (loss), net of tax:				
Unrealized (loss) gain on debt securities	(4.9)	1.0	10.9	31.5
Unrealized gain (loss) on cash flow hedges	0.2	(0.3)	(1.2)	(2.7)
Comprehensive income	$ 837.4	$ 670.3	$ 2,373.7	$ 1,352.6

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
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.9	—	297.5	—	—	—	—	297.5
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.2)	—	(80.9)	—	—	—	—	(80.9)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	8.6	—	—	—	1.3	9.9
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.1)	(100.4)	(100.4)
Stock-based compensation charges	—	—	—	—	104.6	—	—	—	—	104.6
Net income	—	—	—	—	—	842.1	—	—	—	842.1
Other comprehensive loss, net of tax	—	—	—	—	—	—	(4.7)	—	—	(4.7)
Balance, September 30, 2020	1.8	—	120.5	$ 0.1	$ 6,592.8	$ 9,743.8	$ 30.8	(15.7)	$(6,242.0)	$ 10,125.5

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
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.1	—	8.3	—	—	—	—	8.3
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(0.1)	—	—	—	—	(0.1)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	3.9	—	—	—	2.1	6.0
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.2)	(48.7)	(48.7)
Conversion of Class A Stock to Common Stock	(0.1)	—	0.1	—	—	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	112.7	—	—	—	—	112.7
Net income	—	—	—	—	—	669.6	—	—	—	669.6
Other comprehensive income, net of tax	—	—	—	—	—	—	0.7	—	—	0.7
Balance, September 30, 2019	1.8	—	112.1	$ 0.1	$ 4,388.4	$ 6,587.8	$ 16.5	(4.2)	$ (488.4)	$ 10,504.4

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

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

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net income	$ 2,364.0	$ 1,323.8
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	174.2	156.0
Non-cash compensation expense	310.5	330.8
Other non-cash items, net	(111.3)	113.2
Deferred taxes	117.9	(110.0)
Changes in assets and liabilities:		
Increase in Sanofi, trade, and other accounts receivable	(1,275.3)	(464.5)
Increase in inventories	(402.4)	(227.2)
Decrease in prepaid expenses and other assets	16.4	24.8
Increase in deferred revenue	112.3	166.8
Increase in accounts payable, accrued expenses, and other liabilities	80.8	328.9
Total adjustments	(976.9)	318.8
Net cash provided by operating activities	1,387.1	1,642.6
Cash flows from investing activities:		
Purchases of marketable and other securities	(2,642.7)	(2,834.9)
Sales or maturities of marketable and other securities	3,330.3	1,306.4
Capital expenditures	(453.2)	(290.6)
Net cash provided by (used in) investing activities	234.4	(1,819.1)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	1,981.9	—
Proceeds from bridge loan facility	1,500.0	—
Repayment of bridge loan facility	(1,500.0)	—
Proceeds from issuance of Common Stock	2,471.1	163.5
Payments in connection with Common Stock tendered for employee tax obligations	(652.5)	(40.5)
Repurchases of Common Stock	(5,465.7)	(29.4)
Net cash (used in) provided by financing activities	(1,665.2)	93.6
Net decrease in cash, cash equivalents, and restricted cash	(43.7)	(82.9)
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	$ 1,586.6	$ 1,397.3

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

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

1. Interim Financial Statements

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 nine months ended September 30, 2019, and the Condensed Consolidated Statement of Cash Flows for the nine months ended September 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 September 30, 2019			Nine Months Ended September 30, 2019		
Statement of Operations Data:	**As Previously Reported**	**Adjustments**	**As Revised**	**As Previously Reported**	**Adjustments**	**As Revised**
Sanofi collaboration revenue	$ 404.2	$ (229.2)	$ 175.0	$ 999.7	$ (766.9)	$ 232.8
Bayer collaboration revenue	$ 302.8	$ (9.2)	$ 293.6	$ 868.0	$ (33.2)	$ 834.8
Other revenue	$ 103.1	$ (66.3)	$ 36.8	$ 278.2	$ (199.7)	$ 78.5
Total revenues	$ 2,048.4	$ (304.7)	$ 1,743.7	$ 5,693.9	$ (999.8)	$ 4,694.1
Research and development	$ 663.4	$ (137.4)	$ 526.0	$ 2,353.5	$ (455.9)	$ 1,897.6
Selling, general, and administrative	$ 419.9	$ (115.5)	$ 304.4	$ 1,248.0	$ (357.9)	$ 890.1
Cost of collaboration and contract manufacturing[(1)]	$ 110.7	$ (1.1)	$ 109.6	$ 304.5	$ (14.9)	$ 289.6
Other operating (income) expense, net	—	$ (50.7)	$ (50.7)	—	$ (171.1)	$ (171.1)
Total operating expenses	$ 1,309.9	$ (304.7)	$ 1,005.2	$ 4,159.8	$ (999.8)	$ 3,160.0

[(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.

	Nine Months Ended September 30, 2019		
Cash Flows Data:	**As Previously Reported**	**Adjustments**	**As Revised**
Cash flows from operating activities:			
Increase in deferred revenue	$ 375.8	$ (209.0)	$ 166.8
Increase in accounts payable, accrued expenses, and other liabilities	$ 119.9	$ 209.0	$ 328.9

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 nine months ended September 30, 2020; however, actual results could differ from those estimates and there may be changes to our estimates in future periods.

Recently Adopted Accounting Standards

We adopted Accounting Standards Update 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as of January 1, 2020. ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized credit losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the previous other-than-temporary impairment model. The adoption of this standard did not have a material impact on our financial statements or a significant impact on our internal controls.

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

2. Product Sales

Net product sales consist of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net Product Sales in the United States	**2020**	**2019**	**2020**	**2019**
EYLEA®	$ 1,318.3	$ 1,187.7	$ 3,604.0	$ 3,422.1
Libtayo®	71.6	47.6	196.6	115.2
Praluent®	48.5	*	95.7 *	*
REGN-COV2	40.2	—	40.2	—
ARCALYST®	3.6	3.0	9.3	10.7
	$ 1,482.2	$ 1,238.3	$ 3,945.8	$ 3,548.0

* 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 nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	50 %	57 %	52 %	57 %
McKesson Corporation	34 %	34 %	34 %	33 %

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 collaborators	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)
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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 September 30,		Nine Months Ended September 30,	
		2020	2019	2020	2019
Antibody:					
Regeneron's share of profits in connection with commercialization of antibodies	Sanofi collaboration revenue	$ 212.8	$ 94.2	$ 555.6	$ 105.2
Sales-based milestone earned	Sanofi collaboration revenue	$ 50.0	—	$ 50.0	—
Reimbursement for manufacturing of commercial supplies	Sanofi collaboration revenue	$ 94.3	$ 85.4	$ 275.0	$ 143.8
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 45.5	$ 60.2	$ 174.4	$ 216.5
Regeneron's obligation for its share of Sanofi research and development expenses	Research and development expense	$ (17.5)	$ (10.2)	$ (59.1)	$ (29.8)
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 83.2	$ 111.6	$ 260.4	$ 349.3
Immuno-oncology:					
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	Sanofi collaboration revenue	$ (4.7)	$ (4.6)	$ (17.3)	$ (16.2)
Reimbursement for manufacturing of commercial supplies	Sanofi collaboration revenue	$ 0.9	—	$ 6.0	—
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 49.8	$ 38.0	$ 136.7	$ 120.9
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 14.5	$ 3.0	$ 39.2	$ 7.0
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ (31.5)	$ (20.1)	$ (86.5)	$ (51.5)
Amounts recognized in connection with up-front payments received	Other operating income	$ 20.0	$ 18.5	$ 57.0	$ 73.8

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 research, 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 itepekimab (collectively, the "Dupilumab/Itepekimab 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 nine months ended September 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

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effective April 1, 2020. In addition to profit and loss sharing, the Company is entitled to receive sales milestone payments from Sanofi. In the third quarter of 2020, the Company earned, and recognized as revenue, the first $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.0 billion on a rolling twelve-month basis. We are entitled to receive up to an aggregate of $200.0 million in additional sales milestone payments from Sanofi.

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

	September 30, 2020	December 31, 2019
Accounts receivable	$ 453.2	$ 272.7
Deferred revenue	$ 433.6	$ 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

The Company is party to a collaboration with Sanofi to research, 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/Itepekimab Eligible Investments incurred in

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periods through September 30, 2020 by selling certain shares of our Common Stock directly or indirectly owned by Sanofi; if Sanofi desires to sell such shares, we may elect to purchase, in whole or in part, such shares from Sanofi. See Note 10 for additional information regarding shares purchased by us from Sanofi during the three and nine months ended September 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:

	September 30, 2020	December 31, 2019
Accounts receivable, net	$ (4.5)	$ (16.7)
Deferred revenue	$ 13.6	$ 9.4
Other liabilities	$ 441.8	$ 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 September 30, 2020 was $951.0 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.

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 September 30,		Nine Months Ended September 30,	
		2020	2019	2020	2019
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	Bayer collaboration revenue	$ 287.9	$ 275.0	$ 772.6	$ 793.3
Reimbursement for manufacturing of commercial supplies	Bayer collaboration revenue	$ 12.0	$ 18.6	$ 52.9	$ 41.5
Reimbursement of development expenses	Reduction of Research and development expense	$ 11.5	$ 5.0	$ 34.3	$ 15.6
Regeneron's obligation for its share of Bayer research and development expenses	Research and development expense	$ (12.9)	$ (7.0)	$ (26.3)	$ (13.6)
Reimbursement of other expenses	Cost of collaboration and contract manufacturing	$ 2.0	$ 3.7	$ 5.3	$ 16.6

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.

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

	September 30, 2020	December 31, 2019
Accounts receivable - other	$ 299.2	$ 311.6
Deferred revenue	$ 122.1	$ 123.0

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 September 30,		Nine Months Ended September 30,	
		2020	2019	2020	2019
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 25.9	$ 34.2	$ 82.1	$ 102.9
Amounts recognized in connection with up-front and development milestone payments received	Other operating income	$ 17.2	$ 22.8	$ 54.5	$ 68.8

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

	September 30, 2020	December 31, 2019
Accounts receivable - other	$ 26.6	$ 21.2
Other liabilities	$ 61.0	$ 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 September 30, 2020 was $130.3 million. This amount is expected to be recognized over the remaining period in which the Company is obligated to satisfy its obligation in connection with performing development activities.

d. Intellia

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

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

In May 2020, we expanded our existing collaboration with Intellia to provide us with rights to develop products for additional *in vivo* CRISPR/Cas9-based therapeutic targets and for the parties to jointly develop potential products for the treatment of hemophilia A and B. In addition, we also received non-exclusive rights to independently develop and commercialize *ex vivo*

gene edited products. In connection with the agreement, we made a $70.0 million up-front payment, which was recorded to Research and development expense in the second quarter of 2020, and purchased 925,218 shares of Intellia common stock for an aggregate purchase price of $30.0 million. The amount paid in excess of the fair market value of the shares purchased, or $15.0 million, was also recorded to Research and development expense in the second quarter of 2020.

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

In the first quarter of 2020, we announced an expansion of our Other Transaction Agreement ("OTA") with BARDA, pursuant to which the U.S. Department of Health and Human Services ("HHS") is obligated to fund 80% of certain 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. See Note 2 for REGN-COV2 net product sales recognized in connection with this agreement during the three months ended September 30, 2020.

4. Net Income Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Net income - basic and diluted	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
(Shares in millions)				
Weighted average shares - basic	105.5	109.4	108.3	109.2
Effect of dilutive securities:				
Stock options	7.8	4.8	7.3	5.5
Restricted stock	0.6	—	0.5	—
Weighted average shares - diluted	113.9	114.2	116.1	114.7
Net income per share - basic	$ 7.98	$ 6.12	$ 21.83	$ 12.12
Net income per share - diluted	$ 7.39	$ 5.86	$ 20.36	$ 11.54

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(Shares in millions)	**2020**	**2019**	**2020**	**2019**
Stock options	0.1	18.3	2.6	18.2
Restricted stock	—	0.4	—	0.4

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5. Marketable Securities

Marketable securities as of September 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 September 30, 2020	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 2,796.6	$ 40.1	$ (0.7)	$ 2,836.0
U.S. government and government agency obligations	133.5	1.3	(0.1)	134.7
Sovereign bonds	65.4	1.2	—	66.6
Commercial paper	390.4	0.2	—	390.6
Certificates of deposit	122.4	0.1	—	122.5
	$ 3,508.3	$ 42.9	$ (0.8)	$ 3,550.4
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 September 30, 2020 mature at various dates through September 2025. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	September 30, 2020	December 31, 2019
Maturities within one year	$ 1,452.9	$ 1,596.5
Maturities after one year through five years	2,097.5	2,638.0
	$ 3,550.4	$ 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 September 30, 2020	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 560.5	$ (0.7)	—	—	$ 560.5	$ (0.7)
U.S. government and government agency obligations	45.5	(0.1)	—	—	45.5	(0.1)
	$ 606.0	$ (0.8)	—	—	$ 606.0	$ (0.8)
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)

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For the three months ended September 30, 2020, realized gains on sales of marketable securities were not material. For the nine months ended September 30, 2020, realized gains were $28.5 million. Realized losses were not material for the three and nine months ended September 30, 2020. There were no realized losses on sales of marketable securities, and realized gains were not material, for the three and nine months ended September 30, 2019.

With respect to marketable securities, for the three and nine months ended September 30, 2020 and 2019, amounts reclassified from Accumulated other comprehensive income into Other (expense) income, net were related to realized gains and losses 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 September 30, 2020	**Fair Value**	**Level 1**	**Level 2**
Available-for-sale debt securities:			
Corporate bonds	$ 2,836.0	—	$ 2,836.0
U.S. government and government agency obligations	134.7	—	134.7
Sovereign bonds	66.6	—	66.6
Commercial paper	390.6	—	390.6
Certificates of deposit	122.5	—	122.5
Equity securities (unrestricted)	41.3	$ 41.3	—
Equity securities (restricted)	736.3	720.0	16.3
	$ 4,328.0	$ 761.3	$ 3,566.7
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 September 30, 2020 which are subject to transfer restrictions that expire at various dates through 2024.

During the three and nine months ended September 30, 2020, we recorded $37.5 million of net unrealized losses and $133.8 million of net unrealized gains, respectively, on equity securities in Other (expense) income, net. During the three and nine months ended September 30, 2019, we recorded $15.7 million of net unrealized gains and $58.4 million of net unrealized losses, respectively, on equity securities in Other (expense) income, net.

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In addition to the investments summarized in the table above, as of September 30, 2020 and December 31, 2019, the Company had $60.6 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.

The fair value of our long-term debt (see Note 8 "*Senior Notes*" for additional details) was estimated to be $1.929 billion as of September 30, 2020, and was determined based on Level 2 inputs.

7. Inventories

Inventories consist of the following:

	September 30, 2020	December 31, 2019
Raw materials	$ 400.4	$ 216.3
Work-in-process	715.4	727.7
Finished goods	132.1	70.6
Deferred costs	553.7	400.9
	$ 1,801.6	$ 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

Bridge Loan Facility

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 bore interest at a variable interest rate based on either the London Interbank Offered Rate or the alternate base rate, plus an applicable margin that varied with our debt rating and total leverage ratio. The Bridge Facility was repaid in full during the third quarter of 2020 following the closing of the issuance and sale of the Company's senior notes (as described below).

Senior Notes

In August 2020, we issued and sold $1.250 billion aggregate principal amount of senior unsecured notes due 2030 (the "2030 Notes") and $750 million aggregate principal amount of senior unsecured notes due 2050 (the "2050 Notes" and, together with the 2030 Notes, the "Notes"). Net proceeds from the issuance and sale of the Notes (after deducting underwriting discounts and offering expenses) were used in part to repay in full the Bridge Facility described above. The underwriting discounts and offering expenses are being amortized as additional interest expense over the period from issuance through maturity.

The 2030 Notes accrue interest at the rate of 1.750% per year and will mature on September 15, 2030. The 2050 Notes accrue interest at the rate of 2.800% per year and will mature on September 15, 2050. Interest on each series of Notes is payable semi-annually in arrears on March 15 and September 15 of each year until their respective maturity dates. Interest expense related to the Notes for the three months ended September 30, 2020 was $6.4 million.

The Notes may be redeemed at the Company’s option at any time at 100% of the principal amount plus accrued and unpaid interest, and, until a specified period before maturity, a specified make-whole amount. The Notes contain a change-of-control provision that, under certain circumstances, may require the Company to offer to repurchase the Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest.

The Notes also contain certain limitations on the Company’s ability to incur liens and enter into sale and leaseback transactions, as well as customary events of default.

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9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 15.6% and 12.9% for the three months ended September 30, 2020 and 2019, respectively, and 8.6% and 14.0% for the nine months ended September 30, 2020 and 2019, respectively. The Company's effective tax rate for the three and nine months ended September 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 nine months ended September 30, 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by federal tax credits for research activities, the foreign-derived intangible income deduction, and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, partly offset by the taxation of certain global intangible low-taxed income and the non-deductible Branded Prescription Drug Fee.

The Company believes it is reasonably possible that its unrecognized tax benefits as of September 30, 2020 may decrease within the next twelve months, and, as a result, positively impact our effective tax rate, as a result of expected settlement of audits and statute of limitation lapses.

10. Stockholders' Equity

Share Repurchase Program

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

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.

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Number of shares repurchased	179,824	898,991
Total cost of shares received	$ 100.4	$ 373.3

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

As of September 30, 2020, the Company had $372.7 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/Itepekimab 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Libtayo:				
Number of shares purchased (by issuing a credit towards the amount owed by Sanofi)	—	103,761	77,677	210,733
Total cost of shares received	—	$ 29.2	$ 41.7	$ 73.3
Dupilumab/Itepekimab:				
Number of shares purchased (in cash)	—	69,143	171,471	93,286
Total cost of shares received	—	$ 19.4	$ 93.3	$ 29.4

As of September 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/Itepekimab Eligible Investments incurred in periods 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"). See Note 8 for additional information. 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).

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:

	September 30, 2020	September 30, 2019
Cash and cash equivalents	$ 1,573.0	$ 1,384.8
Restricted cash included in Other noncurrent assets	13.6	12.5
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$ 1,586.6	$ 1,397.3

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

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

Supplemental disclosure of non-cash investing and financing activities

The following amounts were included in accounts payable, accrued expenses, and other liabilities:

	September 30, 2020	December 31, 2019	September 30, 2019	December 31, 2018
Accrued capital expenditures	$ 100.4	$ 133.7	$ 100.5	$ 54.5

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 September 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 enjoined Kymab from infringing the '287 Patent and '163 Patent (subject to certain exceptions) and required 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). 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. An oral hearing before the Federal Circuit has been scheduled for December 9, 2020.

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

United Kingdom. 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. On October 22, 2020, the court lifted the stay upon application by the Company and the Sanofi defendants, and the case will proceed in due course.

Germany. 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 November 3, 2020, Amgen filed a motion withdrawing this lawsuit without prejudice.

France. 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.

The Netherlands. 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 February 12, 2021.

Italy. 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 August 12, 2020, the court denied Amgen's preliminary injunction motion.

Spain. 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 was not named as a defendant in this action. Amgen alleged, 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 sought, 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. On October 30, 2020, the stay was automatically lifted. On November 2, 2020, Amgen filed a motion withdrawing this lawsuit.

EPO Proceedings. 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 was held on October 28–29, 2020, at which the TBA ruled that the '124 Patent claims directed to compositions of matter and medical use were invalid based on a lack of inventive step.

Other

Japan. 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 was held on August 5, 2020. On October 13, 2020, the Federal Circuit affirmed the PTAB's decision on the Additional IPR Petition that invalidated all 17 claims of the '487 Patent as obvious.

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.

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). The ITC instituted the investigation on July 22, 2020.

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 ("Vetter") 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. On September 4, 2020, Novartis filed, and Vetter moved to join, a motion to dismiss the complaint, to transfer the lawsuit to the Northern District of New York, or to stay the suit; and on October 19, 2020, Novartis filed, and Vetter moved to join, a second motion to dismiss the complaint on different grounds.

Proceedings Relating to fasinumab

On May 21, 2020, the Company and Teva Pharmaceutical Industries Limited ("Teva") 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.

The '048 Patent is subject to opposition proceedings in the EPO, which were initiated by the Company on August 10, 2016 and two other opponents on August 11, 2016. On January 3, 2018, the Opposition Division of the EPO issued a preliminary, non-binding opinion regarding the validity of the '048 Patent, indicating that it considered the granted patent to be invalid. An oral hearing on the oppositions against the '048 Patent was held on November 29–30, 2018, at which the Opposition Division upheld the validity of the '048 Patent's claims in amended form. The Company filed a notice of appeal to the TBA of the EPO on March 7, 2019. On October 21, 2020, Teva filed a notice of intervention with the TBA to take part in the appeal proceedings as an intervener.

The '711 Patent is also subject to opposition proceedings in the EPO, which were initiated by the Company on May 1, 2018. On January 31, 2019, the Opposition Division of the EPO issued a preliminary, non-binding opinion regarding the validity of the '711 Patent, indicating that it considered the granted patent to be invalid. An oral hearing on the opposition against the '711 Patent was held on December 3, 2019, at which the Opposition Division upheld the validity of the '711 Patent's claims in amended form. The Company filed a notice of appeal to the TBA on December 20, 2019. An oral hearing before the TBA has been scheduled for July 29, 2021.

Proceedings Relating to REGN-COV2

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit against the Company in the United States District Court for the Southern District of New York, asserting infringement of U.S. Patent No. 10,221,221 (the "'221 Patent"). Allele seeks a judgment of patent infringement of the '221 Patent, a judgment that such infringement was willful, and an award of monetary damages (together with interest), treble damages, costs and expenses of the lawsuit, and attorneys' fees.

Department of Justice Matters

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. On August 24, 2020, the Company filed a motion to dismiss the complaint in its entirety. An oral hearing on the motion to dismiss was held on October 7, 2020.

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.

Shareholder Demand

On or about September 30, 2020, the Company's board of directors received a demand letter from a purported shareholder of the Company. The demand alleges that Regeneron and its shareholders have been damaged by the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. The demand letter requests that the Company's board of directors investigate alleged breaches of fiduciary duty by its officers and directors and other alleged violations of law and corporate governance practices and procedures; bring legal action against the persons responsible for causing the alleged damages; and implement and maintain an effective system of internal controls, compliance mechanisms, and corporate governance practices and procedures. The Company's board of directors, working with outside counsel, is evaluating this demand letter.

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 or otherwise commercialized 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, Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn), REGN-COV2, fasinumab, evinacumab, garetosmab, pozelimab, 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, Inmazeb, REGN-COV2, fasinumab, evinacumab, garetosmab, pozelimab, and odronextamab; 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 payors, including private payor 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 payors and new policies and procedures adopted by such payors; 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), as well as Regeneron's agreement with Roche relating to REGN-COV2, to be cancelled or terminated; 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 September 30,		Nine Months Ended September 30,	
(In millions, except per share data)	**2020**	**2019***	**2020**	**2019***
Revenues	$ 2,294.0	$ 1,743.7	$ 6,074.2	$ 4,694.1
Net income	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
Net income per share - diluted	$ 7.39	$ 5.86	$ 20.36	$ 11.54

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

Products

		Territory			
Product	**Disease Area[1]**	**U.S.**	**EU**	**Japan**	**ROW[6]**
EYLEA (aflibercept) Injection[2]	- Neovascular age-related macular degeneration ("wet AMD")	✔	✔	✔	✔
	- Diabetic macular edema ("DME")	✔	✔	✔	✔
	- Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	✔	✔	✔	✔
	- Myopic choroidal neovascularization ("mCNV")		✔	✔	✔
	- Diabetic retinopathy	✔			
	- Neovascular glaucoma ("NVG")			✔	
Dupixent (dupilumab) Injection[3]	- Atopic dermatitis (in adults and adolescents)[7]	✔	✔	✔	✔
	- Atopic dermatitis (in pediatrics 6–11 years of age)	✔			✔
	- Asthma (in adults and adolescents)	✔	✔	✔	✔
	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔	✔
Libtayo (cemiplimab) Injection[3][4]	- Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔		✔

Product *(continued)*	Disease Area[1]	Territory			
		U.S.	EU	Japan	ROW[6]
Praluent (alirocumab) Injection[5]	- LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD") (in adults)	✔	✔	[9]	✔
	- Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔		✔
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	- Rheumatoid arthritis ("RA") (in adults)	✔	✔	✔	✔
Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn) Injection	- Infection caused by *Zaire ebolavirus*	✔			
ARCALYST® (rilonacept) Injection for Subcutaneous Use	- Cryopyrin-Associated Periodic Syndromes ("CAPS"), including Familial Cold Auto-inflammatory Syndrome ("FCAS") and Muckle-Wells Syndrome ("MWS")	✔			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[8]	- Metastatic colorectal cancer ("mCRC")	✔	✔	✔	✔

Note: Refer to "Net Product Sales of Regeneron-Discovered Products" section below for information regarding whether net product sales for a particular product are recorded by us, Bayer, or Sanofi

[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, License, and Other 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 September 30, 2020 U.S.	2020 ROW	2020 Total	2019 U.S.	2019 ROW	2019 Total	% Change (Total Sales)
EYLEA[a]	U.S.	$ 1,318.3	$ 780.0	$ 2,098.3	$ 1,187.7	$ 730.2	$ 1,917.9	9 %
Dupixent	(b)	$ 851.2	$ 221.4	$ 1,072.6	$ 508.3	$ 124.8	$ 633.1	69 %
Libtayo[b]	U.S.	$ 71.6	$ 24.5	$ 96.1	$ 47.6	$ 3.9	$ 51.5	87 %
Praluent[c]	U.S.	$ 48.5	$ 43.0	$ 91.5	$ 33.5	$ 36.2	$ 69.7	31 %
Kevzara	(b)	$ 33.2	$ 36.8	$ 70.0	$ 36.5	$ 18.3	$ 54.8	28 %
REGN-COV2[d]	U.S.	$ 40.2	—	$ 40.2	—	—	—	(e)
ZALTRAP	(b)	$ 1.7	$ 22.5	$ 24.2	$ 3.1	$ 25.3	$ 28.4	(15 %)
ARCALYST	U.S.	$ 3.6	—	$ 3.6	$ 3.0	—	$ 3.0	20 %

	Net Product Sales Recorded by Regeneron	Nine Months Ended September 30, 2020 U.S.	2020 ROW	2020 Total	2019 U.S.	2019 ROW	2019 Total	% Change (Total Sales)
EYLEA[a]	U.S.	$ 3,604.0	$ 2,102.7	$ 5,706.7	$ 3,422.1	$ 2,114.9	$ 5,537.0	3 %
Dupixent	(b)	$ 2,300.6	$ 572.2	$ 2,872.8	$ 1,266.0	$ 298.1	$ 1,564.1	84 %
Libtayo[b]	U.S.	$ 196.6	$ 54.3	$ 250.9	$ 115.2	$ 3.9	$ 119.1	111 %
Praluent[c]	U.S.	$ 130.8	$ 127.1	$ 257.9	$ 82.9	$ 124.4	$ 207.3	24 %
Kevzara	(b)	$ 105.0	$ 93.4	$ 198.4	$ 91.4	$ 55.6	$ 147.0	35 %
REGN-COV2[d]	U.S.	$ 40.2	—	$ 40.2	—	—	—	(e)
ZALTRAP	(b)	$ 4.9	$ 74.0	$ 78.9	$ 4.9	$ 74.6	$ 79.5	(1 %)
ARCALYST	U.S.	$ 9.3	—	$ 9.3	$ 10.7	—	$ 10.7	(13 %)

[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 "Products" section above and "Collaboration, License, and Other Agreements - Sanofi" section below for further details.

[d] Regeneron records net product sales of REGN-COV2 in connection with our agreement with the U.S. government. Refer to "Agreements Related to COVID-19 - *BARDA*" below for further details.

[e] Percentage not meaningful

Programs in Clinical Development

All 24 of our product candidates in clinical development, including the five U.S. Food and Drug Administration ("FDA") approved products which we are investigating in additional indications, were discovered in our research laboratories and are summarized in the table below. We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*® technology platforms. 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 oversee trial management while also working to ensure patient safety and provide sufficient supply of product candidates for the studies. At this time, we expect fully enrolled clinical studies to remain generally on track. However, the ongoing pandemic continues to impact clinical trial execution in many regions across the world for us and our collaborators. The ultimate impact (including possible delays in recruiting and/or obtaining data) resulting from the COVID-19 pandemic will depend, among other factors, on the extent of the pandemic in the areas with study sites and patient populations. 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*		- Grass allergy - 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[d], adolescents[d], and pediatrics - Chronic obstructive pulmonary disease ("COPD") - Bullous pemphigoid (Phase 2/3)[c] - Chronic spontaneous urticaria - Prurigo nodularis - Allergic bronchopulmonary aspergillosis ("ABPA")	- Atopic dermatitis in pediatrics (6–11 years of age) (EU)[d]	- 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 - European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP") recommended approval for an additional indication in children aged 6 to 11 with atopic dermatitis - Reported that Phase 3 trial for asthma in children aged 6 to 11 years met its primary and key secondary endpoints - Approved by MHLW for CRSwNP in Japan - Approved by FDA and MHLW for 300 mg auto-injector	- EC decision for expanded atopic dermatitis indication in pediatrics (6–11 years of age) (fourth quarter 2020) - Report results from Phase 3 study for atopic dermatitis in pediatric patients (6 months–5 years of age) (2022) - Submit supplemental Biologics License Application ("sBLA") and Marketing Authorization Application ("MAA") for asthma in pediatrics (6–11 years of age) (first quarter 2021) - Report results from Part B of the Phase 3 study in adults and adolescents with EoE (2022) - Report results from Phase 2 study in peanut allergy (fourth quarter 2020) - Resubmit sBLA for 200 mg auto-injector (fourth quarter 2020)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
					- 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	- Report results from Phase 3 chronic spontaneous urticaria and prurigo nodularis studies (second half 2021) - Initiate Phase 3 studies in chronic inducible urticaria, chronic sinusitis without nasal polyposis, and allergic fungal rhinosinusitis (fourth quarter 2020) - Initiate Phase 3 study in hand and foot atopic dermatitis (first half 2021)
Kevzara (sarilumab)[a] *Antibody to IL-6R*		- Polyarticular-course juvenile idiopathic arthritis ("pcJIA") - Systemic juvenile idiopathic arthritis ("sJIA")			- Reported that Phase 3 studies in COVID-19 patients did not meet primary and key secondary endpoints - Discontinued clinical development in polymyalgia rheumatica and giant cell arteritis	
Itepekimab[a] (REGN3500) *Antibody to IL-33*		- Asthma - COPD			- Discontinued further clinical development in atopic dermatitis due to lack of efficacy	- Initiate Phase 3 study in COPD (fourth quarter 2020)
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					- Initiate Phase 3 study in birch allergy (first half 2021)
REGN7257 *Antibody to IL2Rg*	- Aplastic anemia					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
Oncology						
Libtayo (cemiplimab)[a][h] *Antibody to PD-1*	- Solid tumors and advanced hematologic malignancies	- Basal cell carcinoma ("BCC") (potentially pivotal study) - Metastatic or locally advanced CSCC[d] - Neoadjuvant CSCC	- First-line non-small cell lung cancer ("NSCLC"), monotherapy - First-line NSCLC, chemotherapy combination - Second-line cervical cancer[e] - Adjuvant CSCC	- First-line NSCLC, monotherapy (U.S. and EU) - Advanced BCC (U.S. and EU)	- Reported that Phase 3 monotherapy trial in first-line NSCLC met primary endpoint. Independent Data Monitoring Committee ("IDMC") recommended stopping the trial early due to highly significant improvement in overall survival. - Completed patient enrollment in Phase 3 first-line NSCLC chemotherapy combination study - Reported that Phase 2 study in BCC demonstrated clinically-meaningful and durable responses - Presented positive data from pivotal NSCLC and BCC studies at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020	- FDA decision on sBLA (target action date of February 28, 2021) and EC decision on regulatory submission (mid-2021) for first-line NSCLC, monotherapy - FDA decision on sBLA (target action date of March 3, 2021) and EC decision on regulatory submission (mid-2021) for advanced BCC - Interim analysis from Phase 3 study in cervical cancer (2021)
Odronextamab (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 (fourth quarter 2020)
REGN5458[a] *Bispecific antibody targeting BCMA and CD3*		- Multiple myeloma				- Report updated results from initial study in multiple myeloma (fourth quarter 2020)
REGN5459[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma					
REGN4018[a] *Bispecific antibody targeting MUC16 and CD3*	- Platinum-resistant ovarian cancer					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
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					
REGN6569 *Antibody to GITR*	- Solid tumors					
Cardiovascular/Metabolic Diseases						
Praluent (alirocumab)[j] *Antibody to PCSK9*			- Homozygous familial hypercholesterolemia ("HoFH")[c] in pediatrics - HeFH in pediatrics	- HoFH in adults (U.S.)	- 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. and EU)[c][d]	- *New England Journal of Medicine* published positive results from Phase 3 trial in HoFH	- FDA decision on BLA (target action date of February 11, 2021) 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 (fourth quarter 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 - Paused dosing in the open-label portion of the Phase 2 study in FOP based on reports of serious adverse events	- Further review trial data and determine next steps for the program

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2020 Events to Date	Select Upcoming Milestones[k]
REGN4461[f] *Agonist antibody to leptin receptor ("LEPR")*		- Generalized lipodystrophy[e]				
REGN5381 *Agonist antibody to NPR1*	- Heart failure					
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 - Discontinued actively treating patients following recommendation from the IDMC that the program should be terminated	- Report additional longer-term safety results from Phase 3 studies in osteoarthritis pain of the knee or hip (first half 2021) - Continue discussions with regulatory authorities and determine next steps for the program (first half 2021)
Infectious Diseases						
REGN-COV2[g][n] **(REGN10933-10987)** *Multi-antibody therapy to SARS-CoV-2 virus*	- COVID-19 multi-dose safety study	- COVID-19 treatment in non-hospitalized patients (Phase 2/3) - COVID-19 treatment in hospitalized patients (Phase 2/3)	- COVID-19 prevention[m] - COVID-19 treatment in hospitalized patients (RECOVERY trial)	- Adults with mild-to-moderate COVID-19 who are at high risk for poor outcomes	- Reported that Phase 2/3 trial in non-hospitalized patients with COVID-19 met primary and key secondary endpoints - Submitted request to FDA for an Emergency Use Authorization ("EUA") for COVID-19 - IDMC recommended further enrollment of hospitalized patients requiring high-flow oxygen or mechanical ventilation be placed on hold - Two papers published in *Science* describing REGN-COV2	- FDA decision on EUA for COVID-19 (fourth quarter 2020) - Complete Phase 3 portion of COVID-19 study in non-hospitalized patients and submit BLA (first half 2021)

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

Note 2: We have discontinued further clinical development of REGN5069, an antibody to GFRα3, which was previously being studied in osteoarthritis pain of the knee

[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 this product candidate

[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, License, and Other 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 with the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH")

[n] In collaboration with Roche

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 and asymptomatic COVID-19 patients, uninfected people with close exposure to a COVID-19 patient (such as the patient's housemate), and healthy volunteers.

In October 2020, we submitted a request to the FDA for an EUA for REGN-COV2 in patients with mild-to-moderate COVID-19 who are at high risk for poor outcomes.

In October 2020, we announced positive results from the ongoing Phase 2/3 seamless trial in non-hospitalized patients with COVID-19, showing that REGN-COV2 significantly reduced viral load and patient medical visits (hospitalizations, emergency room, urgent care visits, and/or physician office/telemedicine visits). The trial met the primary and key secondary endpoints. In September 2020, we had announced initial data from the trial showing that REGN-COV2 reduced viral load and time to alleviate symptoms.

In October 2020, the IDMC for the REGN-COV2 treatment trials for COVID-19 recommended that the current hospitalized patient trial be modified. Specifically, based on a potential safety signal and an unfavorable risk/benefit profile at this time, the IDMC recommended that further enrollment of patients requiring high-flow oxygen or mechanical ventilation be placed on hold pending collection and analysis of further data on patients already enrolled. The IDMC also recommended continuing enrollment of hospitalized patients requiring either no or low-flow oxygen as the risk/benefit remains acceptable in these cohorts. Finally, the IDMC recommended continuation of the outpatient trial (described further above) without modification.

In September 2020, we and the University of Oxford announced that the RECOVERY trial in the UK will evaluate REGN-COV2. The RECOVERY trial, which is a Phase 3 open-label trial in patients hospitalized with COVID-19, will compare the effects of adding REGN-COV2 to the usual standard-of-care versus standard-of-care on its own. The trial is being coordinated by researchers at the University of Oxford. The RECOVERY IDMC is aware of the IDMC recommendations made in connection with the REGN-COV2 treatment trials (described above), and will be discussing the impact, if any, on the RECOVERY trial.

Inmazeb

In October 2020, the FDA approved Inmazeb for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including newborns of mothers who have tested positive for the infection. In connection with this approval, we were also granted a material threat medical countermeasure priority review voucher by the FDA.

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.

In August 2020, we also announced that we discontinued actively treating patients with fasinumab, which at such time only involved dosing in an optional second-year extension phase of one trial. This followed a recommendation from the fasinumab program's IDMC that the program should be terminated, based on available evidence to date. We will continue to gather long-term safety data, which we expect to report in 2021, along with our decision on next steps for the program.

Garetosmab

In October 2020, we notified clinical investigators to pause dosing of garetosmab in the ongoing Phase 2 LUMINA-1 trial in patients with the ultra-rare genetic disorder FOP. The decision was based on reports of fatal serious adverse events in the trial during the open-label portion during which all patients received active treatment. These deaths are being further investigated to understand if they are related to garetosmab treatment. During the 28-week double-blind treatment period, there were no deaths in the trial.

We also shared this update with the trial's IDMC and relevant regulatory authorities, and will conduct a review of the trial data to date to better understand the benefit/risk profile of garetosmab in people with FOP. The Company announced top-line 28-week results from the LUMINA-1 trial earlier this year; this is the only active trial evaluating garetosmab.

Agreements Related to COVID-19

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 certain 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, as well as fill/finish and storage activities. See "Results of Operations - *Revenues*" below for REGN-COV2 net product sales recognized in connection with this agreement during the three months ended September 30, 2020.

Roche

In August 2020, we entered into a collaboration agreement with Roche to develop, manufacture, and distribute REGN-COV2. We will continue to lead global development activities for REGN-COV2, and the parties will jointly fund the ongoing Phase 3 prevention and Phase 1 healthy volunteer safety studies, as well as any mutually agreed additional new global studies to evaluate further the potential of REGN-COV2 in treating or preventing COVID-19. Roche will be responsible for securing regulatory approvals outside the United States, following the initial EMA approval (if any), and conducting any additional studies specifically required for approval by regulators outside the United States.

Under the terms of the agreement, each party is obligated to dedicate a certain amount of manufacturing capacity to REGN-COV2 each year. We will distribute the product in the United States and Roche will distribute the product outside of the United States. The parties will share gross profits from worldwide sales based on a pre-specified formula, depending on the amount of manufactured product delivered by each party. Any profit sharing will commence after product manufactured by Roche receives regulatory approval and is supplied to the market.

Collaboration, License, and Other 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 (see further details below regarding Sanofi's use of these shares for the funding of certain development costs).

Antibody

As of September 30, 2020, we were collaborating with Sanofi on the global development and commercialization of Dupixent, Kevzara, and itepekimab (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 itepekimab (collectively, the "Dupilumab/Itepekimab 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/Itepekimab 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 in 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 sales milestone payments from Sanofi. In the third quarter of 2020, the Company earned, and recognized as revenue, the first $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.0 billion on a rolling twelve-month basis. We are entitled to receive up to an aggregate of $200.0 million in additional milestone payments from Sanofi, including the second sales milestone in the amount of $50.0 million, when such sales outside the United States exceed $1.5 billion on a rolling twelve-month basis.

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.

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.

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, 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 September 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/Itepekimab 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/Itepekimab 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/Itepekimab 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 September 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

Odronextamab (REGN1979)

In April 2020, we entered into an agreement with Zai Lab Limited to develop and commercialize odronextamab 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 odronextamab, 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 odronextamab to Zai. If odronextamab 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 up-front payment and the amount paid in excess of the fair market value of the shares purchased, or $15.0 million, were recorded to Research and development expense in the second quarter of 2020.

BARDA

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 Inmazeb. We expect to deliver a pre-specified number of Inmazeb treatment doses over the course of approximately six years.

See "Agreements Related to COVID-19 - *BARDA"* section above for information related to our COVID-19 agreement.

Corporate Information

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

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

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

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

Results of Operations

Three and Nine Months Ended September 30, 2020 and 2019

Certain revisions have been made to the previously reported September 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

(In millions, except per share data)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Revenues	$ 2,294.0	$ 1,743.7	$ 6,074.2	$ 4,694.1
Operating expenses	1,240.9	1,005.2	3,664.6	3,160.0
Income from operations	1,053.1	738.5	2,409.6	1,534.1
Other (expense) income, net	(54.8)	30.0	176.2	5.2
Income before income taxes	998.3	768.5	2,585.8	1,539.3
Income tax expense	156.2	98.9	221.8	215.5
Net income	$ 842.1	$ 669.6	$ 2,364.0	$ 1,323.8
Net income per share - diluted	$ 7.39	$ 5.86	$ 20.36	$ 11.54

Revenues

(In millions)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	$ Change*	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	$ Change*
Net product sales in the United States:						
EYLEA	$ 1,318.3	$ 1,187.7	$ 130.6	$ 3,604.0	$ 3,422.1	$ 181.9
Libtayo	71.6	47.6	24	196.6	115.2	81.4
Praluent	48.5	*	*	95.7	*	*
REGN-COV2	40.2	—	40.2	40.2	—	40.2
ARCALYST	3.6	3.0	0.6	9.3	10.7	(1.4)
Sanofi and Bayer collaboration revenue:						
Sanofi	353.3	175.0	178.3	869.3	232.8	636.5
Bayer	299.9	293.6	6.3	825.5	834.8	(9.3)
Other revenue	158.6	36.8	121.8	433.6	78.5	355.1
Total revenues	$ 2,294.0	$ 1,743.7	$ 550.3	$ 6,074.2	$ 4,694.1	$ 1,380.1

* 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 increased for the three and nine months ended September 30, 2020, compared to the same periods in 2019, due to higher sales volume partly offset by an increase in sales-related deductions primarily due to higher rebates and discounts. Overall U.S. EYLEA demand was lower in April 2020 due to the impact of the COVID-19 pandemic compared to the same period of 2019. While we observed an increase in U.S. EYLEA demand during the subsequent months of the second and third quarters 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, social distancing, and other similar measures 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, License, and Other Agreements - *Sanofi - Antibody*" section above for further details.

During the three months ended September 30, 2020, net product sales of REGN-COV2 were recorded in connection with our agreement with the U.S. government. Refer to "Agreements Related to COVID-19 - *BARDA*" section above for further details.

Sanofi Collaboration Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 212.8	$ 94.2	$ 555.6	$ 105.2
Sales-based milestone earned	50.0	—	50.0	—
Reimbursement for manufacturing of commercial supplies[(1)]	94.3	85.4	275.0	143.8
Total Antibody	357.1	179.6	880.6	249.0
Immuno-oncology:				
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(4.7)	(4.6)	(17.3)	(16.2)
Reimbursement for manufacturing of commercial supplies[(1)]	0.9	—	6.0	—
Total Immuno-oncology	(3.8)	(4.6)	(11.3)	(16.2)
Total Sanofi collaboration revenue	$ 353.3	$ 175.0	$ 869.3	$ 232.8

[(1)] 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 nine months ended September 30, 2020, the change in our share of profits in connection with commercialization of antibodies, compared to the same periods of 2019, was driven by higher Dupixent profits and, to a lesser extent, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Dupixent, Praluent, and Kevzara net product sales[1]	$ 1,142.6	$ 757.6	$ 3,151.0	$ 1,918.4
Regeneron's share of collaboration profits	$ 233.7	$ 105.0	$ 618.1	$ 120.1
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(20.9)	(10.8)	(62.5)	(14.9)
Regeneron's share of profits in connection with commercialization of antibodies	$ 212.8	$ 94.2	$ 555.6	$ 105.2
Regeneron's share of collaboration profits as a percentage of Dupixent, Praluent, and Kevzara net product sales[1]	19 %	12 %	18 %	5 %

[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, License, and Other 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.

In the third quarter of 2020, the Company earned, and recognized as revenue, the first $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.0 billion on a rolling twelve-month basis.

Bayer Collaboration Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 287.9	$ 275.0	$ 772.6	$ 793.3
Reimbursement for manufacturing of commercial supplies[1]	12.0	18.6	52.9	41.5
Total Bayer collaboration revenue	$ 299.9	$ 293.6	$ 825.5	$ 834.8

[1] 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 September 30,		Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
EYLEA net product sales outside the United States	$ 780.0	$ 730.2	$ 2,102.7	$ 2,114.9
Regeneron's share of collaboration profit from sales outside the United States	$ 302.5	$ 289.2	$ 816.0	$ 835.5
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(14.6)	(14.2)	(43.4)	(42.2)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 287.9	$ 275.0	$ 772.6	$ 793.3
Regeneron's net profit as a percentage of EYLEA net product sales outside the United States	37 %	38 %	37 %	38 %

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 nine months ended September 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 antibodies for the treatment of COVID-19 and Inmazeb for the treatment of Ebola; 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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except headcount data)	**2020**	**2019**	**$ Change**	**2020**	**2019**	**$ Change**
Research and development[1]	$ 684.6	$ 526.0	$ 158.6	$ 1,990.5	$ 1,897.6	$ 92.9
Selling, general, and administrative[1]	326.9	304.4	22.5	1,042.5	890.1	152.4
Cost of goods sold[2]	131.0	115.9	15.1	312.3	253.8	58.5
Cost of collaboration and contract manufacturing[3]	143.0	109.6	33.4	454.5	289.6	164.9
Other operating (income) expense, net	(44.6)	(50.7)	6.1	(135.2)	(171.1)	35.9
Total operating expenses	$ 1,240.9	$ 1,005.2	$ 235.7	$ 3,664.6	$ 3,160.0	$ 504.6
Average headcount	8,657	7,925	732	8,314	7,674	640

[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 $101.2 million and $117.1 million for the three months ended September 30, 2020 and 2019, respectively, and $310.5 million and $330.8 million for the nine months ended September 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 September 30, 2020	2019*	$ Change	Nine Months Ended September 30, 2020	2019*	$ Change
Direct research and development expenses:						
Libtayo (cemiplimab)	$ 46.9	$ 33.6	$ 13.3	$ 118.4	$ 112.0	$ 6.4
Dupixent (dupilumab)	31.3	22.6	8.7	97.4	67.9	29.5
REGN-COV2	70.2	—	70.2	84.3	—	84.3
Fasinumab	39.9	57.0	(17.1)	123.6	166.7	(43.1)
EYLEA	19.7	16.3	3.4	48.5	41.6	6.9
Evinacumab	8.0	9.6	(1.6)	26.8	24.6	2.2
Kevzara (sarilumab)	6.9	4.6	2.3	66.3	11.0	55.3
Up-front payments related to license and collaboration agreements	—	—	—	85.0	400.0	(315.0)
Other product candidates in clinical development and other research programs	100.3	82.1	18.2	294.6	243.2	51.4
Total direct research and development expenses	323.2	225.8	97.4	944.9	1,067.0	(122.1)
Indirect research and development expenses:						
Payroll and benefits	205.1	171.8	33.3	596.5	510.5	86.0
Lab supplies and other research and development costs	41.8	32.8	9.0	107.2	94.3	12.9
Occupancy and other operating costs	83.0	79.6	3.4	245.8	226.7	19.1
Total indirect research and development expenses	329.9	284.2	45.7	949.5	831.5	118.0
Clinical manufacturing costs	177.8	153.4	24.4	539.3	455.0	84.3
Reimbursement of research and development expenses by collaborators	(146.3)	(137.4)	(8.9)	(443.2)	(455.9)	12.7
Total research and development expenses	$ 684.6	$ 526.0	$ 158.6	$ 1,990.5	$ 1,897.6	$ 92.9

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

Research and development expenses for the nine months ended September 30, 2020 included $85.0 million in aggregate up-front payments made in connection with our collaboration agreement with Intellia (see "Collaboration, License, and Other Agreements - *Intellia*" above). Research and development expenses for the nine months ended September 30, 2019 included a $400.0 million up-front payment to Alnylam.

Research and development expenses included non-cash compensation expense of $55.9 million and $60.0 million for the three months ended September 30, 2020 and 2019, respectively, and $169.5 million and $178.0 million for the nine months ended September 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 nine months ended September 30, 2020, compared to the same period in 2019, primarily due to higher headcount-related costs, an increase in commercialization-related expenses for EYLEA and Libtayo, higher contributions to independent not-for-profit patient assistance organizations, additional accruals for loss contingencies associated with ongoing litigation, and, effective April 1, 2020, no longer receiving Praluent-related cost reimbursements from Sanofi for Regeneron-incurred expenses. Selling, general, and administrative expenses also included non-cash compensation expense of $35.9 million and $40.8 million for the three months ended September 30, 2020 and 2019, respectively, and $114.4 million and $122.3 million for the nine months ended September 30, 2020 and 2019, respectively.

Cost of Goods Sold

Cost of goods sold increased for the nine months ended September 30, 2020, compared to the same period in 2019, primarily in connection with higher product sales including (i) our obligation to pay Sanofi its share of Libtayo U.S. gross profits and (ii) third-party royalties. These increases were partly offset by lower period costs for our Limerick commercial manufacturing facility.

Cost of Collaboration and Contract Manufacturing

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

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 months ended September 30, 2020, compared to the same period in 2019, was negatively impacted by the recognition of unrealized losses on equity securities. In addition, interest expense for the three months ended September 30, 2020, compared to the same period in 2019, increased as a result of the 2020 bridge loan facility and issuance of senior notes (as described below). Other income (expense), net, for the nine months ended September 30, 2020, compared to the same period in 2019, was primarily affected by the positive impact of the recognition of unrealized gains on equity securities.

Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except effective tax rate)	**2020**	**2019**	**2020**	**2019**
Income tax expense	$ 156.2	$ 98.9	$ 221.8	$ 215.5
Effective tax rate	15.6 %	12.9 %	8.6 %	14.0 %

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

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	September 30, 2020	December 31, 2019	$ Change
Financial assets:			
Cash and cash equivalents	$ 1,573.0	$ 1,617.8	$ (44.8)
Marketable securities - current	1,452.9	1,596.5	(143.6)
Marketable securities - noncurrent	2,875.1	3,256.8	(381.7)
	$ 5,901.0	$ 6,471.1	$ (570.1)
Working capital:			
Current assets	$ 9,097.6	$ 7,689.1	$ 1,408.5
Current liabilities	2,337.8	2,096.6	241.2
	$ 6,759.8	$ 5,592.5	$ 1,167.3

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

Sources and Uses of Cash for the Nine Months Ended September 30, 2020 and 2019

(In millions)	September 30, 2020	September 30, 2019	$ Change
Cash flows provided by operating activities	$ 1,387.1	$ 1,642.6	$ (255.5)
Cash flows provided by (used in) investing activities	$ 234.4	$ (1,819.1)	$ 2,053.5
Cash flows (used in) provided by financing activities	$ (1,665.2)	$ 93.6	$ (1,758.8)

Cash Flows from Operating Activities

Our net income for the nine months ended September 30, 2020 included a $50.0 million sales-based milestone related to Sanofi sales of antibodies outside the United States (see "Collaboration, License, and Other Agreements - *Sanofi - Antibody*" above for further details) and $85.0 million up-front payments made to Intellia pursuant to our collaboration agreements. Our net income for the nine months ended September 30, 2020 also included $133.8 million related to unrealized gains (net) on equity securities (included in other non-cash items). As of September 30, 2020, Sanofi, trade, and other accounts receivables increased by $1.275 billion, compared to December 31, 2019, primarily as a result of extending payment terms to certain of our EYLEA customers due to the COVID-19 pandemic. Deferred taxes as of September 30, 2020 decreased by $117.9 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 nine months ended September 30, 2020 included proceeds in connection with funding our stock repurchase from Sanofi (as described below). Capital expenditures during the nine months ended September 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 $570 million to $600 million for the full year of 2020 primarily in connection with these projects.

Cash Flows from Financing Activities

During the nine months ended September 30, 2020, we paid an aggregate of $5.5 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 additional information under "*Secondary Offering and Purchase of Regeneron Common Stock Held by Sanofi*" below. During the three months ended September 30, 2020, we issued and sold $2.0 billion aggregate principal amount of senior unsecured notes and used a portion of the net proceeds to repay in full the bridge loan facility. See additional information under "*Issuance of Senior Notes*" below.

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $2.5 billion during the nine months ended September 30, 2020, compared to $163.5 million during the nine months ended September 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 nine months ended September 30, 2020, we repurchased 898,991 shares of our Common Stock under the program and recorded the cost of the shares received, or $373.3 million, as Treasury Stock. As of September 30, 2020, the Company had $372.7 million which remained available for share repurchases under the program.

Sanofi Funding of Certain Development Costs

As described above in "Collaboration, License, and Other Agreements - *Sanofi*," effective January 7, 2018, we agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development and/or Dupilumab/Itepekimab Eligible Investments incurred in periods through September 30, 2020 by selling shares (of which 279,766 shares remained available to be sold as of September 30, 2020) of our Common Stock directly or indirectly owned by Sanofi. During the nine months ended September 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 nine months ended September 30, 2020. In addition, during the nine months ended September 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/Itepekimab Eligible Investments. Consequently, we recorded the cost of the shares received, or $93.3 million, as Treasury Stock during the nine months ended September 30, 2020.

Secondary Offering and Purchase of Regeneron Common Stock Held by Sanofi

As described above in "Collaboration, License, and Other 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/Itepekimab 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 bore interest at a variable interest rate based on either the London Interbank Offered Rate or the alternate base rate, plus an applicable margin that varied with our debt rating and total leverage ratio. As described below, the Bridge Facility was repaid in August 2020 following the issuance and sale of the Company's senior unsecured notes.

Issuance of Senior Notes

In August 2020, we issued and sold $1.250 billion aggregate principal amount of senior unsecured notes due 2030 (the "2030 Notes") and $750 million aggregate principal amount of senior unsecured notes due 2050 (the "2050 Notes" and, together with the 2030 Notes, the "Notes"). Net proceeds from the issuance and sale of the Notes (after deducting underwriting discounts and offering expenses) were used in part to repay in full the Bridge Facility described above, including accrued interest and related fees and expenses in connection therewith.

The 2030 Notes accrue interest at the rate of 1.750% per year and will mature on September 15, 2030. The 2050 Notes accrue interest at the rate of 2.800% per year and will mature on September 15, 2050. Interest on each series of Notes is payable semi-annually in arrears on March 15 and September 15 of each year, commencing on March 15, 2021, until their respective maturity dates.

The Notes may be redeemed at the Company's option at any time at 100% of the principal amount plus accrued and unpaid interest, and, until a specified period before maturity, a specified make-whole amount. The Notes contain a change-of-control provision that, under certain circumstances, may require the Company to offer to repurchase the Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest.

The Notes also contain certain limitations on the Company's ability to incur liens and enter into sale and leaseback transactions, as well as customary events of default.

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 nine months ended September 30, 2020.

Future Impact of Recently Issued Accounting Standards

As of September 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 September 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 September 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 or otherwise commercialized by us and/or our collaborators under our collaboration agreements with them, unless otherwise stated or required by the context. In this section, we first provide a summary of the more significant risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Summary of Risk Factors

As noted above, we are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in this "Risk Factors" section. Please carefully consider all of the information in this Form 10-Q, including the full set of risks set forth in this "Risk Factors" section, and in our other filings with the U.S. Securities and Exchange Commission before making an investment decision regarding Regeneron.

Risks Related to the COVID-19 Pandemic

- Our business may be further adversely affected by the effects of the COVID-19 pandemic, including those impacting 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, as well as the demand for our marketed products.
- We face risks related to the development, manufacturing, and potential commercialization of REGN-COV2.

Commercialization Risks

- We are substantially dependent on the success of EYLEA and Dupixent.
- Sales of our products are dependent on the availability and extent of reimbursement from third-party payors, including private payors and government programs such as Medicare and Medicaid, which could change due to various factors such as the drug price control measures recently announced by the Trump administration.
- The commercial success of our products is subject to significant competition from products or product candidates that may be superior to, or more cost effective than, our products or product candidates.
- We and our collaborators on which we rely to commercialize some of our marketed products may be unable to continue to successfully commercialize or co-commercialize our products, both in the United States and abroad.

Regulatory and Development Risks

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- Serious complications or side effects in connection with the use or development of our products or product candidates 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.
- 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.
- Many of our products are intended to be used in combination with drug-delivery devices, which may result in additional regulatory, commercialization, and other risks.

Intellectual Property and Market Exclusivity Risks

- We may not be able to protect the confidentiality of our trade secrets, and our patents or other means of defending our intellectual property may be insufficient to protect our proprietary rights.
- Patents or proprietary rights of others may restrict our development, manufacturing, and/or commercialization efforts and subject us to patent litigation and other proceedings that could find us liable for damages.
- Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products, including EYLEA.

Manufacturing and Supply Risks

- We rely on limited internal and contracted manufacturing and supply chain capacity, which could adversely affect our ability to commercialize our products and to advance our clinical pipeline. As we increase our production in anticipation of potential regulatory approval for our product candidates (such as REGN-COV2), 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.
- 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 products approved for marketing and could jeopardize our clinical development programs.

- 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.
- 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.
- Third-party service or supply failures, failures at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, or failures at the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.
- 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 regulatory approval is obtained, and a reduction in sales.

Other 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.
- Our business activities have been, and may in the future be, challenged under federal or state healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.
- We face risks from the improper conduct of our employees, agents, contractors, or collaborators, including those relating to potential non-compliance with relevant laws and regulations such as the Foreign Corrupt Practices Act.
- Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials.
- Changes in laws and regulations affecting the healthcare industry could adversely affect our business.
- Tax liabilities and risks associated with our operations outside of the United States could adversely affect our business.
- 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.

Risks Related to Our Reliance on Third Parties

- If our collaborations with Sanofi or Bayer are terminated or breached, 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.
- 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.

Other Risks Factors – Risks Related to Employees, Information Technology, Financial Results and Liquidity, and Our Common Stock

- Our business is dependent on our key personnel and will be harmed if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations.
- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.
- 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.
- Our indebtedness could adversely impact our business.
- Our stock price is extremely volatile.
- Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.

* * *

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," the ongoing COVID-19 pandemic continues to impact clinical trial execution in many regions across the world for us and our collaborators. 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, the timing of regulatory review, and any anticipated program milestones. Further, while we continue to focus on developing a novel therapy 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.

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.

We face risks related to the development, manufacturing, and potential commercialization of REGN-COV2.

In response to the recent global outbreak of COVID-19, we are pursuing the development and manufacturing of REGN-COV2, a novel investigational antibody "cocktail" treatment designed to prevent and treat infection from the SARS-CoV-2 virus. While we recently announced positive results from the ongoing Phase 2/3 seamless trial in non-hospitalized patients with COVID-19, there are multiple ongoing clinical trials to evaluate the and efficacy of REGN-COV2 and there is no assurance of favorable results from any ongoing or future clinical trials or the timing of their completion. For example, in October 2020, the IDMC for the REGN-COV2 treatment trials recommended that further enrollment of hospitalized patients requiring high-flow oxygen or mechanical ventilation be placed on hold. It is possible that the FDA and other regulatory authorities may not approve REGN-COV2 for the treatment of COVID-19, or that any marketing approvals, if granted, may have significant limitations on its use. Further, other parties may be successful in developing a more effective treatment for COVID-19. As a result, we may never successfully commercialize REGN-COV2. The intense public interest, including speculation by the media, in the development of REGN-COV2 has caused significant volatility in our stock price, which we expect to continue as data and other information from the ongoing and any future clinical trials evaluating REGN-COV2 and third-party product candidates for the treatment or prevention of COVID-19 as well as any regulatory actions become public.

We also face risks related to our significant investment in the development, supply, allocation, distribution, pricing, and potential commercialization of REGN-COV2. Given the severity and urgency of the COVID-19 pandemic, we have committed significant capital and resources to fund and supply clinical trials and to accelerate and scale up the production of REGN-COV2, which involves a complex manufacturing process that is both resource- and time-sensitive. We expect our investment in the development and manufacture of REGN-COV2 to continue through 2021 and beyond, although the magnitude of our investment will be subject to clinical data results, the duration of the COVID-19 pandemic, and other factors, including regulatory outcomes. If we are unable to obtain regulatory approvals, or if we make a strategic decision to discontinue development of REGN-COV2 or are otherwise not successful in the commercialization of REGN-COV2, we will be unable to recoup our significant expenses incurred to date and in the future related to the development and production of REGN-COV2.

In addition, our internal manufacturing capacity will likely not be sufficient to cover the demand for REGN-COV2 if we receive regulatory approval or are otherwise authorized to market this therapy. While we have entered into a collaboration agreement with Roche to develop, manufacture, and distribute REGN-COV2, we cannot be certain that the technology transfer process required to allow Roche to manufacture REGN-COV2 will be completed in the expected time frame or at all nor can we be certain that this collaboration will result in the anticipated increase in the current manufacturing and distribution capacity for REGN-COV2 or that any increased manufacturing and distribution capacity will be sufficient. We and Roche also face challenges related to the allocation of existing and future supply of REGN-COV2, particularly with respect to geographic distribution. As supplies of REGN-COV2 are expected to remain constrained, it is possible that the U.S. government may limit or restrict our ability to distribute and commercialize REGN-COV2 outside of the United States. In addition, as a result of the emergency situations in many countries, there is a heightened risk that REGN-COV2 may be subject to adverse governmental actions in certain countries. 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. 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. Further, we have observed and are likely to continue to face significant public attention and scrutiny over the complex decisions made regarding the REGN-COV2 development program, including any allocation, distribution, or pricing decisions with respect to REGN-COV2. If we are unable to successfully manage these risks, we could face significant reputational harm, which could negatively affect our stock price.

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 nine months ended September 30, 2020 and 2019, EYLEA net sales in the United States represented 59% and 73% 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 proceedings relating to EYLEA, 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 and other matters 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 regulatory approval is obtained, 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 HHS 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 September 2020, President Trump signed an executive order entitled "Lowering Drug Prices by Putting America First" (the "MFN Executive Order"). The MFN Executive Order provides that it is "the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price" within the member countries of the Organization for Economic Co-operation and Development (the "MFN Price"); and directs the Secretary of the HHS to implement rulemaking to test a payment model pursuant to which Medicare would pay no more than the MFN Price for certain drugs covered by Medicare Parts B and D. While the scope, details, and implementation 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. There are several other potentially competitive products in development that may compete with Dupixent in asthma, as well as potential future indications, including antibodies against thymic stromal lymphopoietin ("TSLP"), the IL-33 ligand, or the IL-33 receptor (ST2). Dupixent also faces competition from orally administered small molecule agents and inhaled products in asthma and potential future indications.

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 or otherwise commercialized 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 small interfering RNA molecules, or 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, including antibody generation technologies and other approaches such as RNA interference (RNAi) and chimeric antigen receptor T cell (CAR-T cell) technologies. For example, 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 nine months ended September 30, 2020, our gross product sales of such products to two customers accounted on a combined basis for 86% 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 if we decide 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 regulatory approval is obtained, 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 regular way drug approval process, the FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. If we are granted an EUA for any of our product candidates (such as REGN-COV2), we would be able to commercialize any such product candidate prior to FDA approval. However, there is no guarantee that the FDA will grant an EUA for any of our product candidates; in addition, the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long an EUA (if it is granted with respect to any of our product candidates) would remain in effect for any such product candidate. Such revocation could adversely impact our business in a variety of ways, including by having to absorb related manufacturing and overhead costs as well as potential inventory write-offs if regulatory approval is not obtained timely or at all.

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 IDMCs. 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 IDMCs based on their review of such interim trial results. For example, in August 2020, we discontinued actively treating patients with fasinumab (which at such time only involved dosing in an optional second-year extension phase of one trial) following a recommendation from the responsible IDMC that the program be terminated based on available evidence to date. The

recommended termination or material modification of any of our ongoing late-stage clinical trials by an IDMC 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 and the EU, 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. In addition, other parties may allege that our drug-delivery devices 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. 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 and other means. 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 awards of damages 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; garetosmab, an antibody to Activin A; pozelimab, an antibody to C5; odronextamab, a bispecific antibody targeting CD20 and CD3; and

REGN-COV2, a novel investigational antibody "cocktail" treatment designed to prevent and treat infection from the SARS-CoV-2 virus.

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 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 we receive regulatory approval or are otherwise authorized to market this therapy. 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. For example, as described in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations," in August 2020, we announced a collaboration agreement with Roche to develop, manufacture, and distribute REGN-COV2. We cannot be certain that the technology transfer process required to allow Roche to manufacture REGN-COV2 will be completed in the expected time frame or at all nor can we be certain that this collaboration will result in the anticipated increase in the current manufacturing and distribution capacity for REGN-COV2 or that any increased manufacturing and distribution capacity will be sufficient. 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 regulatory approval is obtained, 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.

Other 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.

Our business activities have been, and may in the future be, challenged under federal or state healthcare laws, which may subject us to civil or criminal proceedings, investigations, or 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 are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. 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 U.S. government 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 itepekimab), 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.

We are developing MUC16xCD3 Program antibodies (such as REGN4018) and BCMAxCD3 Program antibodies (such as REGN5458 and REGN5459) under the amended and restated IO Discovery and Development Agreement with Sanofi and Sanofi has the right to elect to co-develop these antibodies under our IO Collaboration. 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 and ransomware, 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 or extortion) 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, there is no guarantee that we will have the ability to pay the principal amount due on the Notes at maturity or redeem, repurchase, or refinance the Notes prior to maturity on acceptable terms or at all. 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 September 30, 2020, we had an aggregate of $2.695 billion of outstanding indebtedness under the Notes 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 or otherwise commercialized 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 September 30, 2020, we had $1.573 billion in cash and cash equivalents and $4.328 billion in marketable securities (including $777.6 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 interest for borrowings (if any) with an interest rate based on the LIBOR rate under our revolving credit facility, all of 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 September 30, 2020, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 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 $372.7 million remained available as of September 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 September 30, 2020, holders of Class A Stock held 15.0% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2020:

- our current executive officers and directors beneficially owned 8.5% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2020, and 19.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2020; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2020. In addition, these five shareholders plus our Chief Executive Officer held approximately 46.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 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 we repurchased under our share repurchase program, as well as 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, during the three months ended September 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
7/1/2020–7/31/2020	9	$ 655.57	—	473,117,435
9/1/2020–9/30/2020	179,828 [(a)]	$ 558.55	179,824 [(a)]	372,677,037
Total	179,837 [(a)]		179,824 [(a)]	

[(a)] The difference between the total number of shares purchased and the total number of shares purchased as part of a publicly announced program is related to Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock awards or restricted stock units granted under one of our long-term incentive plans.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
4.1	Indenture, dated August 12, 2020, between Regeneron Pharmaceuticals, Inc. (the "Registrant") and U.S. Bank National Association. (Incorporated by reference from the Form 8-K for the Registrant, filed August 12, 2020.)
4.2	First Supplemental Indenture, dated August 12, 2020, between the Registrant and U.S. Bank National Association. (Incorporated by reference from the Form 8-K for the Registrant, filed August 12, 2020.)
4.3	Form of 1.750% Senior Note due 2030 (included in Exhibit 4.2).
4.4	Form of 2.800% Senior Note due 2050 (included in Exhibit 4.2).
10.1*	Base Agreement, dated as of July 6, 2020, by and between the Registrant and Advanced Technology International.
10.2*	Project Agreement, dated as of July 6, 2020, by and between the Registrant and Advanced Technology International.
10.3*	License Agreement, dated as of August 18, 2020, by and among the Registrant, F. Hoffman-La Roche Ltd, and Genentech, Inc.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2020 and 2019; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2020 and 2019; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the nine months ended September 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).

* 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: November 5, 2020

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

Exhibit 10.1

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.

BASE AGREEMENT

BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL (ATI)
315 SIGMA DRIVE

SUMMERVILLE, SC 29486

AND

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) BASE AGREEMENT NO.: 2020-504

Authority: MCDC Other Transaction Agreement (OTA) No. W15QKN-16-9-1002 and 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act (NDAA), Public Law (P.L.) 114-92.

This Agreement is entered into between the Advanced Technology International hereinafter referred to as the "Consortium Management Finn (CMF)," and Regeneron Pharmaceuticals. Inc, hereinafter referred to as "Project Agreement Holder." This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

ADVANCED TECHNOLOGY INTERNATIONAL

/s/
(Signature)

_____
(Name & Title)

July 6 2020
(Date)

REGENERON PHARMACEUTICALS, INC.

/s/ Robert Landry
(Signature)

Robert Landry, Executive Vice President, Finance and Chief Financial Officer
(Name & Title)

July 6 2020
(Date)

Article I. SCOPE OF THE AGREEMENT

Section 1.01 Background

The U.S. Army Contracting Command-New Jersey (ACC-NJ) is entering into a Section 815 Prototype Other Transaction Agreement (OTA) with the Medical CBRN Defense Consortium, c/o Advanced Technology International 315 Sigma Drive, Summerville, SC 29486. The Joint Project Manager for Medical Countermeasure Systems (JPM-MCS) through the Joint Program Executive Office for Chemical and Biological Defense (JPEO- CBD) seeks to collaborate with the MCDC to carry out a coordinated research and development program. An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel. The MCDC was formed in response to the Government's expressed interest to engage with an industry consortium comprised of traditional and nontraditional government contractors, small and large businesses, for-profit and not-for-profit entities, academic organizations and their affiliates for the purpose of entering into an OTA for prototype projects.

Under the OTA and associated awards, the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the areas contained within the scope of this OTA as listed in Article I, Section 1.03.

Section 1.02 Definitions

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreement" refers to the Base Agreement between the Medical CBRN Defense Consortium (MCDC) Consortium Management Firm (CMF) Advanced Technology International (ATI) and the Project Agreement Holder.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final OTA for the Government.

"Agreements Officer Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of the specific project; the AOR shall only assist in agreement administration of the specific project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

"Basket" is an electronic file containing proposals that have been submitted by MCDC Members in response to Requests for Prototype Proposals (RPP), reviewed by the Government, and favorably evaluated in accordance with the procedures outlined in Section 1.03 of this Article.

"Cash Contribution" means a MCDC member organization's financial resources expended to conduct a project awarded under this Agreement. The cash contribution can be derived from MCDC member organization funds or outside sources or may also come from non-federal contract or grant revenues or from profit or fee on a federal procurement contract. A MCDC member organization's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds can be utilized as a cash contribution provided those funds identified by the MCDC member organization are to be spent on the conduct of a project's Statement of Work. Prior IR&D will not be considered as part of the MCDC member organization's cash or in kind contributions nor will fee be considered on the Project Awards that include cost sharing. Cash contributions include the funds a MCDC member organization will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), subcontractor efforts expended on a project, and restocking the parts and material consumed under a project.

"Consortium Management Firm (CMF)" refers to the organization acting on behalf of the MCDC to execute and administer the efforts under the Other Transaction Agreement for this program as defined in the specific agreement

entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

“Cost Share” means resources expended by the PAH on the proposed project SOW and subject to the direction of the AOR. There are two kinds of cost share: cash contribution and in-kind contribution. Cost Share may only be proposed and collected on cost-reimbursement type agreements.

“Contracting Activity” means an element of an agency designated by the agency head and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency which has been delegated contracting authority through its agency charter.

“Date of Completion” is the date on which all work is completed or the date on which the period of performance ends.

“Development” means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service) for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

“Effective Date” means the date when this Agreement is signed and executed by the Agreements Officer for the Government.

“Government” means the US Government and its departments and agencies.

“Government Fiscal Year” means the period commencing on October 1 and ending September 30 of the following calendar year.

“In Kind Contribution” means the MCDC member organization’s nonfinancial resources expended by the MCDC member organization to conduct a project, such as wear and tear on in-place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of the project.

“JPM-MCS” means the Joint Project Manager-Medical Countermeasure Systems Office created for the advanced development of medical countermeasures for chemical and biological defense. The JPM-MCS is also the program management office for this overall effort. The JPM-MCS includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

“Milestone” means a scheduled event signifying the completion of a major deliverable or a set of related deliverables.

“Medical CBRN Defense Consortium” is the consortium formed by industry in response to the Government’s expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions. The MCDC was originally named the National Chemical and Biologic Defense Consortium.

“MCDC Executive Committee” is the Executive Committee, comprised of Traditional and Nontraditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions.

“MCDC Members” means the Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and Academic Research Institutions that are members in good standing of the MCDC.

“Nontraditional Defense Contractor” with respect to applicable authority, means an entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

“Other Transaction Agreement (OTA)” refers to the Section 815 Other Transaction Agreement between the Government and the MCDC by its Consortium Management Firm, Advanced Technology International, Agreement No. W15QKN-16-9-1002.

“Other Transactions for Prototype Projects” refers to this type of Other Transaction Agreement (OTA). Section 815 of Public Law 114-92 authorizes the use of OTAs, under the authority of 10 U.S.C. 2371(b), under certain circumstances for prototype projects directly relevant to enhancing the mission effectiveness of military personnel and supporting the platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. This type of OTA is treated by DoD as an acquisition instrument, commonly referred to as an “other transaction” for a prototype project or Section 815 “other transaction”.

“Parties” means the Consortium Management Firm, Advanced Technology International, and the Project Agreement Holder where collectively identified and “Party” where each entity is individually identified.

“Payable Milestone” means that once a milestone has been met (see definition of “milestone”), the Government can approve payment to the MCDC of a predetermined dollar amount in relation to performance of a particular project under the Other Transaction Agreement.

“Program Manager” means the Technical Administrator for the Program (located at the JPM-MCS) responsible for Government oversight of the MCDC OTA program.

“Project” refers to the scope of work being completed under a Project Agreement.

“Project Agreement (PA)” means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms and conditions for the MCDC member entity performance and payment under the Government funded project. Project Agreements shall comply with all provisions contained within the OTA and any other supporting documents referenced therein. The Project Agreement is initiated by the CMF based on the Technical Direction Letter sent by the Government to the CMF.

“Project Agreement Holder (PAH)” means the MCDC member entity issued a Project Agreement by the CMF.

“Technical Direction Letter (TDL)” is a Government document to be issued to the CMF reflecting the Government's decision to select and fund all or part of a particular proposal submitted by a MCDC member or team of MCDC members through the RPP process conducted under this OTA. The TDL shall establish the scope of work, terms and conditions for performance and payment and include the MCDC member proposal selected for Government funding. Where a specific Government agency laboratory, test facility, center or other location will be used by the MCDC member entity in performance of the Project Agreement, it will be identified and the cost of such use, whether Government-contributed or MCDC member reimbursed, will be identified in the TDL.

“United States Army Contracting Command – New Jersey Contracting Activity” (ACC-NJ) means the contracting activity who is designated as the lead Government organization in charge of executing the Program.

“White Paper” means a document limited to a few pages prepared and submitted by a MCDC member(s) in response to a Government solicitation issued under the terms and conditions of the OTA that briefly describes and summarizes a technology idea or concept for an indicated research area in a Government-specified format. The White Papers are evaluated by the Government to determine whether submission of a full proposal on the summarized concept or idea might be warranted. To the extent that a MCDC member(s) desires to include

proprietary information in the white paper it shall be identified and marked in accordance with the terms for protection of information under Article VIII. Confidential Information.

Section 1.03 Scope

The Government in conjunction with the MCDC member entities shall perform a coordinated research and development program designed to support the DoD's medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel. The mission of JPM-MCS is to provide the
U.S. military forces and the nation safe, effective, and innovative medical solutions to counter Chemical Biological Radiological and Nuclear (CBRN) threats. Under the OTA and associated Project Agreements, the Government along with the Consortium member entities, shall perform coordinated planning and research and development prototype efforts in support of the JPM-MCS mission through the development of products in three (3) major Medical Countermeasure Systems (MCS) objective areas:

- Detection: Systems and devices to identify CBRN agents and assist in making medical decisions
- Prevention: Prophylaxis, pretreatment, and post-exposure prophylaxis
- Treatment: Therapeutics (post-exposure, post-symptomatic)

The Government will determine which endeavors to pursue and projects to fund. At any time throughout the term of the OTA, the Government may address the needs for the desired MCS objective areas or other related Government needs as they arise. The MCDC and the Government agree that other organizations and agencies within the U.S. Government may participate in the collaborative activities through a Memorandum of Agreement or other such arrangement. It is anticipated that these other organizations may include JPEO-CBD and DTRA.

Request for Prototype Proposal (RPP) Process:

Once the Government identifies a need under one of the MCS objective areas above, the Government will issue a Request for Prototype Proposal (RPP). The RPP will include a Request for White Papers (RWP) and/or a Request for Prototype Proposal (RPP) to the Consortium Management Firm (CMF). Due dates will be indicated for each. The CMF shall in turn issue a similar request to MCDC's member entities, for which the Government will review and evaluate all responses. The Government will be solely responsible for evaluation of the white papers and/or proposal submissions, as applicable. If the RPP includes a RWP, only members submitting white papers will be permitted to submit full proposal submissions. Based on the evaluation of the white papers, the Government will make a recommendation on whether the member should or should not submit a full proposal submission. Any member submitting a white paper, regardless of the Government's recommendation, may submit a proposal.

MCDC member white papers and proposals shall be submitted to the CMF in accordance with the RPP instructions which will include evaluation criteria and a Statement of Work (SOW) template on the due date indicated in the RPP. The CMF will review white paper and proposal submissions for completeness and format compliance. The CMF shall in turn prepare and transmit MCDC's member's white papers and proposals to the Government for evaluation. The Government will be responsible for technical evaluation and selection of the projects from the proposals submitted. The CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government Agreement Officer will review this assessment and make the final determination regarding whether the negotiated project cost is fair and reasonable. All Project Agreements will be subject to discussions/negotiations and proposal updates, as appropriate, prior to execution.

Once all steps are complete, the Government will issue a Technical Direction Letter (TDL) to the CMF for the authorization and execution of the selected project to be performed by the selected MCDC's member entity(ies). Once the CMF receives notification of selection of a project for funding via TDL, the CMF will enter into a Project Agreement with the MCDC member.

A modification will be included with the TDL, which will include the funding for the negotiated and agreed-upon project. After receipt of the TDL and review and execution of the funding modification, the CMF shall enter into a Project Agreement (PA) with MCDC member whose project was selected. MCDC CMF shall administer the

Government-funded Project Agreements. The Government's designated Agreements Officer Representative (AOR) for the specific project will supervise the technical work performed by MCDC's member entity in execution of the

PA. The Government reserves the right to revise the terms and conditions of these projects in accordance with Article III, Section 3.04.

Placement in the Electronic "Basket File":

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. The RPP will contain the available ratings and their definitions to be assigned to proposals as a result of the technical evaluation as well as which specific ratings will qualify a proposal for inclusion in the Basket. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria.

Once in the Basket, a proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1.) request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2.) fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the Basket, the CMF will receive notification of the award decision through a TDL whereupon the CMF will enter into a Project Agreement with the indicated MCDC member as required.

A selected proposal will reside in the Basket for thirty-six (36) months from the date the corresponding RPP is closed unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

SBIR Phase III Project Requests

It will be incumbent upon the MCDC member, on their own with some general support and guidance from the CMF, to find a Government Technical POC with both (1) available funding and (2) an interest in furthering technology developed under a current or prior SBIR project. Upon doing so, the Government Technical POC will coordinate the feasibility of placing the award under the OTA with the Government AO and OTA Program Manager and the following areas will be considered when making a determination for appropriateness of award under the OTA:

- How the proposed effort derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements;
- How the proposed effort fits within the definition of a prototype effort related to medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel in accordance with the statutory requirement;
- How the proposed effort fits within the overall scope of work and the goals and objectives of the OTA.

Should the Government AO and the OTA Program Manager determine it is appropriate to award the SBIR Phase III under the OTA, the Government AO will send a proposal request to the MCDC member through the CMF, as is standard for any Government request under the OTA. The CMF will provide a cost analysis summary to the Government Agreements Officer (AO) for consideration in the Government's award determination. The Government will evaluate the proposal, conduct any necessary negotiations through the CMF, and make an award determination. If the Government makes the determination to award to the MCDC member, the Government AO will issue a TDL letter to the CMF, resulting in the issuance of a Project Agreement between the CMF and MCDC member.

SBIR Phase III awards under this Agreement shall include the Data Rights provisions and Data Rights granted to the MCDC member contained within Article XI of this Agreement. All administrative, reporting, and other aspects of awards made for SBIR Phase III efforts under this Agreement will be in accordance with the terms and conditions of the OTA. MCDC Members must have been awarded and performed under a previous SBIR Phase I and/or Phase II contract in order to qualify for SBIR Phase III award under this Agreement.

Section 1.04 Goals/Objectives

The following goals/objectives will be pursued through the execution of the OTA:

- Accelerate the development of mission critical technologies in the areas of concern from applied research into advanced development.
- Deliver therapeutic MCM prototypes targeting viral, bacterial, and biological toxin targets of interest to the DOD. MCM prototypes are drug products that have completed all or part of the activities required to support FDA licensure. This may include meeting warfighter requirements of protection against an aerosolized route of exposure.
- Deliver enabling technologies that will support the development and regulatory review of MCM prototypes. The enabling technologies can include animal models of viral, bacterial or biological toxin disease and pathogenesis (multiple routes of exposure), assays, diagnostic technologies or other platform technologies applicable to development and regulatory review of MCM.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Chemical threats. This will include diagnosis of, and prophylaxis and treatment for, exposure to traditional and emerging chemical nerve agent threats, as well as other emerging chemical threat agents other than nerve agents.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Radiological and Nuclear threats. This will include prototype candidates for diagnosis of, and prophylaxis and treatment for Acute Radiation Syndrome.
- Develop soldier-carried autoinjector delivery devices for single drug administration. Develop soldier- carried autoinjector delivery devices for administration of two or more drugs.
- Develop vaccine-manufacturing platforms that offer early stage manufacturing flexibility and diversity using a deep knowledge of protein(s) expression in a biological system that is reproducible and scalable, and preferably with direct FDA experience. The goal is to manufacture and test identified protective molecule(s) and target molecule(s) (along with associated reagents and standards) in multiple scalable, flexible manufacturing platforms encompassing a diverse array of manufacturing systems (e.g., insect, mammalian, live viral, plant, *E.coli*, yeast, etc.) for use in appropriate animal model(s) and in Phase 1 trials.
- Pharmaceutical development will address the FDA Animal Rule, as appropriate.
- Utilize adjuvants and excipients supporting the ability to develop up to 300,000 equivalent doses within 60 days at clinical quality.
- Support a family of systems diagnostic approach that increases the speed, accuracy, and confidence of agent identification and disease diagnosis. Diagnostic areas include those for organisms that circulate freely and at relatively high numbers at or near the onset of symptoms, organisms that circulate in low numbers early in infection but then integrate with host cells, organisms that have significant genomic diversity from strain to strain, and non-BW agents such as toxins/chemical agents/radiological agents that do not replicate and require low quantities to cause illness.
- Support the Defense Biological Products Assurance Office (formally the Critical Reagents Program), the principal DoD resource of high quality, validated, and standardized biological reference materials, reagents, and assays, as necessary.
- DoD Advanced Development and Manufacturing Capabilities: To facilitate lessons learned and to ensure DoD MCM product development schedules are not impacted, the consortium will consider Advanced Development and Manufacturing (ADM) capability contractors for biologics manufacturing activities for monoclonal antibodies, vaccines, and recombinant proteins may utilize the DoD funded facility.
- Pursue collaborative research with non-traditional technology providers in a manner that enables effective transition of technologies to Government prototyping programs during any phase of life cycle support (affordability, manufacturability, sustainment, etc.).

Section 1.05 Reports

The MCDC member organizations conducting projects in accordance with this Agreement shall maintain records of the activities performed and funding expended under the projects and the results of any studies analyses, tests, and other investigations conducted. Based on the progress of the funded projects and other

information known to the AO or authorized designee, the MCS Program Office shall review the relevant projects throughout the period to determine if any changes to planning or budget are required. If such a change is expected which will cause a need to modify the OTA, the Technical Direction Letter or an individual Project Agreement may be modified to incorporate such changes. The AO is the only authorized representative of the Government who may make modifications to the OTA. PAHs shall submit the following reports to the CMF who will review and provide one cumulative report detailing status of all funded projects to the MCS Program Office.

a.) Project Agreement Quarterly Report. The report will have two major sections:

(i) Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. Each of the topics described below shall be addressed for the effort performed:

(1) A comparison of actual accomplishments with the goals and objectives of the project established for the period.

(2) Reasons why established goals and objectives were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost variances.

(4) A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors, and titles.

(5) Papers presented at meetings, conferences, seminars, etc.

(ii) Business Status Report. The business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plans shall be explained with discussion of proposed actions to address the deviations. The report will also include an accounting of interest earned on Government Funds, if any. It is not expected that any interest will accrue under the Project Agreement(s), as milestone payments will be tracked and adjusted accordingly. In any event, the Government reserves the right to require interest amounts in excess of $250 per year to be remitted to the US Treasury.

b.) Annual Technical Report. Annual technical reports are required for projects whose periods of performance are greater than one year. The PAH's report will provide a concise and factual discussion of the significant accomplishments and progress during the year covered by the report.

c.) Final Technical Report.

(i) Final Technical Report (FTR). A Final Technical Report shall be submitted to the CMF within thirty (30) calendar days of the completion of the Project Agreement. This report will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. Upon receipt, the AOR will review and provide any comments within 30 days. If necessary, the PAH will update the FTR within 30 days of receipt of AOR's comments. Once the CMF has informed PAH that the FTR has been approved by the AOR, the PAH shall forward a copy of the FTR to the Defense Technical Information Center, Attn. DTIC-O, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.

(ii) Format. The cover and title page shall be Standard Form (SF) 298, Report Documentation Page. Item 13 of the form should contain a 100 to 200 word abstract summarizing technical progress during the reporting

period. Style should be third person singular using past tense. Jargon, special symbols or notations, subscripts, mathematical symbols or foreign alphabet letters are not permitted. All pages should be prepared for acquisition and distribution by the Defense Technical Information Center (DTIC). All pages should be good quality for copying purposes. The report shall be prepared in accordance with American National Standards Institute (ANSI) document Z39.18-1987, "Scientific and Technical Reports: Organization, Preparation, and Production," which may be obtained from American National Standards Institute Incorporated, 1430 Broadway, New York, NY, 10018. The FTR front page shall be marked in a conspicuous place with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations.

d.) Final Business Status Report. The final business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a final accounting of cumulative expenditures. If a project is terminated prior to the end of a quarter or a year and sufficient funding is available, the PAH, through the CMF, must submit a final technical and business status report in the same format as detailed herein.

Note: Deficiencies in regulatory reports must be adequately assessed by the Government, MCDC and the individual performer, or consortium as a whole, to come to resolution.

Article II. TERM

Section 2.01 The Term of this Agreement

The period of performance for this Agreement is from the effective date, which is the date of last signature, to April 7, 2036. If at any time funds expended exceed the amount obligated on a Project Agreement prior to the expiration of the term, the Parties have no obligation to continue performance and may elect to cease their efforts at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

Section 2.02 Termination of this Agreement by Mutual Agreement

Except for the rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government, the CMF and the MCDC member organizations, unless extended by mutual written agreement of the Parties, this Agreement shall automatically terminate by written agreement of the Parties. Unless otherwise directed by the AO through the CMF, individual Project Agreements pursuant to this Agreement shall also terminate upon the termination of this Agreement.

Section 2.03 Termination Provisions

Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA or a specific project, in whole or in part, if the AO determines that a termination is in the Government’s interest. The AO shall terminate by delivering to the MCDC through its CMF a Notice of Termination specifying the extent of termination and the effective date.

After receipt of a Notice of Termination, and except as directed by the CMF, the PAH shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its subawardees to stop work as specified in the notice.

(2) Place no further subagreements or orders (referred to as orders in this clause) for materials, services, or facilities, except as necessary to complete the continued portion of the project.

(3) Terminate all orders to the extent they relate to the work terminated.

(4) Assign to the Government, as directed by the AO, all right, title, and interest of the PAH under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.

(5) With approval or ratification to the extent required by the AO, the CMF may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this clause.

(6) Provide CMF, and/or obtain from the subawardees under the terminated portion of the Agreement a transfer of title to the following where applicable and deliver to the Government --

(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.

(7) Complete performance of any work not terminated, if applicable.

(8) Take any action that may be necessary, or that the AO may direct through the CMF, for the protection and preservation of the property related to this project that is in the possession of the PAH(s) or any subawardee and in which the Government has or may acquire an interest.

(9) Use commercially reasonable efforts to sell, as directed or authorized by the CMF, any property of the types referred to under Article II. Section 2.03 Termination Provisions, (6)(i) and (ii); provided, however, that the PAH:

(i) is not required to extend credit to any purchaser and

(ii) may arrange for the subawardee who was performing the terminated work to acquire the property under the conditions prescribed by, and at prices approved by, the CMF.

(iii) will in no event be required to continue with such efforts for more than three (3) months after notice by the CMF to sell or disposition such property.

(10) The PAH has no obligation to continue to cost share on the terminated project or terminated portion of the project.

The requirement for at least 1/3 cost share of the total project cost by the PAH is assessed prior to award. In the event that during the course of the performance of the Project Agreement any of the parties to the Project Agreement believe the cost sharing funds available will be insufficient, the PAH shall notify the CMF within twenty-five (25) days of the event that gave rise to the insufficient cost sharing funds. CMF will notify the Government within five
(5) days of receiving such notice from the PAH. The Government will determine whether it is in its best interest to either renegotiate the scope and/or terms of the Project Agreement to meet the cost share requirement or terminate the Project Agreement in whole or in part.

The proceeds of any transfer or disposition of project property will be applied to reduce any payments to be made by the Government under that particular project, including credited to the price or cost of the work, or paid in any other manner directed by the CMF.

In the event of a termination of the Project Agreement, the Government shall have patent rights as described in Article X, Patent Rights, and rights in Data as described in Article XI, Data Rights. Failure of the PAH and Government to agree to an equitable adjustment shall be resolved pursuant to Article VII, Disputes.

Section 2.04 Termination Cost

The CMF will negotiate with the Government and PAH in good faith equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects. The Government will allow full credit for the Government share of the obligations properly incurred by a PAH prior to termination. Costs incurred by a PAH during a suspension or after termination of a project are not allowable unless the CMF expressly authorizes them in either the notices of suspension, termination, or subsequently. Other PAH's costs incurred during a suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(a) The costs result from obligations which were properly incurred by the PAH before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

Section 2.05 Close-out Procedure.

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by the PAH.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(iii) "Disallowed costs" – those charges that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

(b) Upon request, the Government shall make prompt payments to the PAH through the CMF for allowable reimbursable costs under the MCS Project Agreement being closed out.

(c) The PAH shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by the PAH for use in the performance of the Project Agreement.

(d) The CMF shall obtain from the PAH within 90 calendar days after the date of completion of an MCS Project Agreement all financial, performance, and other reports required as a condition of the MCS Project Agreement. The CMF may grant extensions when requested by the PAH.

(e) When authorized, the CMF shall make a settlement for any upward or downward adjustments to the Government's share of costs after these reports are received based on final, actual expenditures in accordance with the Termination Costs provision of the Agreement.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) The PAH shall account for any property received from the Government.

Section 2.06 Stop Work

As directed by the AO, the CMF may, at any time, by written order to the PAH, require the PAH to stop all, or any part, of the work called for under this Agreement or any Project Agreement for a period of 90 days after the written order is delivered to the PAH, and for any further period to which the parties may agree. The order shall be

specifically identified as a stop-work order issued under this section. Upon receipt of the order, the PAH shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the PAH, or within any extension of that period to which the parties shall have agreed, the CMF shall either:

(a) Cancel the stop-work order; or

(b) Terminate the work covered by the Project Agreement as provided in Article II, Term and Termination.

If a stop work order issued under this clause is canceled, the PAH shall resume work. The CMF shall make an equitable adjustment in the delivery schedule or Project Agreement estimated cost/price, or both, and the Government's share of the Project Agreement shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the PAH's cost properly allocable to, the performance of any part of the Project Agreement; and

(2) The PAH asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Government decides the facts justify the action, the Government through the MCDC CMF may receive and act upon a proposal submitted at any time before final payment under the Project Agreement.

If a stop work order is not canceled and the work covered by the Project Agreement is terminated in accordance with Article II, the MCDC CMF shall work with the PAH to negotiate an equitable reimbursement in accordance with Article II. Section 2.03, Termination Provisions.

Article III. MANAGEMENT OF THE PROJECT

Section 3.01 The Medical CBRN Defense Consortium (MCDC)

The MCDC, as defined in the OTA, was formed to work with the Government and provide input in developing technologies to support the Department of Defense's (DoD) medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel ultimately resulting in fully executed research and development prototype projects selected by the Government. Every Member in this MCDC is independent of the other, and there is no affiliation between the MCDC members within the definition of 13 C.F.R. 121.103 of the Federal Small Business Regulations and no such affiliation is intended either by the formation or implementation of the MCDC.

As appointed by the MCDC Executive Committee, the CMF has the authority to execute the Other Transaction Agreement (OTA) on behalf of the MCDC and has the responsibility for day to day overall administration of this Agreement, subject to the supervision of the MCDC Executive Committee.

Section 3.02 The following MCDC decisions are subject to the ACC-NJ approval:

1. Changes to the MCDC Articles of Collaboration if such changes substantially alter the relationship of the MCDC and the Government as originally agreed upon when the OTA was executed;
2. Changes to, or elimination of, any ACC-NJ funding allocation to any MCDC Member as technically and/or financially justified.

Section 3.03 Management and Project Structure

Technical and project management of the coordinated research program established under this Agreement shall be accomplished through the management structures and processes detailed in this Article.

The Government competitively selected the MCDC, organized by its Consortium Management Firm Advanced Technology International, a Section 501(c)(3) nonprofit organization. MCDC has entered into an agreement with Advanced Technology International authorizing Advanced Technology International to enter into this OTA as the

consortium manager, engage in overall day to day management of the MCDC under the guidance of and as designated by the MCDC Executive Committee, including technical, programmatic, reporting, financial, administrative and contractual matters and administer Project Agreements required for performance under this OTA.

As established by funded projects under the OTA, the Government Program Manager shall fully participate in the appropriate program technical meetings held by the MCDC. The AORs and Other Government personnel, as deemed appropriate, also may participate in the technical portion of these meetings.

Section 3.04 Modifications

As a result of scheduled meetings, end of program reviews, or at any time during the term of the OTA, research progress or results may indicate that a change in the OTA's scope, objectives or Term would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the OTA Scope, will be documented in a letter and submitted by the PAH to the CMF, who will then forward it to the Program Manager with a copy to the AO. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the OTA. The Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the OTA Scope or other proposed changes to the terms and conditions of the OTA and subsequently this Agreement.

With regard to projects the Government determines to fund as a result of the RPP process specified in the Agreement Scope, any PAH recommendations for modifications, including justifications to support any changes to the funded projects, will be documented in a letter and submitted by the CMF to the AO with a copy to the Government Agreements Officer Representative designated for the particular project. The AO shall be responsible for review of proposed changes and for all modifications to the terms and conditions of the project awards. The CMF shall modify the Project Agreement(s) in the event of any such modifications or changes to the project.

Management of Projects

(1) Performance of the work on each project is subject to the technical direction of the AOR designated in the Project Agreement. For the purposes of this clause, technical direction includes the following:

   a. Direction to the PAH, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;
   b. Guidelines to the PAH that assist in the interpretation of drawings, specifications or technical portions of work description.
   c. Review and, where required by the Project Agreement, approval of technical reports, drawings, specifications, or technical information to be delivered by the PAH under the Project Agreement.

   The AOR shall monitor the PAH's performance with respect to compliance with the technical requirements of the Project Agreement.

(2) Technical direction must be within the general scope of work stated in the Project Agreement. Technical direction may not be used to
   a. Assign additional work under the Project Agreement;
   b. Increase or decrease the estimated Project Agreement cost, fee (if any), or the time required for the project performance;
   c. Change any of the terms, conditions or specifications of the Project Agreement; or
   d. Accept non-conforming work.

   As such, no verbal or written request, notice, authorization, direction or order received by the PAH shall be binding upon the MCDC, CMF or Government, or serve as the basis for a change in the Project Agreement cost or any other provision of the Project Agreement, unless issued (or confirmed) in writing by the MCDC CMF Contractual Representative designated in the Project Agreement.

(3) The PAH shall immediately notify the MCDC CMF Contractual Representative whenever a written change notification has been received from anyone other than the MCDC CMF Contractual Representative, which would affect any of the terms, conditions, cost, schedules, etc. of the Project Agreement, and the PAH is to perform no work or make any changes in response to any such notification or make any claim on the MCDC through its CMF or Government, unless the MCDC CMF Contractual Representative directs the PAH, in writing, to implement such change notification.

Article IV. AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

MCDC: Advanced Technology International

Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Project Agreement Holder: _____
_____
_____
_____
_____
_____

Each party may change its representatives named in this Article by written notification to the other parties. Agreements Officer

Representative (AOR): AOR will be designated by the Government on a per project basis.

Article V. OBLIGATION AND PAYMENT

Section 5.01 Obligation:

Except as specified in Article VII: Disputes, the CMF's liability to make payments to the PAH is limited only to those funds obligated under the Project Agreement(s). The CMF may incrementally fund the Project Agreement(s). If modification becomes necessary in performance of projects, pursuant to Article V of this Agreement, the CMF and the PAH shall establish and execute a revised Schedule of Payable Milestones consistent with the current Project Agreement.

Section 5.02 Project Payments:

The detailed instructions for project payments will be included in the Technical Direction Letter to be issued by the CMF on a project by project basis.

Section 5.03 Accounting System Requirements:

Prior to the submission of invoices, the PAH shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this Agreement. The PAH shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds under this Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

Section 5.04 Invoicing Instructions:

Project Payable Milestones: The PAH shall segregate and track all individual project costs separately and shall document the accomplishments of each Payable Milestone under each Project Agreement. A Payable Milestones report shall be detailed on a project basis and submitted with each request to the AOR or designee for approval.

Section 5.04 a. Payment Method Types

Project Agreements will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

(a) *Fixed Price Milestone Payment Method:* Payments shall be made in accordance with the Payable Milestone Schedule of each Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Project Agreement. Quarterly reviews by the AOR and the CMF will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone; and

(iii) lists the milestone cost negotiated and contained in each Project Agreement

(b) *Cost Reimbursable Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Task Assignment):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(c) *Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):* Payment is contingent

upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The PAH will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base t Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(d) *Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;

(iv) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(v) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(vi) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

Section 5.04 b. Submission of Invoices

Invoices may be submitted no more frequently than monthly. The PAH shall submit invoices and any necessary supporting documentation via email to .

For Cost type Project Agreements, the PAH's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

Section 5.04 c. Payment Terms

Payment terms are NET 30 days after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Article V Section 5.04a. Payment Method Types.

Section 5.05 Advance Payments:

On a per project basis, advance payments may be approved by the AO. If the AO has approved advance payments, there will be a requirement to establish a separate interest bearing account. The PAH sets up and maintains funds in a separate interest bearing account unless one of the following applies:

(1) The PAH receives less than $120,000 in Federal awards per year;

(2) The best reasonably available interest bearing account would not expect to earn interest in excess of $250 per year on such cash advances;

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected cash resources for the project; or

(4) The advance payments are made one time to reduce financing costs for large up-front expenditures and the fund will not remain in the PAH's account for any significant period of time.

Where a separate interest bearing account is set up, any interest earned should be remitted annually to the CMF. CMF shall forward the funds to the Government as directed by the AO. Interest payments shall be made payable to the U.S. Treasury.

Section 5.06 Limitation of Funds:

Except as set forth in Article VII, the Government's financial liability will not exceed the amount obligated for projects and available for payment.

Section 5.07 Financial Records and Reports:

The PAH shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for Project Agreement funding provided under this Agreement, should cost sharing procedures be implemented for funding a particular project. PAH's relevant financial records are available and subject to examination or audit on behalf of the ACC-NJ for a period not to exceed five (5) years after final payment of the PAH's project. The AO or designee shall have direct access to sufficient records and information of the PAH to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Government using Government auditors or, at the request of the PAH, by the requesting PAH's external CPA accounting firm at the expense of the requesting PAH.
AGREEMENT

Article VI. NONTRADITIONAL DEFENSE/COST SHARING

In accordance with provisions of 10 USC 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L. 114-92, which provides the Department of Defense (DoD) authority to enter into transactions *other than* contracts, grants, or cooperative agreements, the Department of Defense (DoD) has the authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or the improvement of platforms, systems, components, or materials in use by the armed forces. Section 815 revised the definition for the term ‘nontraditional defense contractor’ as defined in Article I. Section 1.01, Definitions.

Each MCDC Member Organization must meet the definition of a Nontraditional Defense Contractor or have at least one Nontraditional Defense Contractor participating to a significant extent in the performance of an awarded Project Agreement. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

If significant Nontraditional Defense Contractor participation cannot be fulfilled, the Member Organization must provide at least one third cost share of the value of the Project Agreement awarded to the Member Organization. Proposals that fail to comply with this requirement will not be awarded under the OTA.

Cost Sharing is not required under this Other Transaction Agreement for projects that contain significant nontraditional defense contractor participation. Where both Parties agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by the Parties and in accordance with the “Other Transactions” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors without a significant nontraditional defense contractor teaming partner, a one third cost share of the project costs is required as described in the “Other Transaction” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors with significant nontraditional defense contractor participation, cost sharing is not required for Projects under this OTA.

Throughout the period of performance of any Project Agreement, the Government AO and AOR will actively monitor Nontraditional Defense Contractor participation and/or cost sharing to ensure compliance with this provision in accordance with implementation guidance from HQDA and/or OSD. The PAH will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

Article VII. DISPUTES Section 7.01 General

For the purposes of this Article, “Parties” means the CMF, the PAH and the Government where collectively identified and “Party” where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

Section 7.02 Dispute Resolution Procedures

Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the ACC-NJ, Center Director for Emerging Technologies, in the interest of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the ACC-NJ, Center Director for Emerging Technologies. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ACC-NJ, Center Director for Emerging Technologies, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

If requested within thirty (30) calendar days of the ACC-NJ, Center Director for Emerging Technologies’ decision, further review will be conducted by the Chair of the MCDC Executive Committee and the ACC-NJ Associate Director. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Chair of the MCDC Executive Committee and the ACC-NJ, Associate Director (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law, including but not limited to the right to seek extraordinary relief under Public Law 85-804. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

Section 7.03 Limitation of Liability and Damages

In no event shall the liability of the MCDC PAH or any other entity performing research activities under a Project Agreement exceed the funding such entity has received for their performance of the specific Project Agreement under which the dispute arises.

No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Article VIII. CONFIDENTIAL INFORMATION

Section 8.01 Definitions

(1) “Disclosing Party” means CMF, MCDC PAHs, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) “Receiving Party” means CMF, MCDC PAHs, or the Government who receives Confidential Information disclosed by a Disclosing Party.
(3) “Confidential Information” means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. “Confidential Information” includes any information and materials considered a Trade Secret by the PAH. “Trade Secret” means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Section 8.02 Exchange of Information:

Neither the Government nor MCDC on behalf of the MCDC member entities or PAHs nor the CMF shall be obligated to transfer Confidential Information independently developed by the Government or the MCDC member entities or PAHs or the CMF absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

Section 8.03 Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such “Confidential Information” and “Trade Secrets” shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article VIII entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Section 8.04 Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

Section 8.05 Term:

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Section 8.06 Flow Down

The PAH shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, subawardees (including employees) at all levels, receiving such Confidential Information under this OTA.

Article IX. PUBLICATION AND ACADEMIC RIGHTS

Section 9.01 Use of Information.

For the purposes of this Article, “Parties” means the PAH and the Government where collectively identified and “Party” where each entity is individually identified.

Subject to the provisions of Article VIII, Confidential Information, Article IX, Publication and Academic Rights, and Article XI Data Rights, the PAH and the Government shall have the right to publish or otherwise disclose information and/or data developed by the Government and/or the respective MCDC PAH under the Research Project. The PAH and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Projects by the Government and the MCDC PAH in such publication or disclosure. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or the PAH.

Section 9.02 Publication or Public Disclosure of Information

(a) Classified Project Agreements

If a release of Confidential Information or Trade Secrets is for a classified Project Agreement, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply.

(b) Review or Approval of Technical Information for Public Release.

(1) At least 30 days prior to the scheduled release date PAH shall submit to the CMF a copy of the information to be released. In turn, CMF shall submit to the Government AOR a copy of the information to be released.

The Government AOR is hereby designated as the approval authority for the AO for such releases.

(2) Where the PAH is an Academic Research Institution performing fundamental research on campus. PAH shall provide papers and publications for provision to the CMF for provision to the Government AOR for review and comment 30 days prior to formal paper/publication submission. However, if that Academic Research Institution incorporates into its research results or publications artifacts produced by and provided to these institutions on behalf of other (non-educational institution) MCDC PAHs (or has authors listed on the paper who are not employees or students of the Academic Research Institution) then the procedures in Section 9.02(a) ABOVE must be followed.

(3) Parties to this Agreement are responsible for assuring that an acknowledgment of government support will appear in any publication of any material based on or developed under this OTA, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002 between the MCDC, and the Government**.** The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

(4) Parties to this Agreement are also responsible for assuring that every publication of material based on or developed under this project contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

The PAH shall flowdown these requirements to its subawardees, at all tiers.

(c) Notices. To avoid disclosure of Confidential Information or Trade Secrets belonging to an MCDC member entity or PAH and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the PAH that is proposing to publish or disclose such information shall provide advance notice to the MCDC, through its CMF, and identify such other parties as may have an interest in such Confidential Information. The CMF shall notify such parties at least [* * *] prior to any PAH's submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the parties during the term of and pursuant to this Agreement. The Government must notify the MCDC, through its CMF, of any objection to disclosure within this [* * *] period, or else the PAH, shall be deemed authorized to make such disclosure.

(d) Filing of Patent Applications. During the course of any such [* * *] period, the PAH shall
provide notice to the CMF as to whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that a PAH and/or the Government desires that such a patent be filed, the PAH or the Government proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

(1) Filing of a patent application covering such invention, or

(2) Written agreement, from the AO and the CMF (on behalf of the PAH to whom such Confidential Information belong) that no patentable invention is disclosed in such materials.

(3) Further, during the course of any such [* * *] period, the PAH shall notify the AO and the Government, through the CMF, if PAH believes any of its Confidential Information have been included in the proposed publication or disclosure and shall identify the specific Confidential Information or Trade Secrets that need to be removed from such proposed publication. The Government and the CMF on behalf of the PAH proposing the publication or disclosure of such materials agrees to remove from the proposed publication or disclosure all such Confidential Information so identified by the CMF.

Article X. PATENT RIGHTS

Section 10.01 Definitions

“Invention” means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

“Made” when used in relation to any invention means the conception or first actual reduction to practice of such invention.

“Practical application” means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

“Subject Invention” means any invention of the MCDC’s PAH or its subcontractors of any tier conceived or first actually reduced to practice in the performance of work on a Project Agreement under this Agreement.

"Background Invention" means any invention, or improvement to any invention, other than a Subject Invention, made by a PAH (or their subcontractors of any tier) that was conceived, designed, developed, produced, and/or actually reduced to practice prior to performance of the Agreement or outside the scope of work performed under this Agreement.

Section 10.02 Allocation of Principal Rights

The PAH, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C § 202. In the event that a PAH consists of more than one entity or person, those entities or persons may allocate such right, title interest between themselves or others as they may agree in writing. With respect to any Subject Invention in which the PAH retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. The PAH may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government.

Section 10.03 Invention Disclosure, Election of Title, and Filing of Patent Application

(1) The PAH shall disclose each Subject Invention to the CMF within [* * *] after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to the CMF shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

(2) If the PAH determines that it does not intend to retain title to any such invention, the PAH shall notify the CMF, in writing, within [* * *] of disclosure. However, in any case where publication, sale or public use has initiated the one (1) year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the ACC-NJ through CMF to a date that is no more than [* * *] prior to the end of the project.

(3) The PAH shall file its initial patent application on a Subject Invention to which it elects to retain title within [* * *] after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The MCDC PAH may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either [* * *] of the corresponding initial patent application or [* * *] from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

(4) After considering the position of the CMF on behalf of the PAH, a request for extension of the time for disclosure election, and filing under this Article IX, paragraph C, may be approved by ACC-NJ, which ACC-NJ approval shall not be unreasonably withheld.

Section 10.04 Conditions When the Government May Obtain Title

Upon written request to the CMF, the PAH shall convey to the Government title to any Subject Invention under any of the following conditions:

(1) If the PAH fails to disclose or elects not to retain title to the Subject Invention within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that the Government may only request title within [* * *] after learning of the failure of the PAH to disclose or elect within the specified times.

(2) In those countries in which the PAH fails to file patent applications within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that if the PAH has filed a patent application in a country after times specified in Section 10.03 of this Article X, Patent Rights, but prior to its receipt of the written request by the Government through the CMF, the PAH shall continue to retain title in that country; or

(3) In any country in which the PAH decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

Section 10.05 Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File

The Parties agree that:

(1) The PAH shall retain a non-exclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the PAH fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. PAH's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the PAH within the corporate structure of which the PAH is a party and includes the right to grant licenses of the same scope to the extent that PAH was legally obligated to do so at the time the Project Agreement was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

(2) The PAH domestic license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the PAH has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the Government to the extent

the PAH, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the Government shall furnish the CMF, and the CMF shall forward to the PAH, a written notice of the Government's intention to revoke or modify the license, and the PAH shall be allowed [* * *] (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

Section 10.06 Action to Protect the Government's Interest

(1) The PAH shall execute or have executed and promptly deliver to CMF all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the PAH elects to retain title, and (ii) convey title to the Government when requested under Section 10.04 of this Article X, Patent Rights, and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

(2) The PAH agrees to require, by written agreement, that its employees working on Project Agreements, other than clerical and non-technical employees, agree to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format acceptable to the CMF, each Subject Invention made under this Agreement in order that the CMF on behalf of the PAH can comply with disclosure provisions of Section 10.03 of the Article X, Patent Rights, and to execute all papers necessary to file the patent applications on the Subject Invention and to establish the Government's rights in the Subject Invention. The PAH acknowledges and shall instruct its employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The PAH shall notify the CMF of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than [* * *] before the expiration of the response period required by the relevant patent office.

(4) The PAH shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with U.S. Government support under Agreement No. W15QKN-16-9-1002 awarded by the ACC-NJ to the MCDC. The Government has certain rights in the invention."

Section 10.07 Lower Tier Agreements

The PAH shall include the Article X, Patent Rights, suitably modified to identify the parties, in all lower tier agreements, regardless of tier, for experimental, development, or research work.

Section 10.08 Reporting on Utilization of Subject Inventions

The PAH shall submit, on request during the term of the Project Agreement, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the PAH or its licensees or assignees. Such reports shall include information regarding the status of development date of first commercial sale or use, gross royalties received by the PAH, and such other data and information as the agency may reasonably specify. The PAH also agrees to provide additional reports as may be requested by the Government, through CMF, in connection with any march-in proceedings undertaken by the Government in accordance with Section 10.10 of this Article X, Patent Rights. Consistent with 35 U.S.C. § 205, the Government agrees it shall not disclose such information to persons outside the Government without permission of the MCDC on behalf of the PAHs.

Section 10.09 Preference for American Industry

Notwithstanding any other provision of the Article X, Patent Rights, the PAH is not to grant to any person the exclusive right to use or sell any Subject Invention in the United States or Canada unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by the Government upon a showing by the PAH that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

Section 10.10 March-in Rights

The PAH agrees that, with respect to any Subject Invention in which its PAH has retained title, the Government, through CMF, has the right to require the PAH to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the PAH refuses such a request, the Government has the right to grant such a licensee itself if the Government determines that:

(1) Such action is necessary because the PAH or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the PAH, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the PAH, assignee, or licensees; or

(4) Such action is necessary because the Agreement required by Section 10.09 of this Article X, Patent Rights, has not been obtained or waived or because a licensee who has the exclusive right to use or sell any Subject Invention in the United States is in the breach of such Agreement.

Section 10.11 Opportunity to Cure

Certain provisions of this Article X, Patent Rights, provide that the Government may gain title or license to a Subject Invention by reason of the PAH's action, or failure to act, within the times required by this Article X, Patent Rights. Prior to claiming such rights (including any rights under Article X, Section 10.10 March-In Rights), the Government will give written notice to MCDC, through its CMF, and CMF will convey such written notice to PAH, of the Government's intent, and afford the PAH a reasonable time to cure such action or failure to act. The length of the cure period will depend on the circumstances, but in no event will be more than 60 days. PAH may also use the cure period to show good cause why the claiming of such title or right would be inconsistent with the intent of this Agreement in light of the appropriate timing for introduction of the technology in question, the relative funding and participation of the parties in the development, and other factors.

Section 10.12 Background Information

In no event shall the provisions set forth in this Article X apply to any Background Inventions or Patents. The PAHs or their subcontractors shall retain the entire right, title, and interest throughout the world to each such Inventions and Patents that each party has brought through MCDC to the project issued under this Agreement and the Government shall not have any rights under this Agreement. Projects to be funded under this Agreement will list Background Inventions and Patents anticipated to be used on the project; such listing may be amended by the parties as appropriate to reflect changes in such plans.

Section 10.13 Survival Rights

Provisions of this Article X shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this Article, differing rights in patents may be negotiated among the Parties to each individual project on a case-by-case basis.

Article XI. DATA RIGHTS

This is a Data Rights Clause specifically tailored for this OTA to address respective rights of the Government and MCDC on behalf of its actual or prospective MCDC PAHs to such Data as is owned, developed, to be developed or used by an actual or prospective MCDC member entity or PAH (1) as identified in a MCDC member entity(ies) proposal submitted to the Government through the CMF in response to a competitive Government OTA call for proposals, and (2) when such proposal is selected by the Government for funded performance and the Project Agreement is issued by the CMF to that MCDC member entity for performance of such Government OTA project.

Section 11.01 Definitions

(1) "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).

(2) "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this OTA) is sold or offered for sale, lease or license to the general public.

(3) "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) "Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) "Government purpose rights" means the rights to use, modify, duplicate or disclose the "Data" licensed with such rights under this OTA within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than ten (10) years and during such time the MCDC member entity or PAH developing or providing such Data to the Government with government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another project issued to that MCDC member entity or PAH under this OTA during this ten (10) year period, the period of

government purpose rights shall be extended an additional ten (10) years starting with the date of completion of performance of the additional project.

(10) “Limited rights” as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).

(11) “Restricted rights” as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).

(12) “Specially Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the MCDC on behalf of the member entity or PAH whose proposal is selected by the Government under a call for proposals issued under the OTA.

(13) “Technical data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) “Unlimited rights” as used in this Article is as defined n DFARS 252.227-7013(a)(16).

Section 11.02 Data Categories

(1) Category A is the Data developed and paid for totally by private funds, or the PAH's (or its subcontractor's) IR&D funds and it is Data to which the PAH (or its subcontractor) retains all rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the PAH for a project under this Agreement which was not developed in the performance of work under that project, and for which the PAH retains all rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the project by any of the MCDC member entities or PAHs. Such Data shall be marked “Category A” and any rights to be provided to the Government for such Data under a specific project shall be as identified in the proposal submitted to the Government and included into the Technical Direction Letter and CMF issued Project Agreements.

(2) Category B is any Data developed under this OTA with mixed funding, i.e. development was accomplished partially with costs charged to a PAH’s indirect cost pools and/or costs not allocated to a PAH’s Project Agreement under this OTA, and partially with Government funding under this OTA. Any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(3) Category C is any Data developed exclusively with Government funds under this OTA. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

(a) the Government will have Government Purpose Rights in Data developed exclusively with Government funds under a project funded by the Government under this OTA that is:

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the OTA that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

The Government can only order such Data as is developed under the OTA project where the order request is made within one (1) year following OTA project completion. In the event the Government orders such Data, it shall pay the PAH the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

(b) The Government shall have unlimited rights in Data

(i) Otherwise publicly available or that has been released or disclosed by PAH without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(iii) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with—

(1) Government Purpose Rights or limited rights and the restrictive condition(s) has/have expired; or

(2) Government purpose rights and the PAH's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.

(c) However, any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(d) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this OTA, and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

(4) The parties to this Agreement understand and agree that the CMF shall require PAHs stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

Section 11.03 Allocation of Principal Rights

(1) The Government shall have no rights to Category A Data.

(2) The Government shall have immediate Government Purpose Rights to Category B or C Data upon delivery or project or Agreement completion (whichever is earlier), except that

(a) where the PAH whose Data it is, is a small business as defined under the Small Business Innovation research Program (SBIR) under 15 U.S.C. 638, and such data was developed under a project designated by the Government in the RPP as an SBIR program project, such PAH automatically shall be entitled to a delay in the start of the Government Purpose Rights period for at least five (5) years from project completion, or such longer period as may be negotiated among the Government and MCDC on behalf of the PAH, and

(b) The CMF, at the request of small business or an other than small business MCDC member entity or PAH, may request on such member entity's or PAH's behalf a delay of the start of Government Purpose Rights in Category B or C Data for a period not to exceed five (5) years from project or Agreement completion (whichever is earlier). Such requests will only be made in those cases where the CMF has provided information from the affected actual or prospective PAH demonstrating the need for this additional restriction on Government use and shall be submitted to the ACC-NJ AO for approval, which approval shall not be unreasonably withheld. In the event of any dispute regarding approval of this request, the parties agree to treat this as a dispute and shall follow the provisions of Article VII, Disputes.

(c) for Article XI.Section 11.02 3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(d) for Article XI.Section 11.02 3(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

(3) Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific project award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government’s rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(4) Each proposal submitted by the MCDC member entities in response to a Government call for proposals under this OTA shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The Government AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.

Following issuance of a Technical Direction Letter and subsequent CMF issuance of the Project Agreement to the Government selected MCDC member entity (the PAH), the PAH shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

Section 11.04 Marking of Data

Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the MCDC, Agreement No. W15QKN-16-9-1002, Project Title and the MCDC Project Agreement with [insert name of company] No.___.

It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.

In the event commercial computer software and Data is licensed under a commercial computer software license under this OTA, a Special License rights marking legend shall be used as agreed to by the parties.

The Government shall have unlimited rights in all unmarked Data. In the event that a PAH learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CMF on behalf of the member

entity or PAH will have the opportunity to cure such omission going forward by providing written notice to the Government AO within three (3) months of the erroneous release.

Section 11.05 Copyright

The PAHs reserve the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual PAH. The PAH(s) hereby grant to the U.S. Government a non- exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.

In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

Copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.

The PAHs are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.

The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

Section 11.06 Data First Produced by the Government:

As to Data first produced by the Government in carrying out the Government's responsibilities under this OTA and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CMF on behalf of any PAH, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CMF and any PAH to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CMF or any PAH, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Section 11.07 Prior Technology

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the CMF or any MCDC member entity or PAH, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by CMF, PAHs, PAH subcontractors of any tier and their respective employees to whom such Data is provided for use under the OTA. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

(2) CMF and PAH Prior Technology: In the event it is necessary for the CMF or any PAH to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this

Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CMF nor any PAH shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CMF on behalf of itself or PAHs.

(3) Oral and Visual Information: If information which the PAH (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government and/or CMF, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government and/or CMF within ten (10) calendar days after such oral or visual disclosure, or the Government and/or CMF shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government and/or CMF request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor the CMF shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article VIII entitled “Confidential Information” above, if such information is or becomes generally known without breach of the above, is properly known to the Government or CMF or is generated by the Government or CMF independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the PAH has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual project on a case-by-case basis.

Section 11.08 Lower Tier Agreements

The PAH shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

Section 11.09 Survival Rights

Provisions of this Article shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Technology Project Agreement on a case-by-case basis.

Article XII. EXPORT CONTROL

Export Control

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR):

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act and that such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general

guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- this document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401 et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown.

The PAH shall include this Article, suitably modified, to identify all Parties, in all Project Agreements or lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

Article XIII. TITLE AND DISPOSITION OF PROPERTY

Section 13.01 Definitions

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Section 13.02 Title to Property

No significant items of property are expected to be acquired under this Agreement by the PAH. Title to any item of property valued $10,000.00 or less that is acquired by the PAH pursuant to a Project Agreement with the MCDC, in performance of the project issued to the PAH under this OTA shall vest in the PAH upon acquisition with no further obligation of the Parties unless otherwise determined by the Government AO. Should any item of property with an acquisition value greater than $10,000.00 be required, the PAH through the CMF shall obtain prior written approval of the Government AO. Title to this property shall also vest in the MCDC member entity or PAH upon acquisition. That PAH shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this clause shall not be considered as in exchange for services in performance of the project, but shall be considered a Government contribution to the project.

Section 13.03 Government Furnished Property

The Government may provide the PAH Government Furnished Property (GFP) to facilitate the performance of individual projects under this Other Transaction Agreement. Such GFP will be specifically identified to a particular project and incorporated into the applicable Project Agreement. The GFP shall be utilized only for the performance of that individual project unless a specific exception is made in writing by the Agreements Officer.

The PAH shall assume the risk of and be responsible for any loss or destruction of, or damage to, any Government Furnished Property while in its possession or control, with the exception of reasonable wear and tear or reasonable and proper consumption. All property shall be returned at the end of the Project Agreement in as good as condition as when received with the exception of said reasonable wear and tear or in accordance with the provisions of the Project Agreement regarding its use. The PAH shall obtain explicit written authorization for any transfer or disposition of Government Furnished Property.

Article XIV. CIVIL RIGHTS ACT

This Agreement and any resulting Project Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. It is the responsibility of each PAH to assure the PAH has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (Attachment 1).

Article XV. NO SMALL BUSINESS AFFILIATION

Reserved

Article XVI. ANTITRUST

In the MCDC Articles of Collaboration, members agree to comply with all applicable U.S. laws, including U.S. antitrust laws. The MCDC is recognized under the National Cooperative Research and Production Act of 1993 and the MCDC will be similarly filing under the Act.

Article XVII. SECURITY & OPSEC

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information (CDI) will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

Work performed by a PAH under a Project Agreement may involve access to Controlled Unclassified Information (CUI). All Controlled Unclassified Information (CUI) developed under this Agreement will be managed in accordance with DoD Manual 5200.01, Volume 4 dated February 24, 2012. Contractor personnel shall comply with applicable Technology Protection Plans (TPP), Interim Program Protection Plans (IPPP) and/or Program Protection Plans (PPP). If a project involves a Controlled Unclassified Information (CUI) effort, the below listed Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS), and ARDEC clauses will be incorporated into the Project Agreements by reference with the same force and effect as if they were given in full text.

(1) Each project Scope of Work will be provided by the Agreements Officer Representative (AOR) to the Joint Project Manager-Medical Countermeasure Systems Office for dissemination to the appropriate Fort Detrick COMSEC officer prior to award for review.
(2) Each project Scope of Work will be subject to Ft. Detrick policy and procedure according to DoD 5220.22- M, (National Industrial Security Program Operating Manual, NISPOM), as deemed applicable and appropriate during the security review process and prior to award. Additional COMSEC requirements may be required at other locations/facilities (based on service/command requirements).
(3) Specific applicable policies, instructions, and regulations will be identified in each project. Throughout the life of the Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
    a) DoDM 5200.01 DoD Information Security Program, 24 Feb 12
    b) DoD 5200.2-R Personnel Security Regulation, Jan 87
    c) DoDD 5220.22 National Industrial Security Program, 28 Feb 06
    d) DoDI 5200.01, Information Security Program and Protection of Sensitive Compartmented Information, 24 Feb 2012
    e) DoD 5400.7-R, DOD Freedom of Information Act, Sept 98
    f) DoDD 2000.12, Antiterrorism Program, 18 Aug 03
    g) FAR Clause 4.402, Safeguarding Classified Information Within Industry
    h) FAR Clause 52.204-2, Security Requirements, Aug 1996

(4) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - “The security level for this agreement is UNCLASSIFIED.”

(5) Anti-Terrorism Level I Training. This provision is for PAH employees with an area of performance within an Army controlled installation, facility or area. All PAH employees requiring access to Army installations, facilities and controlled access areas shall complete AT Level I awareness training within sixty (60)-calendar- days after project start date or effective date of incorporation of this requirement into the project, whichever is applicable. PAH(s) shall submit certificates of completion for each affected employee and PAH employee, to the AOR or to the Agreements Officer, if an AOR is not assigned, within thirty (30)-calendar-days after completion of training by all employees or personnel. AT level I awareness training is available at the following website: https://atlevel1.dtic.mil/at.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is for PAH employees with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

(7) Anti-Terrorism Awareness Training for PAH Personnel Traveling Overseas. This standard language text requires U.S.-based PAH employees to make available and to receive Government provided area of responsibility (AOR) specific AT awareness training as directed by AR 525-13. Specific AOR training content is directed by the combatant commander with the unit Anti-terrorism Officer (ATO) being the local point of contact.

(8) iWATCH Training. This standard language is for PAH employees with an area of performance within an Army- controlled installation, facility or area. PAH(s) shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This local developed training will be used to inform employees of the types of behavior to watch for and instruct employees to report suspicious activity to the AOR. This training shall be completed within sixty (60)-calendar-days of a Project Agreement award and within sixty (60)-calendar- days of new employees’ commencing performance with the results reported to the AOR NLT thirty (30)-calendar-days after Project Agreement award.

(9) Impact on PAH performance during increased FPCON during periods of increased threat. During FPCONs Charlie and Delta, services may be discontinued / postponed due to higher threat. Services will resume when FPCON level is reduced to Bravo or lower.

(10) Random Antiterrorism Measures Program (RAMP) participation. PAH personnel working on an installation are subject to participation in Installation RAMP security program (e.g. vehicle searches, wearing of ID badges, etc.).

(11) PAH Employees Who Require Access to Government Information Systems. All PAH employees with access to a government information system must be registered in the ATCTS (Army Training Certification Tracking System) at commencement of services, and must successfully complete the DOD Information Assurance Awareness prior to access to the IS and then annually thereafter.

(12) For projects that Require an OPSEC Standing Operating Procedure/Plan. The PAH shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security.

This plan will be submitted by MCDC on behalf of the PAH(s) to the AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it and how to protect it. In addition, MCDC shall identify an individual who will be an OPSEC Coordinator. MCDC will ensure this individual becomes OPSEC Level II certified per AR 530-1.

(13) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new PAH employees assigned by the PAH(s) to perform under a MCDC Project Agreement must complete Level I OPSEC awareness training within thirty (30)-calendar-days of their reporting for duty. All PAH employees performing under an OPSEC-designated project must complete annual Level I OPSEC awareness training. Level I OPSEC awareness training is available at the following website: http://cdsetrain.dtic.mil/opsec/.

(14) For Information assurance (IA)/information technology (IT) training. All PAH employees must complete the DoD IA awareness training before issuance of network access and annually thereafter. All PAH(s) working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M and AR 25-2 within six (6) months of employment.

(15) For information assurance (IA)/information technology (IT) certification. Per DoD 8570.01-M , DFARS 252.239-7001 and AR 25-2, the PAH employees supporting IA/IT functions shall be appropriately certified upon Project Agreement award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon Project Agreement award.

(16) For PAH personnel authorized to accompany the Force. DFARS Clause 252.225-7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States. The clause shall be used in projects that authorize PAH personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance) and personnel data required.

(17) For projects requiring Performance or Delivery in a Foreign Country, DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S. The clause shall be used in projects that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national PAH personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the PAH’s compliance with combatant commander and subordinate task force commander policies and directives.

(18) For projects requiring the PAH to obtain U.S. Government Common Access Cards, installation badges, and/or access passes, the PAH shall return all issued U.S. Government Common Access Cards, installation badges, and/or access passes to the AOR when the project is completed or when the PAH employee no longer requires access to the installation or facility.

(19) For projects that require access to Potential Critical Program Information (PCPI) / Critical Program Information (CPI):

a) The PAH shall comply with the associated Interim Program Protection Plan (IPPP) / Program Protection Plan (PPP) / or Technology Protection Plan (TPP). The PAH shall comply with DOD, DA and AMC technology protection requirements in DODI 5200.39, AR 70-1, DA PAM 70-3 and AMC- R-380-13.

(20) Work by the Consortium Management Firm (CMF) and Project Agreement Holder/Consortium Member (PAH) under Project Agreements may involve access to Controlled Unclassified Information (CUI) as well as information classified as "Confidential", "Secret", or "Top Secret". The CMF and the PAH and their employees who work on such Project Agreements shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DOD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the Agreement security classification specification (DD form 254) if included, and all security requirements including but not limited to OPSEC plans and those security requirements specific to the individual projects. During the course of this Agreement the Parties may determine that information developed by the PAH and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DOD 5220.22M.

a) Each project Scope of Work will be provided by the AOR to the AOR's local Security Office prior to award for review. For classified efforts that Security Office will provide the overall Security Classification Specification (DD Form 254). The PAH will be responsible for providing a copy of any Subcontract Security Classification Specification (DD Form 254) to lower tier awards.

b) If a Project Agreement involves a classified effort or a Controlled Unclassified Information (CUI) effort, Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS) clauses by reference, and local clauses will be incorporated with the same force and effect as if they were given in full text shall be incorporated into this agreement.

c) Specific applicable policies, instructions, and regulations will be identified in each Project Agreement. Throughout the life of the Project Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply.

d) Agreement Structure

i) Research and Development under these Project Agreements will be in accordance with the Other Transaction Agreement (OTA) between the United States Army Contracting Command – New Jersey (ACC-NJ) and the MCDC in care of its Consortium Management Firm (CMF), Advanced Technology International (ATI).

ii) Within the Project Agreements, sharing of classified information will be on a need to know basis as directed in required Project Agreements.

iii) Upon Project Agreement completion or termination, the PAH must:

(1) Return ALL classified information received or generated under the Project Agreement;
(2) Destroy all of the classified information; or,
(3) Request retention for a specified period of time

Flowdown for OPSEC/Security Requirements:

MCDC shall include the aspects of this Article as they pertain to each project requirement. Each project will include specific OPSEC / Security requirements within each SOW and RPP. The requirements delineated within each project, in turn, shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

Article XVIII. SAFETY

The PAH shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non- hazardous occupational environment throughout the duration of the project. At a minimum, the PAH shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The PAH shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage may be involved; identifying a potential hazard requiring corrective action. The PAH shall prepare the report (DI-SAFT-81563) for each incident.

Material Safety Data Sheets (MSDS): The PAH shall prepare and maintain MSDS for all materials used and generated under this Agreement.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, Executive orders, treaties, and agreements. The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under this Agreement.

Hazardous Waste Report: The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during this Agreement. The PAH shall submit a Hazardous Waste Report IAW DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The PAH shall dispose of all residual and scrap materials generated from this Agreement, including high explosives. The PAH shall specify the anticipated quantities, methods, and disposal costs.

Article XIX. REPRESENTATIONS AND WARRANTIES

Section 19.01 Representations and Warranties of All Parties

Each Party to this Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

Section 19.02 Limitations

Except as expressly provided herein, no party to this Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this agreement, or (2) any invention conceived and/or reduced to practice under this agreement, or (3) any other intellectual property developed under this Agreement, and each party to this Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

Article XX. LIABILITY OF THE PARTIES

Section 20.01 Waiver of Liability

With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.

Section 20.02 Damages

The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Section 20.03 Extension of Waiver of Liability

The PAH agrees to extend the waiver of liability as set forth above subawardees at any tier under an Project Agreement by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this Agreement.

Section 20.04 Applicability

Notwithstanding the other provisions of this article, this Waiver of Liability shall not be applicable to:

(1) Claims between the PAH and the CMF regarding a material breach, noncompliance, or nonpayment of funds;

(2) Claims for damage caused by willful misconduct; and

(3) Intellectual property claims.

Section 20.05 Limitation of Liability

In no case shall the CMF, or the PAH's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a MCDC member entity under a Project Agreement. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

Article XXI. GENERAL PROVISIONS

Section 21.01 Fees

The PAH will not be constrained from the payment of an appropriate fee or profit for the effort being conducted on a Project Agreement when cost share is not being contributed. The fees shall be specific to the individual Project Agreements and negotiated on project by project basis.

Section 21.02 Waiver

No waiver of any rights shall be effective unless assented to in writing by the party (Government, MCDC, CMF, or PAH) to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

Section 21.03 Section Headings

The headings and subheadings of the sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

Section 21.04 Severability

In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

Section 21.05 Force Majeure

No failure or omission by the CMF or the MCDC PAH in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

Section 21.06 Regulatory Affairs

Development and production of medical products and processes fall under the purview of the Food and Drug Administration (FDA) and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. Project Awards under this Agreement that involve work in support of or related to FDA regulatory approval will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

The Government shall ensure performance includes regulatory expertise and guidance for candidate medical countermeasure development efforts:

(1) This includes allowing the government to discuss/negotiate in partnership with the consortium how to assume appropriate risk in regulatory strategies. The government will review, negotiate, and come to consensus with the PAH on product-specific risk-based decisions.

(2) PAHs will use all regulatory programs to accelerate the pace of candidate medical countermeasure development, including fast-track status, and as appropriate meeting requirements for priority review vouchers, applying for breakthrough therapy and accelerated approval as appropriate (see FDA Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics).

(3) PAH will provide FDA submissions to the government such as all documentation requested by FDA and all proposals to FDA.

(4) PAH will allow the government to monitor all FDA communications by listening to teleconferences and attending meetings.

(5) PAH will allow the government to attend regulatory site visits and audits, and actively participate in all third-party audits.

(6) PAH will comply with Quality Assurance according to negotiated standards with the government on reports, material for Interim Fielding Capability (such as Emergency Use Authorization or Expanded Access Protocols), product for trials, prototypes, etc.

(7) PAH will provide strategies to address contingencies that could arise from regulatory directives, and regulatory failures.

Section 21.07 Radioactive Materials

PAH shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

Section 21.08 Recombinant DNA

PAH shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: http://www4.od.nih.gov/oba (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

Section 21.09 Required Compliance for Use of Laboratory Animals

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the PAH is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office,. The PAH shall receive written approval to begin research under the applicable protocol proposed for a Project Agreement from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the PAH and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this clause may result in the termination of award. Information is provided at the following website http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_regulations. The PAH will conduct advanced development/pivotal studies including human safety studies, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies as defined by FDA guidance (21 CFR Parts 210-211).

Section 21.10 Required Compliance for Use of Human Subjects

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following website: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo.

Section 21.11 Required Compliance for use of Human Anatomical Substances

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following web site: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo

Section 21.12 Compliance with current Good Manufacturing Processes (cGMP)

Manufacturing Standards as appropriate for the level of prototype Material used for clinical trials, pivotal non- clinical studies, consistency lots, and other uses as defined in regulatory plans should be compliant with current Good Manufacturing Processes (cGMP) as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure.

Section 21.13 Registration with Select Agent Program

Where required, consortium members performing studies and tasks using select biological agent or toxins should be registered with the program with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied. Listings of select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

Section 21.14 Duty-Free Entry

(a) *Definitions*. As used in this clause –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.
(2) "Customs territory of the United States" means the 50 States, the District of Columbia, and Puerto Rico.
(3) "Eligible product" means –
(i) "Designated country end product" as defined in the Trade Agreements clause;
(ii) "Free Trade Agreement country end product" other than a "Bahrainian end product" or a "Moroccan end product" as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program; or
(iii) "Canadian end product" as defined in Alternate I of the Buy American Act – Free Trade Agreements – Balance of Payments Program.
(4) "Qualifying country" and "qualifying country end product" have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program.

(b) Except as provided in paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a Project Agreement or the applicable subcontract, the price of this Agreement shall not include any amount for duty on-
(1) End items that are eligible products or qualifying country end products;
(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated in U.S – made end products to be delivered under an Project Agreement; or
(3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States

(c) The PAH shall –
(1) Claim duty-free entry only for supplies that the PAH intends to deliver to the Government under an Project Agreement, either as end items or components of end items; and
(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –
(i) Scrap or salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer.

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –
(1) For which no duty is included in the Project Agreement price in accordance with paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –
(1) Consign the shipments to the appropriate –
(i) Military department in care of the PAH, including the PAH's delivery address; or
(ii) Military installation; and

(2) Include the following information:
(i) Prime Agreement number and, if applicable, delivery order number.
(ii) Number of the subcontract for foreign supplies, if applicable.
(iii) Identification of the carrier.
(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 207 New York Avenue, Staten Island, New York, 10305-5013, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."

(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty- free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the PAH shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)

(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)
(vi) Estimated value in U.S. dollars.
(vii) Activity address number of the contract administration office administering the prime contract, e.g., for DCMA Dayton, S3605A.

(f) Preparation of customs forms.

(1)(i) Except for shipments consigned to a military installation, the PAH shall –
(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this Agreement; and
(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.
(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.
(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –
(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;
(2) Consign the shipment as specified in paragraph (e) of this clause; and
(3) Mark on the exterior of all packages –
(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and
(ii) The activity address number of the contract administration office administering the prime Agreement.

(h) The PAH through the MCDC CMF shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH through the MCDC CMF shall furnish the notice to the ACO immediately upon award to the supplier and shall include in the notice –
(1)The PAH's name, address, and Commercial and Government Entity (CAGE) code;
(2) Prime Agreement number and Project Agreement number;
(3) Total dollar value of the prime Agreement or Project Agreement number;
(4) Date of the last scheduled delivery under the prime Agreement or Project Agreement number;
(5) Foreign supplier's name and address;

(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
(i) Scrap of salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this Agreement if –
(1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
(2) It is not economical or feasible to account for such supplies so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this Agreement.

(j) The PAH shall –
(1) Insert the substance of this clause, including this paragraph (j), in all subcontracts for –
(i) Qualifying country components; or
(ii) Nonqualifying country components for which the PAH estimates that duty will exceed $200 per unit;
(2) Require subcontractors to include the number of this Agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
(3) Include in applicable subcontracts –
(i) The name and address of the ACO for this Agreement;
(ii) The name, address, and activity address number of the contract administration office specified in this Agreement; and
(iii) The information required by paragraphs (h)(1), (2), and (3) of this clause.

Section 21.15 Follow-On Production

10 U.S.C. § 2371b, Section 815 authorizes the use of a follow-on production contract (FAR) or transaction (OTA). In order to be eligible for follow-on production, the following criteria is required: (1) the follow-on shall be awarded to the same participants named in the Project Agreement; (2) competitive procedures were used to award the Project Agreement in question; and (3) the Project Agreement was successfully completed. This Agreement was the result of competitive procedures, and competitive procedures are used to award individual projects under this Agreement. The Agreements Officer shall be responsible for documenting whether or not a Project Agreement was successfully completed. Follow-on production efforts shall be strictly limited to the scope of the successfully completed prototype. This Agreement will not be used to award follow-on production efforts; Government customers will be responsible for working with their contracting personnel.

All Project Agreements shall include the following statement:

"In accordance with 10 U.S.C. § 2371b(f), and upon a determination that this competitively awarded prototype project has been successfully completed, this prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures."

Article XXII. ASSIGNMENT OF AGENCY

Section 22.01 Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party.

Article XXIII. ORDER OF PRECEDENCE

In the event of any inconsistency between the general terms of this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Agreement; (2) Attachments to the Agreement; (3) the Project Agreement documentation (including but not limited to the PAH proposal selected for funding by the Government). In any event, specifically negotiated Project Agreement terms will govern over general terms of this Agreement.

Article XXIV. EXECUTION

This Agreement constitutes the entire Agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the PAH and the CMF Contracting Representative designated in this Agreement.

Attachment I – Assurance of Compliance with Title VI of the Civil Rights Act of 1964

Statement of Assurance of Compliance with Title VI of the
Civil Rights Act of 1964
For MCDC Member Organizations

The Regeneron Pharmaceuticals, Inc. hereby agrees that it will comply with the provisions of the Title VI Civil Rights Act of 1964 as amended (42 U.S.C 2000-d) and all requirements imposed pursuant thereto, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be
excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination
under any MCDC Project for which the MCDC member organization receives Federal financial assistance from the Government.

The MCDC member organization agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the MCDC member organization, its successors, transferees and assignees for the period during which such assistance is provided.

The MCDC member organization further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the MCDC member organization to the above provisions.

_____
Signature of Authorized Official

_____
Title of Authorized Official

_____
Name of MCDC Member Organization

_____
Date

Exhibit 10.2

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.

Advanced Technology International

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

PROJECT AGREEMENT NO.: 1

MCDC BASE AGREEMENT NO.: 2020-504

PROJECT TITLE: MCDC2008-005; Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

PARTIES: Advanced Technology International ("MCDC CMF") and Regeneron Pharmaceuticals, Inc. ("Project Agreement Holder")

This Project Agreement is awarded under the authority of MCDC Base Agreement No. 2020-504, and herein incorporates all the terms and conditions thereof, as such terms and conditions are modified by the terms of the Statement Of Work attached hereto as Exhibit A (the "Statement of Work" or "SOW"). The parties agree that, to the extent any terms or conditions of the Statement of Work conflict with the terms and conditions of MCDC Base Agreement No. 2020-504, the terms and conditions of the Statement of Work shall apply and take precedence.

1. PAYMENT METHOD
The Payment Method for this Project Agreement is Firm Fixed Price with a not to exceed ceiling.

2. TERM OF THE PROJECT AGREEMENT
The period of performance for this Project Agreement is from the effective date, which is the date of the last signature through June 30, 2021.

3. OBLIGATION
The MCDC CMF's liability to make payments to the Project Agreement Holder is limited to only those funds obligated under this Project Agreement or by modification to the Project Agreement. MCDC CMF may incrementally fund this Project Agreement.

4. TOTAL FIRM FIXED PRICE
The total firm fixed price for the services to be provided by the Project Agreement Holder is as follows:

Total Firm Fixed Price $450,262,000

5. TOTAL FUNDING

The total amount of funding currently available for payment and allotted to this Project Agreement is **$450,262,000**.

6. MILESTONE PAYMENT SCHEDULE

The Project Agreement Holder shall document the accomplishments of each Project Payable Milestone under each Project Agreement. Acceptance of Milestones shall be contingent upon approval from the Government Agreements Officer Representative (AOR) detailed in Clause No. 9, Technical and Administrative Representatives. Milestone payments will be paid in the amount indicated in the attached Milestone Payment Schedule (Attachment A).

7. APPROACH TO MEETING THE OTHER TRANSACTION AUTHORITY

In accordance with provision contained in 10 USC 2371b governing the use Other Transaction Agreements each MCDC Member Organization must meet at least one of the following conditions: have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the performance of an awarded Project Agreement; all significant participants in the Project Agreement other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors; or provide a cost share of no less than one third of the value of the Project Agreement awarded to the Member Organization. The Project Agreement Holder's approach to meeting the Other Transaction Authority requirement is identified below. Throughout the period of performance of any Project Agreement, the CMF and the Government will actively monitor the award to ensure compliance with this provision in accordance with implementation guidance from Headquarters – Department of the Army (HQDA) and/or Office of the Secretary of Defense (OSD). The Project Agreement Holder will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

The warranties and representations submitted as part of the proposal are hereby incorporated into this Project Agreement. The Project Agreement Holder was proposed as a nontraditional defense contractor and determined to be providing a significant contribution.

8. STATEMENT OF WORK

The Statement of Work, Attachment A, provides a detailed description of the work to be accomplished and reports and deliverables required by this Project Agreement. All changes to Attachment A must be incorporated via written modification to this Project Agreement. Additional guidance on report requirements is in Attachment B, Report Requirements.

9. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES

The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:
Contracts Administrator
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email:
Phone:

Government Technical Representatives:
Agreements Officer Representative
(AOR):

Email:
Phone:

Project Agreement Holder's Representatives:

Technical Representative:	Contractual Representative:
777 Old Saw Mill River Rd	777 Old Saw Mill River Rd
Tarrytown, NY 10591	Tarrytown, NY 10591
Email:	Email:
Phone:	Phone:

10. MARKING OF DELIVERABLES
Any Data delivered under this Project Agreement, by the Project Agreement Holder, shall be marked with a suitable notice or legend.

11. SECURITY ADMINISTRATION
The security level for this project is UNCLASSIFIED.

12. ATTACHMENTS
Attachments listed herein are hereby incorporated by reference into this Project Agreement.
A. Statement of Work, "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2"
B. Report Requirements
C. Technical Direction Letter (TDL) RPP-20-08 Regeneron

13. GOVERNMENT FURNISHED PROPERTY
At this time, Government Furnished Property is not provided for use under this Project Agreement.

14. PATENT RIGHTS AND DATA RIGHTS
Please reference Section 7 of Attachment A, Statement of Work.

15. FOLLOW-ON PRODUCTION PROVISION
Please reference Section 1 of Attachment A, Statement of Work.

16. SECURITY & OPSEC

The below language shall be used as Paragraph 6 of Article XVII in Regeneron's Base Agreement: Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

17. ENTIRE AGREEMENT

This Project Agreement and the MCDC Base Agreement under which it is issued constitute the entire understanding and agreement between the parties with respect to the subject matter hereof.

Except as provided herein (including in the SOW), all Terms and Conditions of the MCDC Base Agreement and its modifications remain unchanged and in full force and effect.

Advanced Technology International

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Regeneron Pharmaceuticals, Inc.

By: /s/ Robert Landry

Name: Robert Landry

Title: Executive Vice President- Finance and Chief Financial Officer

Date: Jul 6, 2020

Advanced Technology International

By: /s/

Name:

Title:

Date: 6 July 2020

Attachment A
Statement of Work

This page intentionally left blank. See separate document for Attachment A.

Statement of Work
For
Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

RPP #: RPP-20-08
Project Identifier: MCDC OTA 2008-005, W15QKN-16-9-1002
Consortium Member: Regeneron Pharmaceuticals, Inc.
Title of Proposal: Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

A. Preamble

Regeneron Pharmaceuticals, Inc. (referred to herein as "Regeneron", "Offeror", "Contractor" or "Recipient") has demonstrated experience with rapid scale-up of biopharmaceutical programs. Our excellent history of receiving development scale processes from Research and Development (R&D) laboratories, and then expanding to clinical or commercial Good Manufacturing Practice (GMP) scale production, is well documented. [* * *] We have consistently demonstrated our ability to expedite the delivery of high quality, safe and efficacious products (Ebola therapeutic) in partnership with the Government (anti-MERS, anti-Ebola).
Fully human monoclonal antibodies (mAbs) are molecules with high potency, predictable Pharmacokinetics (PK), and limited off-target toxicity, and thus provide attractive types of therapeutics for emerging diseases. Importantly, we have repeatedly demonstrated that candidate mAb-based drugs to prevent and/or treat emerging infections, can be rapidly obtained from Regeneron's proprietary VelocImmune® mice. Further, our ability to concurrently generate isogenic cell lines that are optimized for rapid antibody scale up and manufacturing using our proprietary Chemistry, Manufacturing, and Controls (CMC) platform technologies, have facilitated both testing of our mAbs in preclinical models and subsequent development of these mAbs into drugs suitable for human testing. In the process of completing many of these activities we have collaborated with other entities (including BARDA, Research Institutes, Government Laboratories and Universities). Our manufacturing has been designed to be paired with our proprietary VelocImmune® R&D technology, that is a proven process to rapidly take a research concept from the bench, into large scale production, with the ability to delivery medicines to patients.

The Government has advised Regeneron that it is appropriate for the project described in this Project Agreement to be performed through the Medical CBRN Defense Consortium (MCDC), under the authority of the MCDC Other Transaction Agreement No. W15QKN-16-9-1002. Regeneron is amenable to performing the project pursuant to such authority, based on the advice of the Government, and due to the unprecedented circumstances of the Coronavirus Disease 2019 (COVID-19) pandemic and, accordingly, the parties have entered into this Project Agreement.

B. Overall Objectives and Scope

This project is defined by discrete work segments for the continuous manufacture of drug substance, formulated drug substance and filled, packaged and labeled drug product, in accordance with a mutually agreed schedule.

Pursuant to this project, Regeneron will manufacture and sell drug product to the applicable United States (U.S.) Federal Government agency, for distribution in the U.S. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing Oractices (cGMP), as 21 CFR 210 and 211.

1.1 Introduction

The objective is to conduct the manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.

1.2 Scope

These manufacturing production activities will include manufacturing at-scale, filling and finishing, and storage and shipping of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-specific monoclonal antibodies (referred to herein as the "prototype", the "prototype product", the "product" or "drug product") for treatment and/or prophylaxis against COVID-19.

1.3 Definition of the Prototype Project

Consistent with USG objectives, Regeneron will employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act, to manufacture the prototype product. This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of manufacturing the prototype product during the ongoing COVID-19 pandemic. In addition, this is a prototype project because Regeneron will demonstrate, and prove-out the at-scale, multi-lot proprietary manufacturing activities of Regeneron in order to assess the feasibility of these activities to support the necessary quantity of the prototype product to treat the U.S. population. Successful completion of the prototype project will demonstrate Regeneron's capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with little advance notification and (ii) facilitate the Government's ability to stockpile and distribute large quantities of the drug product to respond when needed, including for use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. FDA. For clarity, any manufacturing and supply of drug product in excess of the

specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutual agreement between Regeneron and the Government.

The scope of effort supported by this agreement is further clarified in Section 1.4. It is important to note that nonclinical and clinical studies for the prototype are being conducted by Regeneron outside of this agreement. The results of those studies may be used to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement; however, such results (including the degree to which the data are "positive" or "negative") shall not be a factor in this prototype project.

1.4 Objective

- Conduct its proprietary manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.
- The prototypes will include one or more of the following, as mutually agreed between Offeror and the Government:
    - the mAbs known as REGN10987 and REGN10933, as a cocktail;
    - Other mAbs (as monotherapies or a cocktail) as agreed to by bilateral modification between Offeror and the Government.
- The deliverables will be the products listed above (i.e., REGN10987 and REGN10933), in the form of bulk formulated drug substance and/or filled and finished product in vials, as mutually agreed between Offeror and the Government, packaged and labeled drug product, results, reports and records associated with generation of data demonstrating quality and control.
- The products will be delivered in the form and quantity to be agreed between Offeror and the Government. It is expected that the prototypes will be stored by Offeror until such time as (a) they can be used for pre-clinical or clinical development purposes under an Investigational New Drug application (IND), or (b) upon the FDA's grant of an EUA under Section 564 of the Food, Drug and Cosmetic Act (FD&C Act), or full marketing approval under a full Biologics License Application (BLA) under Section 351(a) of the Public Health Service Act (PHSA).

1.5 Follow-on Activity

In accordance with 10.U.S.C. 2371b(f), and upon successful demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results achieved outside of this Agreement that would justify transitioning to production (e.g., EUA or BLA), additional at-scale manufacturing of [* * *], supported by a mutually agreed upon follow-on production contract or Other Transaction Agreement, may be awarded to Regeneron, without further competition, to partially or completely meet the USG objective of supplying a safe and effective COVID-19 therapeutic or prophylactic treatment courses to ensure nationwide

access. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work shall be subject to a mutually-agreed upon separate agreement between Regeneron and the Government. For further clarity, neither party shall be obligated to negotiate or enter into such a separate agreement for follow-on production.

During the performance of the prototype project, the Government and contractor may negotiate the scope and price of follow-on production.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Practices, 21 CFR 210, 211

[* * *]

4.0 DELIVERABLES

Offeror assumed [* * *]. Regeneron shall have the right to provide deliverables directly to the Government and not to the Consortium Management Firm (CMF).

Deliverable Table (June 2020 - June 2021)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Package/Label Product	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
		$450,262,000 (FFP)	

*Upon payment, delivery and acceptance in accordance with the terms of this Project Agreement, the Government will have title to the product produced under this Statement of Work. The Government will have the rights described below in Section 7.3 to technical data disclosed under this Statement of Work.
** Packaging and labeling of product will be performed following the determination of the use of the applicable drug product (e.g., for clinical trials or for distribution under an EUA or BLA).

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	[* * *]	[* * *]	[* * *]
5.2	[* * *]	[* * *]	[* * *]
5.3	[* * *]	[* * *]	[* * *]
5.4	[* * *]	[* * *]	[* * *]
5.5	[* * *]	[* * *]	[* * *]
5.6	[* * *]	[* * *]	[* * *]
5.7	[* * *]	[* * *]	[* * *]
5.8	[* * *]	[* * *]	[* * *]
5.9	[* * *]	[* * *]	[* * *]
5.10	[* * *]	[* * *]	[* * *]
5.11	[* * *]	[* * *]	[* * *]
Total (Include Payment Type; FFP):			**$450,262,000**
Period of Performance:			**June 2020 – June 2021**

The overall price is fixed price at $450,262,000. Milestone payments will be made quarterly as set forth in the table above, corresponding to the deliverables and any 3rd party commitments Regeneron needs to make. In the event the deliverables in a given quarter are less than or exceed the projected quantity, the milestone payment for such quarter will be equitably adjusted based on the shortfall or excess amount, as applicable, however the price will not exceed $450,262,000 Milestone payment terms will be net 30 days.

Total pricing is a firm fixed price per lot, [* * *]. Regeneron will deliver [* * *] of filled/finished drug product. Regeneron will be entitled to full payment for drug product upon delivery/acceptance (as described herein) of filled/finished drug product, prior to packaging and labeling. However, Regeneron shall be responsible for the packaging and labeling of product at no additional cost following the determination of the use of such drug product (e.g., for clinical trials or for distribution under an EUA or BLA). Drug product will comply with the Drug Supply Chain Security Act serialization and tracking requirements. Drug product will not be co-formulated, except as otherwise mutually agreed by the parties. Unless and until otherwise mutually agreed, the drug product produced under this Statement of Work will be filled for therapeutic use. [* * *] Regeneron will provide the Government with the timeline for fill/finish activities, including the dates by which the parties must determine

the allocation of fill/finish activities. Notwithstanding the foregoing, as part of this Project Agreement, Regeneron will have the right to utilize material and capacity supported by this agreement to fill up to [* * *], as well as any additional drug product mutually agreed upon by Regeneron and the Government (with respect to which use the Government will not unreasonably withhold consent.

In the event this Statement of Work is terminated prior to completion, termination costs recoverable by Regeneron under Section 2.04 of the MCDC Base Agreement, shall include the following: the full contract price for any drug product manufactured and not yet paid for; a pro-rated portion of the contract price for drug substance or drug product that is in process, based on the stage of production; [* * *] and raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products.

[* * *]

7.0 PATENT RIGHTS; DATA RIGHTS; PREP ACT AND TRANSPARENCY

Article X, ("PATENT RIGHTS") and Article XI. ("DATA RIGHTS") of Other Transaction Agreement number W15QKN-16-9-1002 shall not apply to this Project Agreement and are hereby replaced for the purpose of this Project Agreement, with this Section 7.0 (including Sections 7.1-7.4 and the Definitions Appendix).
Definitions:

Capitalized terms used in this Section 7.0 (including Sections 7.1-7.4) shall have the meanings ascribed to such terms in the Definitions Appendix to this Project Agreement.

For purposes of this Project Agreement, all rights of the Government in and to Data or Subject Inventions are granted solely to The United States of America, as represented by the Department of Health & Human Services, Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and to no other agency of the United States of America (including JPEO) or representative of any such other agency (including the CMF). The parties acknowledge that Regeneron is permitted to communicate solely with BARDA regarding the matters described in this Section 7.0 (including Sections 7.1-7.4) and is not obligated to communicate with any other Government agency or representative regarding such matters.

7.1 BACKGROUND INTELLECTUAL PROPERTY

Each party acknowledges that it has no rights to the other party's inventions, discoveries, know-how, Data, technology or intellectual property generated, discovered, conceived or reduced to practice prior to or otherwise outside of this Statement of Work (also referred to herein as, this "Project Agreement" or this "Agreement"), and any improvements or modifications thereto, including, without limitation, the background intellectual property

(and improvements/modifications) for the Government and Regeneron described below, as follows:

Government Background Intellectual Property. None.

Contractor Background Intellectual Property:[* * *]

63/004,312, filed April 2, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/014,687, filed April 23, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/025,949, filed May 15, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/034,865, filed June 4, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

No party relinquishes rights in any of its background intellectual property to any other party under this contract.

Either Party may update its disclosure of background intellectual property under this Section 7.1 upon written notice to the other Party.

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in

accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

i. Regeneron shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Regeneron personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Project Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

ii. Regeneron shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the Government funding agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

iii. Regeneron shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election of title. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Regeneron shall file the application prior to the end of that statutory period. If Regeneron files an initial provisional application, it shall file a non-provisional application within 10 months of the filing of the initial provisional application. Regeneron shall include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention.

iv. Regeneron may request extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause. An extension of time for each deadline, may be granted at the discretion of the Government funding agency.

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory

[* * *]

period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Regeneron shall convey title to any Subject Invention to the Government funding agency if Regeneron fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Section 7.2. The Government may request title after learning of the failure of Regeneron to disclose or elect within the specified times for an unlimited time. The Government funding agency may request title upon Regeneron's omission to timely file patent applications in any country. The Government funding agency may request title in any country in which Regeneron decides to discontinue prosecution.

d. Rights to Regeneron and Protection of Regeneron's Right to File

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

i. The Regeneron license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Regeneron's license shall not be revoked in that field of use or the geographical areas in which Regeneron has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Regeneron's license, the Government shall furnish Regeneron with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Regeneron shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

[* * *]

e. Action to Protect the Government's Interest

Regeneron agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Regeneron elects to retain title, and (ii) convey title to the Government when requested under Subparagraph c of this Section 7.2 and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Regeneron agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Regeneron, each Subject Invention made under this Agreement so Regeneron can comply with the disclosure provisions of this Section 7.2. Regeneron shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Regeneron shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Regeneron shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement **MCDC2020-504**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention."

f. Lower Tier Agreements

Regeneron shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Regeneron to comply with this Section 7.2.

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Regeneron also agrees to

provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Regeneron.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

Regeneron agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Regeneron, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Regeneron, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. Action is necessary to alleviate the following health or safety needs that may affect the United States and Regeneron (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:
   a. Declaration for Public Health Emergency by the Secretary of HHS;
   b. Determination that there is a significant potential for a public Health emergency that has a significant potential to affect a national or health security of U.S. citizens as determined by the Secretary of HHS; or
   c. Declaration by WHO Director General of a public health emergency of international concern.

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement (including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights following the expiration of such ten (10)- year period. For Data produced under this Project Agreement, excluding Computer Software, to the extent developed with private funds and for other Data designated by

Regeneron as "Limited Rights Data", Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

ii. Regeneron agrees to retain and maintain in good condition all Data produced under this Project Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with Regeneron's established record retention practices. In the event of an exercise of the Government's compulsory licensing rights as set forth under Section 7.2.h., Regeneron agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Project Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Regeneron's right to use Data is not restricted and includes the right under Regeneron's established business policies to make public research Data (especially human research Data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

b. Proprietary Manufacturing Data

Notwithstanding anything to the contrary in this Project Agreement, Regeneron retains all rights in and to Data relating to or comprising Regeneron's proprietary manufacturing technology and processes, including any trade secrets, Chemistry, Manufacturing and Controls information (CMC Data), and Data concerning or arising from test method development, device or delivery system development, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up and cell-line development, and the Government shall have no rights to use such Data independently from this Agreement or to disclose such Data to any third party. Regeneron may designate certain Data concerning its manufacturing activities as Limited Rights Data, in which case the Government shall have Limited Rights in and to such Data. Regeneron will use reasonable efforts to mark any Limited Rights Data delivered under this Project Agreement with appropriate Limited Rights markings.

c. Identification and Disposition of Data

Regeneron shall keep copies of all Data relevant to this Project Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. The Government reserves the right to review any other data determined by the Government to be

relevant to this Agreement. The Government further acknowledges that Regeneron holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b of the BARDA OTA.

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

a. Regulatory Data. Regeneron shall provide to the OTTR and OTAS copies of formal FDA submissions pertaining to the scope of the project, no later than 10 business days before submission to the FDA. For clarity, CMC Data included in such submissions shall be subject to Section 7.3.b.

b. Rights of Reference. Upon mutual agreement, Regeneron will grant to the Government a right of reference to any Regulatory Application submitted in support of this Project Agreement, solely for the purpose of the Government conducting a clinical trial with the drug product supplied under this Project Agreement under a protocol approved by Regeneron for performance by the Government. In such a case, Regeneron agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the Government's data rights as articulated in other provisions of this award.

c. Clause 7.4.b. will survive the acquisition or merger of the Contractor by or with a third party. This clause will survive the expiration of this contract.

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activities related to medical countermeasures against COVID-19. To the extent DoD or BARDA is authorized to do so as an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that the drug product provided pursuant to this Project Agreement will not be (a) sold to any entity nor will it be returned after acceptance under the terms of this contract or (b) distributed or used, or authorized for distribution or use, outside the United States or to the extent such activities are not protected from liability under an active PREP Act declaration.

[* * *]

7.6 Transparency. To the extent permitted under applicable laws, the Government will provide Regeneron in a timely manner copies of reports concerning this Project Agreement that are provided to other Government agencies or legislative or executive branches of the government.

8.0 SECURITY

The security classification level for this effort is UNCLASSIFIED.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

None

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Alternate AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION:

Requiring Activity:

US Department of Health & Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA)

Definitions Appendix

Computer Software:

To perform and further this Project Agreement:

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Field: The development of anti-pathogen assets to treat, diagnose or prevent emerging infectious diseases.

Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).

Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—

1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

[* * *]

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such Data pertain to items, components, or processes developed at private expense, including minor modifications.

Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.

Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.

Other Transaction Agreement Officer ("OTAO"): Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.

Other Transaction Agreement Specialist ("OTAS"): Is a supporting official that assists and represents the OTAO. The OTAO is the only official who can bind the Government.

Other Transaction Agreement Technical Representative ("OTTR"): Is the primary Government official for all technical matters on the Agreement.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent.

Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.

Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

[* * *]

Attachment B
Report Requirements

This page intentionally left blank. See separate document for Attachment B.

REPORT REQUIREMENTS

If classified information is required to be submitted under this Agreement, it must be submitted to the addresses specified in the SOW or DD254. No classified information should be submitted directly to ATI.

Any applicable Contract Data Requirements Lists (CDRLs), Data Item Descriptions (DIDs) or other report guidance for this Project may be included at the end of this attachment.

ATI, in addition to the AOR, must receive a copy of the Quarterly Status Reports and the Final Status Report. Quarterly Status Reports, Annual Status Reports, and Final Status Reports should be submitted to . All other deliverables shall be submitted to the AOR only, but ATI must be notified that the deliverable has been submitted to the AOR. The AOR will provide ATI a completed Sign- off Memorandum as evidence the milestone deliverable was received and deemed acceptable.

If you would like a copy of the Report Requirements template in MS Word, please email

A. QUARTERLY STATUS REPORT

The Recipient shall submit or otherwise provide a Quarterly Status Report in the format as shown in this attachment on the last day of the month of the calendar quarter (i.e., **March 31, June 30, and December 31**). A sample template is provided.

I. The Recipient's Technical Status Report will, at a minimum, address the following: Comments on Technical/Cost/Schedule Performance, Project Quad Chart, Milestone Status, Non-Traditional Defense Contractor Participation and Plans for the Next Quarter.

B. PAYABLE MILESTONES/DELIVERABLES

The Recipient shall submit to the Agreements Officer Representative and MCDC CMF Representative documentation describing the extent of accomplishment of Payable Milestones and Deliverables.

I. **Submission of Payable Milestones/Deliverables**. The Recipient is required to submit all deliverables identified as Payable Milestones, as shown in the Payable Milestone Schedule, as well as any other deliverables/reports listed in the Statement of Work.

II. **Sign-off Memorandum.** The Sign-off Memorandum as shown in this attachment shall accompany all submissions indicated in section B.I. The Agreements Officer Representative shall provide written approval using the Sign-off Memorandum to the MCDC Consortium Management Firm. The Sign-off Memorandum will be used to verify that all submissions are technically acceptable. It will also be used to substantiate invoice payment for firm fixed price agreements.

C. ANNUAL STATUS REPORTING

I. The Project Agreement Holder shall submit an Annual Status Report on **September 30** each year (same format as Quarterly Status Report for one year period) for all projects whose periods of performances are greater than

one year in accordance with the terms and conditions of the MCDC Base Agreement. The Annual Status Report must also include the following:

i. A comparison of actual accomplishments with the goals and objectives of the project established for the period.
ii. Reasons why established goals and objectives were not met, if appropriate.
iii. A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors and titles.
iv. Papers presented at meetings, conferences, seminars, etc.
v. New discoveries, inventions or patent disclosures and specific applications stemming from the individual project provided that such disclosure shall not compromise the rights of the inventor.
vi. Reporting on Utilization of Subject Inventions should be included in the Annual Status Report per Section 10.08 of the Base Agreement.

Quarterly Status Report

for

<Project Agreement Holder Name>

Project No. MCDC-XX-XX-XXX

Reporting Period: DATE - DATE

Project Agreement Holder

<Project Lead>

<Other Project Team Member(s)>

Project Team Technical POC

Name Company Street Address
City, State Zip Code Phone Number Email address

Submitted: <date>

1. Comments on Technical/Cost/Schedule Performance

The purpose of this section is to bring project stakeholders up to speed on current project status. It is not intended to be a line-by-line account of the quarter's activities; details of that nature are reserved for the latter section of this report. Rather, this section should highlight technical, cost, and schedule performance for the quarter, and report overall progress towards successful technology transition and implementation – an executive summary-like synopsis. This section should also be used to cite project-related concerns.

Properly crafted, this section is typically about one-half page in length.

2. Project Quad Chart

Quad charts are used for many purposes, including high level briefings. Therefore, it is imperative that information be current and accurate, especially in regards to the lower quadrants. The text - where populated - in the quad chart below is for sample purposes only.

<table>
<tr><th colspan="2">< Project Agreement Title></th></tr>
<tr><td colspan="2"></td></tr>
<tr><th>Goals & Objectives</th><th>Project Information</th></tr>
<tr><td>Briefly describe the goals of the project; include the technical objectives and the implementation targets.</td><td>Project Lead: Team
Members:
Period of Performance:
Funding:
Cumulative Amt Invoiced:
Total Cost Share Reported:</td></tr>
<tr><th>Milestones & Technical Achievements</th><th>Implementation & Payoff</th></tr>
<tr><td rowspan="2">Apr 16: Kickoff Meeting
Jun 16: Design Analysis complete
Jul 16: Materials/Equipment Rec'd
Oct 16: Prototype construction complete
May 17: Initial testing complete
Oct 17: Production units implemented in shipyard processes</td><td>Schedule: Target date for implementation.
Status: Current status towards implementation event.</td></tr>
<tr><td>Briefly describe what benefits will accrue from this project's successful completion and implementation. Be quantitative to the greatest extent possible.</td></tr>
<tr><td colspan="2"><u>Current Status:</u> Technical = Green/Yellow/Red (delta) Schedule = Green/Yellow/Red (delta) Cost = Green/Yellow/Red (delta)</td></tr>
</table>

Current Status Legend: Green = Good/On Budget Yellow = Minor Weakness/Known Risk Red = Major Weakness/Critical Delta: □ = upgrade from last assessment; □ = downgrade from last assessment; □ = no change

3. Supplemental Information

In order to improve the usefulness of the quad charts and provide sufficient project information, the Quarterly Status Report must be supplemented with data described below.

3.1 Milestone Status:

No.	Milestone	Due Date	Percent Complete This Period	Cumulative Percent Complete
1				
2				
3				

3.2 Non-Traditional Defense Contractor Participation

Name of Nontraditional*	Planned Start Date	Actual Start Date	Reason for Deviation from Plan

3.3 Plans for Next Quarter

- Major achievements planned for the next quarter

MEMORANDUM: Agreements Officer Representative Sign-Off

To: Agreements Officer Representative (AOR) From: ___
Date: ___
Reference: (a) MCDC Base Agreement between ATI and
_____ Agreement No. __
(b) Project Agreement No. ___
Subject: Milestone Approval

The following deliverable(s) associated with the Milestone(s) listed below have been completed:

MS#	Deliverable
XX	___

It is requested that verification of these accomplishments be provided to the MCDC Consortium Management Firm.

To: MCDC Consortium Management Firm

CERTIFICATION BY AGREEMENTS OFFICER REPRESENTATIVE:

The Project Agreement Holder has made satisfactory progress and provided the required deliverables associated with this milestone. I certify the work performed is in accordance with the approved Statement of Work (SOW) included in the agreement.

Other comments or concerns regarding this or future milestones:

[Note: For any non-satisfactory areas include a discussion of what was not acceptable, references to previous correspondence on the issue, and what corrective actions are needed to effect payment.]

_____ _____
Agreements Officer Representative Date:

Attachment C
Technical Direction Letter (TDL) RPP-20-08 Regeneron

This page intentionally left blank. See separate document for Attachment C.

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

06 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-08, Objective TRE-PRE-20-08 for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" (Regeneron Pharmaceuticals, Inc.)

REF: Regeneron Request for Technical Direction Letter, RPP 20-08 under OTA W15QKN-16-9- 1002 for Objective TRE-PRE-20-08, dated 30 June 2020

Advanced Technology International
ATTN: Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear ,

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-08 on 17 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Regeneron as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Regeneron to award this proposal under Other Transaction Agreement W15QKN-16-9- 1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Regeneron's proposal for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The cost proposal that has been analyzed and negotiated by the Government, you are hereby directed to issue a Project Agreement to Regeneron for the subject project. The total project value has been determined fair and reasonable and Regeneron's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed [* * *]. The break-out of the costs is as follows: $450,262,000.00 to perform project efforts included in the SOW and [* * *] for the Consortium Management Firm (CMF) Administrative Cost. [* * *] The effort currently has
[* * *] of available funding, comprised of $450,262,000.00 for the Project Agreement and [* * *] for the CMF. PAH COVID-19 work shall be tracked separately using the funding obligated via modification P00074. [* * *]

The PAH is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

The Government and Advanced Technology International ("ATI") hereby agree and confirm that (a) ATI, in its capacity as the Consortium Management Firm under the Medical CBRN Defense Consortium (MCDC) Other Transaction Agreement No. W15QKN-16-9-1002 (the MCDC Agreement), has the authorization to enter into the Medical CBRN Defense Consortium Base Agreement No. 2020-504 and the Statement of Work (collectively, the "Regeneron Agreement") with Regeneron on behalf of the Government, (b) the Government is and shall be bound by its obligations set forth in the Regeneron Agreement, and the MCDC Agreement is hereby amended to incorporate these obligations in the MCDC Agreement, as that Agreement relates to Regeneron, and (c) Regeneron is an intended third-party beneficiary of such obligations that can enforce them directly against the Government, and (d) in the event of any conflict between the Regeneron Agreement, on the one hand, and the MCDC Agreement, on the other hand, the Regeneron Agreement shall control and take precedence.

Points of Contact:

Agreements Specialist:
E-mail:
Phone:

Agreements Officer:
E-mail:
Phone:

Regards,

Agreements Officer
Signed by:

Attachments:
Attachment 1: MCDC2008-005 - Regeneron - 7-3-2020
Attachment 2: OPSEC Language Addendum
[***]

_____
ATI 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.

EXECUTION VERSION

License Agreement

This Agreement is entered into with effect as of August 18, 2020 (the "**Effective Date**")

by and between

F. Hoffmann-La Roche Ltd

with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("**Roche Basel**")

and

Genentech, Inc.

with an office and place of business at 1 DNA Way, South San Francisco, California 94080, United States ("**Genentech**" together with Roche Basel "**Roche**")

on the one hand

and

Regeneron Pharmaceuticals, Inc.

with an office and place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, United States ("**Regeneron**")

on the other hand.

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1.120 US Affiliate
1.121 US Person

License Agreement

WHEREAS, Regeneron is developing an antibody cocktail directed to the SARS-CoV-2 spike protein consisting of two antibodies known as REGN10933 and REGN10987; and

WHEREAS, Roche has expertise in the development, manufacture and commercialization of pharmaceutical products in the field of infectious diseases, including the ability to rapidly scale up commercial supply for pandemic stockpiling and discussions with governments; and

WHEREAS, Roche Basel and Regeneron intend to develop, manufacture and commercialize the antibody cocktail directed to the SARS-CoV-2 spike protein consisting of REGN10933 and REGN10987 globally as a treatment for COVID19; and

WHEREAS, Roche Basel and Regeneron have entered into a Technology Transfer Agreement as of July 22, 2020 (the "**Technology Transfer Agreement**"); and

WHEREAS, Regeneron is willing to grant to Roche Basel rights to use certain of its intellectual property rights to make Compounds and Products in the Territory (as such terms are respectively defined below), develop Compounds and Products in the Territory, and use, offer for sale, sell and import Compounds and Products in the Roche Territory and export Compounds and Products to the Territory, in each case, for use in the Field (as such terms are respectively defined below), as contemplated herein; and

WHEREAS, Roche is willing to grant Regeneron rights to use certain of its intellectual property rights to make Compounds and Products in the Territory and to develop, use, offer for sale, sell and import and export Compounds and Products in the Territory for use in the Field, as contemplated herein; and

WHEREAS, Roche and Regeneron agree that Regeneron will continue to perform certain ongoing activities to develop the Compound; and

WHEREAS, Roche and Regeneron agree that Roche and Regeneron will perform certain activities to develop, manufacture and commercialize the Compound and Product.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

1. Definitions

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 Accounting Standards

The term "Accounting Standards" shall mean the maintenance of records and books of accounts in accordance with IFRS (International Financial Reporting Standards) or GAAP (Generally Accepted Accounting Principles), which standards or principals (as applicable) are currently used at the applicable time by, and as consistently applied by the applicable Party.

1.2 Affiliate

The term “Affiliate” shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of “Affiliate,” the term “control” shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, none of Chugai Pharmaceutical Co., Ltd, a Japanese corporation (“**Chugai**”) and its subsidiaries (if any) shall be deemed to be Affiliates of Roche unless mutually agreed by the Parties.

1.3 Agreement

The term “Agreement” shall mean this document including any and all appendices and amendments to it as may be agreed by the Parties from time to time in accordance with the provisions of this Agreement.

1.4 Agreement Term

The term “Agreement Term” shall mean the period of time commencing on the Effective Date and, unless this Agreement is terminated sooner as provided in Article 20, ending seven (7) years after the First Commercial Sale of the first Product in the EU and any extension thereto mutual agreed by the Parties in writing.

1.5 Alliance Director

The term “Alliance Director” shall mean one person of each Party appointed to be its point of contact with responsibility for facilitating communication and collaboration between the Parties who shall facilitate resolution of potential and pending issues and potential disputes to avert escalation of such issues or potential disputes.

1.6 Antibody

The term “Antibody” shall mean a protein or polypeptide sequence that includes a complementarity-determining region (CDR) of an antibody (e.g. mAb, Fab, scFv, other fragments of an antibody), whether polyclonal or monoclonal, fully human, humanized, chimeric, multiple or single chain, recombinant or naturally occurring. For clarity, Antibodies shall not include other modalities such as nucleic acid, viral or cellular therapy modalities, or antibodies conjugated to a toxin or other active agent where the primary intended function of the antibodies is not to neutralize a target, but to direct such toxin or other active agent to such target (each, an “**Antibody Conjugate**”).

1.7 Applicable Law

The term “Applicable Law” shall mean any law, statute, ordinance, code, rule or regulation that has been enacted by a government authority (including, any Regulatory Authority) and is in force as of the Effective Date or comes into force during the Agreement Term, in each case to the extent that the same is applicable to the Compounds, Products, or performance by the Parties of their respective obligations under this Agreement.

1.8 Back-Up Compound

The term “Back-Up Compound” shall mean [* * *].

1.9 BARDA

The term “BARDA” shall mean the US Biomedical Advanced Research and Development Authority.

1.10 Biosimilar Product

The term “Biosimilar Product” shall mean, with respect to a Product and a country,
any product that is claimed to be biosimilar to or interchangeable with such Product in such country (including a product that is the subject of a biologics license application submitted under Section 351(k) of the PHSA citing such Product as the reference product or any corresponding foreign application in the Territory, including, with respect to the European Union, an MAA for a similar biological medicinal product pursuant to Article 10(4) of Directive 2001/83/EC) or for which the biologics license application otherwise references or relies on such Product in such country.

1.11 Business Day

The term “Business Day” shall mean 9:00 am to 5:00 pm local time on a day other than a Saturday, Sunday or bank or other public or federal holiday in Switzerland (with regard to Roche) or New York, New York or elsewhere in the US (with regard to Regeneron).

1.12 Calendar Quarter

The term “Calendar Quarter” shall mean each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, or December 31.

1.13 Calendar Year

The term “Calendar Year” shall mean the period of time beginning on January 1 and ending December 31, except for the first Calendar Year, which shall begin on the Effective Date and end on December 31.

1.14 Chugai Asset Criteria

The term “Chugai Asset Criteria” shall mean [* * *].

1.15 Chugai Asset Data Package Criteria

The term "Chugai Asset Data Package Criteria" shall mean data, reports, documentation and other information in the Chugai Asset Data Package that are reasonably sufficient to determine whether or not the Chugai Asset satisfies the Chugai Asset Criteria.

1.16 Clinical Study

The term "Clinical Study" shall mean any human clinical trial, including a Phase I Study, Phase II Study, or Phase III Study.

1.17 CMO

The term "CMO" shall mean a Third Party contract manufacturing organization.

1.18 Code

The term "Code" shall mean the US Internal Revenue Code of 1986, as amended.

1.19 Co-Funded Development Plan

The term "Co-Funded Development Plan" shall mean the development plan for the Co-Funded Studies agreed and approved by the JSC. The Co-Funded Development Plan shall initially include the Additional Regeneron Studies and shall be updated by the JSC to include any Clinical Studies described on Appendix 1.20(b) and may further be updated from time to time by the JSC to include additional Co-Funded Studies.

1.20 Co-Funded Studies

The term "Co-Funded Studies" shall mean (a) the Clinical Studies as set forth on Appendix 1.20(a) (the "**Additional Regeneron Studies**") and (b) any additional Clinical Studies for which the Parties, through the JSC, agree to share the out-of-pocket costs, including the Clinical Studies described Appendix 1.20(b).

1.21 Collaboration Timepoint

The term "Collaboration Timepoint" shall mean [* * *].

1.22 Combination Product

The term "Combination Product" shall mean any product containing both the Compound and one or more other pharmaceutically active agents, regardless of their finished forms or formulations or dosages.

1.23 Commercially Reasonable Efforts

The term "Commercially Reasonable Efforts" shall mean, with respect to a Party and any objective or decision pertaining to a Compound or Product under this Agreement, the level of efforts and resources [* * *], taking into account, without limitation, the public health need for therapeutics due to the SARS-CoV-2 pandemic, epidemiology of SARS-CoV-2, commercial

opportunity [* * *], the available production supply of Compound and Product, legal factors, regulatory factors (including requirements of Regulatory Authorities), target product profiles, product liability, market exclusivity, cost of goods, pricing and access considerations, relative safety and efficacy, competitive market conditions, and its proprietary position; provided that [* * *] shall not be considered as a factor to mitigate its obligation to use Commercially Reasonable Efforts under this Agreement.

1.24 Companion Diagnostic

The term "Companion Diagnostic" shall mean any product that is used for predicting or monitoring the response of a human being to treatment with a Product.

1.25 Competitive Infringement

The term "Competitive Infringement" shall mean any (i) known infringement or suspected infringement by a Third Party of any Joint Patent Rights by the exploitation of a Competing Product, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any Joint Know-How by the exploitation of a Competing Product.

1.26 Compound

The term "Compound" shall mean the Lead Compound and each Back-Up Compound.

1.27 [* * *]

[* * *].

1.28 [* * *]

[* * *].

1.29 Confidential Information

The term "Confidential Information" shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by or on behalf of one Party or its Affiliates ("**Disclosing Party**") to the other Party or its Affiliates ("**Receiving Party**") in connection with this Agreement (including pursuant to the Technology Transfer Agreement), whether prior to, on, or after the Effective Date, including information relating to the terms of this Agreement, the Compound, the Products, any development, manufacture or commercialization of the Products, any Know-How with respect thereto developed by or on behalf of the Disclosing Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, (a) Joint Inventions, Joint Know-How and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto, and (b) Arising Regeneron Know-How shall be deemed the Confidential Information of Regeneron, and Regeneron shall be deemed to be the Disclosing Party, and Roche shall be deemed to be the Receiving Party, with respect thereto. For clarity, all Proprietary Manufacturing Information shall be Regeneron's Confidential Information. Confidential Information shall not include any information, data or know-how of the Disclosing Party that the Receiving Party can demonstrate:

(i) was generally available to the public at the time of disclosure, or becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates,

(ii) to have been already known to the Receiving Party or its Affiliates prior to its receipt from the Disclosing Party; provided that this exception shall not apply with respect to Arising Regeneron Know-How or Arising Regeneron Inventions,

(iii) is obtained at any time lawfully from a Third Party under circumstances permitting its use or disclosure,

(iv) is developed independently by the Receiving Party or its Affiliates other than through knowledge of Confidential Information; provided that this exception shall not apply with respect to Arising Regeneron Know-How or Arising Regeneron Inventions, or

(v) is approved in writing by the Disclosing Party for release by the Receiving Party.

For clarity, the references to Arising Regeneron Know-How or Arising Regeneron Inventions in clauses (ii) and (iv) above, do not apply to any component or step of Arising Regeneron Know-How or Arising Regeneron Inventions that is not itself Arising Regeneron Know-How or Arising Regeneron Inventions.

Specific elements of Confidential Information shall not be deemed to be generally available to the public or in the possession of the Receiving Party merely because such elements are encompassed by more general information that falls within the foregoing exclusions. Furthermore, any combination of individual elements of Confidential Information shall constitute Confidential Information and shall not be deemed to fall within the foregoing exclusions merely because one or more individual elements of such combination fall within the foregoing exclusions.

1.30 Continuation Election Notice

The term “Continuation Election Notice” shall mean the notice Regeneron provides to Roche under Section 19.3.1 describing (i) Regeneron’s *bona fide* intentions to continue ongoing development and commercialization of Product(s) and (ii) Regeneron’s request for Roche’s continuation of activities or transfer of the data, material and information relating to the Product(s) in accordance with Section 19.3.1.

1.31 Control

The term “Control” with respect to a Party shall mean (as an adjective or as a verb including conjugations and variations such as “Controls” “Controlled” or “Controlling”) (a) with respect to patent rights, inventions or know-how, the possession by such Party of the ability to assign or grant a license or sublicense of such patent rights, inventions or know-how without violating the terms of any agreement or arrangement between such Party and any Third Party and (b) with respect to proprietary materials, the possession by such Party of the ability to supply such proprietary materials to the other Party as provided herein without violating the terms of any agreement or arrangement between such Party and any Third Party.

1.32 Cover

The term “Cover” shall mean (as an adjective or as a verb including conjugations and variations such as “Covered,” “Coverage” or “Covering”) that the developing, making, using, offering for sale, promoting, selling, exporting or importing of a given compound, formulation or product would infringe a Valid Claim in the absence of a license under or ownership in the Patent Rights to which such Valid Claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis.

1.33 COVID19

The term “COVID19” shall mean the disease caused by the causative agent SARS-CoV-2.

1.34 CRO

The term “CRO” shall mean a Third Party contract research organization.

1.35 CTA

The term “CTA” shall mean clinical trial approval granted by national Regulatory Authorities in the EU.

1.36 Dollars

The term “Dollars” shall mean US dollars.

1.37 [* * *]

[* * *].

1.38 Drug Product

The term “Drug Product” shall mean a Product formulated and filled that meets the specifications determined pursuant to Section 4.1.3.

1.39 Drug Substance

The term “Drug Substance” shall mean drug substance of Product in formulated bulk form that meets the specifications determined pursuant to Section 4.1.3.

1.40 EMA

The term “EMA” shall mean the European Medicines Agency or any successor agency with responsibilities comparable to those of the European Medicines Agency.

1.41 Emergency Use Authorization or EUA

The term “Emergency Use Authorization” or “EUA” shall mean an emergency use authorization issued by the FDA pursuant to Section 564 of the FDCA. The duration of an EUA depends in part on the duration of the declaration of the U.S. Department of Health and Human Services

("**HHS**") that supports the EUA. The HHS declaration must be current for an EUA to remain in effect. The HHS declaration terminates upon the earlier of (a) HHS determining that the circumstances justifying the EUA's issuance no longer exist or (b) a change in the approval status of the product such that an EUA would no longer be needed.

1.42 EU

The term "EU" or "European Union" shall mean the European Union and all its member countries as of the Effective Date.

1.43 Expert

The term "Expert" shall mean a person with no less than ten (10) years of pharmaceutical or biotechnology industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to product development or licensing but excluding (a) any current or former employee or consultant of either Party (or its Affiliates), and (b) any person who has known personal financial interest in or who would benefit from the outcome or resolution of the applicable dispute. Such person shall be fluent in the English language.

1.44 FDA

The term "FDA" shall mean the Food and Drug Administration of the United States of America or any successor agency thereto.

1.45 FDCA

The term "FDCA" shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

1.46 Field

The term "Field" shall mean all prophylactic, therapeutic and diagnostic uses in all indications.

1.47 Finished Product

The term "Finished Product" shall mean the final Product including packaging and its final container(s) ready for delivery to the market that meets the specifications therefor determined pursuant to Section 4.1.3.

1.48 First Commercial Sale

The term "First Commercial Sale" shall mean, on a country-by-country basis, the first invoiced sale or distribution [* * *] of a Product to a Third Party by either Party or any of its Affiliates or Sublicensees following the receipt of any Regulatory Approval required for the sale of such Product, or if no such Regulatory Approval is required, the date of the first invoiced sale or distribution [* * *] of a Product to a Third Party by either Party or any of its Affiliates in such country.

For clarity, compassionate use sales will not be considered in determining the First Commercial Sale.

1.49 [* * *]

[* * *].

1.50 [* * *]

[* * *].

1.51 [* * *]

[* * *].

1.52 [* * *]

[* * *].

1.53 Fully Burdened Manufacturing Costs

The term "Fully Burdened Manufacturing Costs" shall mean with respect to a Product, each Party's consolidated fully-burdened cost incurred by such Party or any of its Affiliates in manufacturing such Product (including all commercial manufacturing activities related to CMC, formulation, quality control, packaging and labeling, failed batches, and including all activities related to the supply of plasmids, raw materials, and where applicable, Drug Substance, Drug Product and Finished Product) in accordance with this Agreement and each Party's Accounting Standards, in bulk, vialed or finished product form as the case may be, including: [* * *].

1.54 GAVI Eligible Countries

The term "GAVI Eligible Countries" shall mean the countries listed by the Global Alliance for Vaccines and Immunization (https://www.gavi.org/types-support/sustainability/eligibility) as of the Effective Date, and such other low income countries (as determined by the World Bank) as may otherwise be agreed by the Parties in writing.

1.55 Global Gross Profit

The term "Global Gross Profit" shall mean, with respect to each Presentation of Product in a given Calendar Quarter, the sum of the Parties' respective Gross Profit for such Presentation of Product for such Calendar Quarter.

1.56 Gross Profit

The term "Gross Profit" shall mean, with respect to each Party and each Presentation in a given Calendar Quarter, the result of the following, for each such Presentation, (a) the Net Sales of such Presentation by such Party or any of its Affiliates or Sublicensees in its Respective Territory during such Calendar Quarter minus (b) [* * *].

1.57 Handle

The term “Handle” (as an adjective or as a verb including conjugations and variations such as “Handling”) shall mean one or more of preparing, filing, prosecuting (including interferences, reissue, re-examination, post-grant reviews, inter-partes reviews, nullity actions, derivation proceedings and opposition proceedings) and maintaining any Patent Rights.

1.58 Hospitalized Patients

The term “Hospitalized Patients” shall mean COVID19 patients that are treated in hospital institutions providing acute, in-patient medical and surgical treatment and nursing care.

1.59 Indemnitees

The term “Indemnitees” shall mean the Regeneron Indemnitees or the Roche Indemnitees, as applicable.

1.60 Insolvency Event

The term “Insolvency Event” shall mean circumstances under which a Party or any entity that controls such Party (i) has a receiver or similar officer appointed over all or a material part of its assets or undertaking; (ii) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); (iii) enters into any composition or arrangement with its creditors (other than relating to a solvent restructuring) or assignment for the benefit of creditors; (iv) ceases to carry on business; (v) is unable to pay its debts as they become due in the ordinary course of business; (vi) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the person or of its assets; or (vii) is the subject of an involuntary petition in any bankruptcy or insolvency proceeding, and such petition is not dismissed within sixty (60) days after the filing thereof.

1.61 Invention

The term “Invention” shall mean an invention that is conceived or first reduced to practice in connection with any activity carried out pursuant to this Agreement. Under this definition, an Invention may be made by or on behalf of Regeneron or any of its Affiliates or Sublicensees solely or jointly with a Third Party (a “**Regeneron Invention**”), by or on behalf of the Roche Group solely or jointly with a Third Party (a “**Roche Invention**”), or jointly by or on behalf of Regeneron or any of its Affiliates, on the one hand, and by or on behalf of the Roche Group, on the other hand, with or without a Third Party (a “**Joint Invention**”); provided any Invention that is specifically related to any Compound or Product (including the composition of, formulations containing, any methods of using, or the manufacture of, a Compound or Product) (an “**Arising Regeneron Invention**”) shall be a Regeneron Invention. For clarity, Roche Invention shall not include Roche Independent IP, and Arising Regeneron Invention shall not include Roche Independent IP, or any Invention that is generally but not specifically related to a Product. For example, an Invention relating to the purification of antibodies generally but not specific to purification of a Compound or Product shall not be considered an Arising Regeneron Invention.

1.62 Joint Know-How

The term “Joint Know-How” shall mean Know-How that is made jointly by or on behalf of Regeneron or any of its Affiliates or Sublicensees, on the one hand, and by or on behalf of the Roche Group, on the other hand, with or without a Third Party in connection with any activity carried out pursuant to this Agreement, excluding any Arising Regeneron Know-How.

1.63 Joint Patent Rights

The term “Joint Patent Rights” shall mean all Patent Rights Covering a Joint Invention.

1.64 Know-How

The term “Know-How” shall mean data, knowledge and information, including materials, samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical and clinical data, assays, platforms, formulations, specifications, quality control testing data, that are confidential and necessary or useful for the discovery, manufacture, development or commercialization of Products.

1.65 Knowledge

The term “Knowledge” shall mean [* * *].

1.66 Lead Compound

The term “Lead Compound” shall mean Regeneron’s proprietary Antibody cocktail consisting of the Antibodies REGN10933 and REGN10987 which as of the Effective Date is under development by Regeneron. The sequences of REGN10933 and REGN10987 are specified in Appendix 1.66.

1.67 Lead Product

The term “Lead Product” shall mean any product containing the Lead Compound as its sole pharmaceutically active agent, regardless of the finished form or formulation or dosage.

1.68 Manufacturing Collaboration Timepoint

The term “Manufacturing Collaboration Timepoint” shall mean [* * *].

1.69 Major Country

The term “Major Country” shall mean any of the following countries: any country in the EU, Australia, Canada, the United Kingdom, Japan and China.

1.70 Net Sales

The term “Net Sales” shall mean, with respect to each Party and Presentation of Product in a particular period, (a) the sum of (i) Sales of such Party and its Affiliates and Sublicensees and (ii) Sublicensee Compensation for such Party, less (b) the Additional Deductions.

"**Sales**" shall mean, with respect to each Party, its Affiliates and, unless otherwise agreed by Regeneron pursuant to Section 2.2.2 or by Roche pursuant to Section 2.5, as applicable, Sublicensees, the amount of net sales of such Presentation of Product for such period (excluding sales among such Party, any of its Affiliates and Sublicensees) as calculated in accordance with such Party's Accounting Standards.

"**Sublicensee Compensation**" for a Party shall mean the compensation received by such Party and its respective Affiliates from [* * *] any other Sublicensees to the extent agreed by Regeneron pursuant to Section 2.2.2 or by Roche pursuant to Section 2.5, as applicable, in each case in accordance with the sublicensee contractual terms and their then-currently used Accounting Standards.

"**Additional Deductions**" shall mean:

(a) A lump sum deduction of [* * *]; and

(b) [* * *]; and

(c) government mandated fees and taxes and other government charges accrued during such period not already taken as a gross-to-net deduction in accordance with the then currently used Accounting Standards in the calculation of Net Sales of such Presentation of Product for such period, including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body.

For clarity, any compensation received from [* * *] will not be considered party of Net Sales and will be addressed as provided in Section 7.4.

Net Sales in currency other than Dollars shall be converted into Dollars according to the provisions of Section 11.4. For purposes of determining Net Sales, (i) the Product shall be deemed to be sold in accordance with the applicable Party's (or its applicable Affiliate's or Sublicensee's) Accounting Standards consistently applied; (ii) and a "sale" shall not include transfers or dispositions of the Product among a Party, its Affiliates, and unless otherwise agreed by the Parties in writing, its or their Sublicensees. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but that are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of the Product for consideration other than cash, such as barter or countertrade, or Sublicensee Compensation received in consideration other than cash, Net Sales shall be calculated on the fair market value of such consideration received as agreed by the Parties.

1.71 NGO

The term "NGO" shall mean a not-for-profit, non-governmental organization providing or facilitating the provision of health care in low income countries (e.g., GAVI Eligible Countries), such as the World Health Organization, UNICEF and Red Cross International. For the avoidance of doubt, the term NGO is limited to organizations that operate independently of government and does not include governmental or quasi-governmental organizations such as the EU or its institutions, bodies or agencies.

1.72 Non-US Affiliate

The term “Non-US Affiliate” shall mean any Affiliate that is not a US Affiliate.

1.73 Ongoing Regeneron Studies

The term “Ongoing Regeneron Studies” shall mean the Clinical Studies that are being conducted by Regeneron as of the Effective Date to support the initial Regulatory Approval for treatment of Hospitalized Patients or Out-Patients that are listed on Appendix 1.73.

1.74 Out-Patients

The term “Out-Patients” shall mean COVID19 patients that are not treated in hospital institutions providing acute, in-patient medical and surgical treatment and nursing care.

1.75 Party

The term “Party” shall mean Regeneron or Roche, as the case may be, and “Parties” shall mean Regeneron and Roche collectively.

1.76 Patent Rights

The term “Patent Rights” shall mean all rights under any patent or patent application, in any country of the Territory, including any patents issuing on such patent application or claiming priority to any such patent or patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.

1.77 Pharmaceutical Company

The term “Pharmaceutical Company” shall mean any company whose primary business is the research, development, marketing and distribution of pharmaceutical or biopharmaceutical products, limited to the top 20 in global sales.

1.78 Phase I Study

The term “Phase I Study” shall mean a human clinical trial in any country that would meet the description in 21 C.F.R. § 312.21(a), as amended from time to time, and the foreign equivalent thereof.

1.79 Phase II Study

The term “Phase II Study” shall mean a human clinical trial, for which the primary endpoints include a determination of dose ranges or a preliminary determination of efficacy in patients being studied as described in 21 C.F.R. § 312.21(b), as amended from time to time, and the foreign equivalent thereof.

1.80 Phase III Study

The term “Phase III Study” shall mean a human clinical trial that is prospectively designed to demonstrate with statistical significance whether a product is safe and effective for use in humans in a manner sufficient to obtain Regulatory Approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. § 312.21(c) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.81 PHSA

The term “PHSA” shall mean the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.82 PPQ

The term “PPQ” shall mean process performance qualification that is a component of process validation. The PPQ combines the actual facility, utilities, equipment (each now qualified), and the trained personnel with the commercial manufacturing process, control procedures, and components to produce commercial batches (i.e. commercial scale Drug Substance batches executed for the purpose of process validation which are commercially eligible upon license approval). PPQ batches do not include preceding engineering/technical batches.

1.83 Presentation

The term “Presentation” shall mean, (a) with respect to a Drug Product, such Drug Product filled in one or more distinct quantities of Drug Substance, and (b) with respect to a Finished Product, such Finished Product filled, packaged and labeled in one or more distinct quantities of Drug Substance.

1.84 Product

The term “Product” shall mean any product containing a Compound as its sole pharmaceutically active agent, regardless of its finished form or formulation or dosage. One Product may be distinguished from another Product by the Compound being a distinctive active pharmaceutical ingredient.

1.85 Product Know-How

The term “Product Know-How” shall mean any Regeneron Know-How that is specifically related to any Product that, without a license from Regeneron or its applicable Affiliate, would be infringed or misappropriated by the exploitation (other than manufacturing) of any Product by a Third Party.

1.86 Product Patent Right

The term “Product Patent Right” shall mean any Regeneron Patent Rights that includes at least one claim specifically related to a Product that, without a license from Regeneron or its applicable Affiliate, would be infringed (or, in the case of a patent application would be infringed

if it were to issue in a patent) by the exploitation (other than manufacturing) of any Product by a Third Party.

1.87 Proprietary Manufacturing Information

The term "Proprietary Manufacturing Information" shall mean all Regeneron Know-How that is used, or intended to be used, to manufacture the Products (or any component or intermediate thereof).

1.88 Regulatory Approval

The term "Regulatory Approval" shall mean any approvals (excluding pricing and reimbursement approvals), licenses, registrations or authorizations by a Regulatory Authority, necessary for the manufacture and sale of a Product in the Field in a regulatory jurisdiction in the Territory, including an Emergency Use Authorization, Biologics License Application submitted to FDA under Section 351 of the PHSA ("**BLA**"), and, with respect to the EU, an application for marketing authorization approval ("**MAA**") filed with the EMA pursuant to the centralized approval procedure, or with the applicable national Regulatory Authority of a country in the European Union with respect to the mutual recognition procedure, decentralized procedure or any other national approval.

1.89 Regulatory Authority

The term "Regulatory Authority" shall mean any national, supranational (e.g., the European Commission, the Council of the European Union, the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity including the FDA, in each country involved in the granting of regulatory approval for the development, manufacture or sale of a Product.

1.90 Regeneron Base Patent Rights

The term "Regeneron Base Patent Rights" shall mean Product Patent Rights in the Territory that are Controlled by Regeneron or any of its Affiliates at the Effective Date, said Patent Rights being exhaustively listed in Appendix 1.90 of this Agreement.

1.91 Regeneron Cell Media

The term "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 any Drug Substance.

1.92 Regeneron Controlled Infringement

The term "Regeneron Controlled Infringement" shall mean (a) any Infringement of a Product Patent Right or Product Know-How, in either case, in the Regeneron Territory or (b) any Competitive Infringement of a Joint Patent Right or Joint Know-How, in either case, in the Regeneron Territory (including any Competitive Infringement of a Joint Patent Right or Joint Know-How, in each case, in both the Regeneron Territory and the Roche Territory).

1.93 Regeneron-DOD/BARDA Agreement

The term “Regeneron-DOD/BARDA Agreement” shall mean that certain agreement between Regeneron and Advanced Technology International for the sale of Products entitled “Project Agreement NO. 1, MCDC BASE AGREEMENT NO. 2020-504, Project Title: MCDC2008-005; Large Scale Manufacturing of Antibodies Directed to SARS-CoV-2”, including any amendment thereto.

1.94 Regeneron Existing BARDA Commitment

The term “Regeneron Existing BARDA Commitment” shall mean Regeneron’s commitment as of the Effective Date to manufacture a total of twenty eight (28) lots of the Antibodies included in the Lead Product for supply under the Regeneron-DOD/BARDA Agreement.

1.95 Regeneron Know-How

The term “Regeneron Know-How” shall mean the Know-How that Regeneron or any of its Affiliates Controls at the Effective Date or during the Agreement Term, including any Arising Regeneron Know-How, For clarity, Regeneron Know-How shall not include any Roche Independent IP or Roche Know-How.

1.96 Regeneron Patent Rights

The term “Regeneron Patent Rights” shall mean the Patent Rights that Regeneron or any of its Affiliates Controls, relating to or arising from the discovery, manufacture, development or commercialization of or Covering a Compound, Product or Regeneron Invention. The term Regeneron Patent Rights shall include Regeneron Base Patent Rights, but excludes any Joint Patent Rights. For clarity, Regeneron Patent Rights shall not include any Roche Independent IP or Roche Patent Rights.

1.97 Regeneron Patent Territory

The term “Regeneron Patent Territory” shall mean the Regeneron Territory.

1.98 Regeneron Territory

The term “Regeneron Territory” shall mean the US.

1.99 Respective Territory

The term “Respective Territory” shall mean, with respect to Regeneron, the Regeneron Territory and with respect to Roche, the Roche Territory.

1.100 Roche Major Countries

The term “Roche Major Countries” shall mean each of the following countries: [* * *].

1.101 Roche Group

The term “Roche Group” shall mean collectively Roche, its Affiliates and its Sublicensees.

1.102 Roche Independent IP

The term “Roche Independent IP” shall mean inventions, patents, trade secrets, know-how or other intellectual property that Roche or any of its Affiliates Controls at the Effective Date, or made or lawfully obtained by Roche or any of its Affiliates independent of the activities carried out pursuant to this Agreement, and without referring to or using any Confidential Information of Regeneron.

1.103 Roche Know-How

The term “Roche Know-How” shall mean the Know-How arising from activities carried out pursuant to this Agreement and that Roche or any of its Affiliates Controls during the Agreement Term. For clarity, the Roche Know-How does not include the Arising Regeneron Know-How or Roche Independent IP.

1.104 Roche Manufacturing Facilities

The term “Roche Manufacturing Facilities” shall mean the facilities listed in Appendix 1.104.

1.105 Roche Patent Rights

The term “Roche Patent Rights” shall mean the Patent Rights that Roche or any of its Affiliates Controls, relating to or arising from the discovery, manufacture, development or commercialization of or Covering a Compound, Product or Roche Invention, but excluding any Roche Independent IP, Regeneron Patent Rights or Joint Patent Rights.

1.106 Roche Production Contribution

The term “Roche Production Contribution” shall mean a fraction, (a) the numerator of which is equal to the sum of [* * *], for which the Drug Substance was manufactured by the Roche Group, and (b) the denominator of which is the equal to the sum of [* * *]; provided that beginning with the Calendar Quarter, if any, in which Regeneron first supplies Drug Substance to Roche for commercial use by Roche in the Roche Territory, Roche may elect to determine in accordance with Appendix 1.106 [* * *] for such Calendar Quarter for which the Drug Substance was manufactured by the Roche Group.

1.107 Roche Shared Infringement

The term “Roche Shared Infringement” shall mean (a) any Infringement of a Product Patent Right or Product Know-How, in either case, in the Roche Territory or (b) any Competitive Infringement of a Joint Patent Right or Joint Know-How, in either case, in the Roche Territory that is unrelated to any Competitive Infringement of a Joint Patent Right or Joint Know-How in the Regeneron Territory.

1.108 Roche Territory

The term “Roche Territory” shall mean all countries other than the US, excluding any Terminated Country from and after the effective date of termination for such Terminated Country.

1.109 ROW

The term “ROW” shall mean all countries in the Roche Territory other than the Roche Major Countries.

1.110 Sales Volume

The term “Sales Volume” shall mean, with respect to each Presentation of Product and a Party for the period measured, the number of units of such Presentation of Product that are sold in such Party’s Respective Territory (i.e., that constitute Net Sales for such Party) during such period (for the avoidance of doubt, excluding any such units distributed as [* * *] by or on behalf of such Party or any of its Affiliates or Sublicensees during such period).

1.111 SARS-CoV-2

The term “SARS-CoV-2” shall mean the virus known as the severe acute respiratory syndrome coronavirus 2.

1.112 Sensitive Information

The term “Sensitive Information” shall mean any Proprietary Manufacturing Information or information relating to Regeneron’s cell lines for any Product.

1.113 Standard Cost

The term “Standard Cost” shall mean, with respect to a Party for a given Calendar Year, (a) with respect to Product in its respective form (Drug Substance, Drug Product, Finished Product), such Party’s reasonable best estimate of its Fully Burdened Manufacturing Costs for such Product for such Calendar Year (without markup) based on such Party’s Fully Burdened Manufacturing Costs for the prior Calendar Year for such Product and any anticipated changes in Fully Burdened Manufacturing Costs for such Calendar Year (e.g., manufacturing efficiencies, changes in cost of raw materials) calculated on a per unit basis (i.e. kilogram for Drug Substance, and unit for Drug Product and Finished Product) and, for Finished Product, on a per Presentation basis, for such Party and with respect to Drug Product and Finished Product, each Party may have a different Standard Cost for each Permutation of each applicable Presentation of such Product, in each case determined pursuant to Section 4.2 and (b) with respect any manufacturing-related services (e.g., filling, finishing, packaging and labelling) that one Party performs for the other Party, the cost for such services determined by the Parties based on the Fully Burdened Manufacturing Costs of performing such services (without mark-up), in each case ((a) and (b)), in accordance with such Party’s Accounting Standards. For clarity, if Finished Product distributed by a Party contains Drug Substance supplied by the other Party or the other Party performed any manufacturing services (e.g., filling, finishing, packaging and labelling) with respect to such Finished Product, then such Party would pay the other Party such other Party’s Standard Costs for such Drug Substance or such services and such Standard Costs shall be included in the Standard Cost for such Finished Product for such first Party. A Party may have a different Standard Costs for Drug Product or Finished Product that is manufactured entirely by or on behalf of such Party as well as Drug Product or Finished Product that is filled, finished, packaged or labelled, or incorporates Drug Substance or Drug Product supplied by or on behalf of the other Party (each such permutation of Drug Product or Finished Product that is manufactured using a different combination of materials and services provided by or on behalf

of the Parties, a "**Permutation**"). Notwithstanding the foregoing, a Party may calculate and use a blended Standard Cost for use with all Permutations of a Presentation of Drug Product or Finished Product as provided in Section 4.2, in its own discretion.

1.114 Sublicensee

The term "Sublicensee" shall mean a Third Party to which either Party has (sub)licensed rights (through one or multiple tiers) licensed to it under this Agreement, other than any Affiliate [* * *].

1.115 Territory

The term "Territory" shall mean all countries of the world.

1.116 Third Party

The term "Third Party" shall mean a person or entity other than (i) Regeneron or any of its Affiliates or (ii) Roche or any of its Affiliates.

1.117 Third Party IP License

The term "Third Party IP License" shall mean any license or other agreement with a Third Party entered into by a Party pursuant to Section 14.18.

1.118 Third Party IP Payments

The term "Third Party IP Payments" shall mean any amounts paid by a Party or any of its Affiliates under any Third Party IP License that are reasonably allocable to the Products.

1.119 US

The term "US" shall mean the United States of America and its territories and possessions.

1.120 US Affiliate

The term "US Affiliate" shall mean any Affiliate that is a US Person.

1.121 US Person

The term "US Person" shall mean a "United States person", as such term is defined in Section 7701(a)(30) of the Code.

1.122 Valid Claim

The term "Valid Claim" shall mean a claim in any unexpired and issued Patent Right that has not been disclaimed, revoked or held invalid by a final non-appealable decision of a court of competent jurisdiction or government agency.

1.123 Additional Definitions

Each of the following definitions is set forth in the Section of this Agreement indicated below:

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[* * *]	10.2
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[* * *]	2.8
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2. Grant of License

2.1 Licenses granted by Regeneron

Regeneron hereby grants to Roche Basel under the Regeneron Patent Rights and Regeneron Know-How and Regeneron's interest in the Joint Patent Rights and Joint Know-How (and in the case of clause (v) below, under Regeneron's rights in the Global Trademarks):

(i) a non-exclusive right and license to make, have made, import, have imported, export and have exported Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.2;

(ii) a non-exclusive right and license to research, have researched, develop, have developed, Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.2;

(iii) a co-exclusive right and license (together with Regeneron) to seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, Compounds and Products in the Roche Territory as contemplated by this Agreement including the right to sublicense pursuant to Section 2.2;

(iv) an exclusive (even as to Regeneron) right and license to market, have marketed, commercially distribute, have commercially distributed, sell and have sold Products in the Field in the Roche Territory and to use, have used, import and have imported Products in the Field in the Roche Territory in connection with such marketing, commercial distribution and sale, including the right to sublicense pursuant to Section 2.2; and

(v) subject to Section 14.3, a non-exclusive, royalty-free, fully paid-up, license to use the Global Trademarks owned by Regeneron in the Regeneron Territory to (a) conduct activities with respect to the Products in the Field in the Regeneron Territory solely to support the marketing, commercial distribution and sale of the Products in the Field in the Roche Territory, if applicable and (b) supply Products to Regeneron pursuant to this Agreement or the Supply Agreement.

2.2 Roche's Right to Sublicense

2.2.1 Right to Sublicense to its Affiliates and [* * *]

Roche Basel shall have the right to grant (a) written sublicenses to its Affiliates (through multiple tiers) and (b) [* * *].

For the avoidance of doubt, if Chugai is not added as an Affiliate hereunder, Chugai shall be considered a Third Party hereunder, provided that Roche Basel may still sublicense rights granted under Section 2.1 to Chugai in Japan without the prior written approval of Regeneron pursuant to this Section.

[* * *]

[* * *]

Roche Basel shall inform Regeneron promptly after having granted a sublicense pursuant to this Section 2.2.1 other than to an Affiliate.

Each permitted sublicense shall be in writing and consistent in all material respects with the terms and conditions of this Agreement and Roche Basel shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable Affiliate or [* * *] to the same extent as they apply to Roche Basel for all purposes; provided that a separate written sublicense shall not be required for Affiliates or distributors who have existing agreements with Roche or its Affiliates that are consistent with the terms and conditions of this Agreement. Roche Basel assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Affiliate or [* * *], as applicable, and shall itself account to Regeneron for all payments due under this Agreement by reason of such sublicense.

2.2.2 Right to Sublicense to Other Third Parties

Roche Basel and its Affiliates shall have the right to grant written sublicenses to Third Parties (other than [* * *], which are addressed in Section 2.2.1), through multiple tiers, under its rights granted under Section 2.1(i) only upon prior written approval of Regeneron.

Roche Basel and its Affiliates shall have the right to grant written sublicenses to Third Parties (other than [* * *], which are addressed in Section 2.2.1), through multiple tiers, under its rights granted under Section 2.1(ii) - 2.1(v) (a) upon the prior written approval of Regeneron (i) in Regeneron's sole discretion if the Third Party is a Pharmaceutical Company, (ii) not to be unreasonably withheld, conditioned or delayed, if such sublicense is granted with respect to a Roche Major Country, and (iii) in Regeneron's sole discretion, if such proposed Sublicensee would have access to any Proprietary Manufacturing Information, including in connection with regulatory filings with applicable Regulatory Authorities in such country, and (b) otherwise without the prior approval of Regeneron.

[* * *]

Each permitted sublicense shall be in writing and consistent in all material respects with the terms and conditions of this Agreement and Roche Basel shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable Sublicensee to the same extent as they apply to Roche Basel for all purposes; provided that a separate written sublicense shall not be required for distributors who have existing agreements with Roche or its Affiliates that are consistent with the terms and conditions of this Agreement. Roche Basel assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Sublicensee and shall itself account to Regeneron for all payments due under this Agreement by reason of such sublicense.

2.3 Roche Basel Right to Subcontract

Roche Basel, at its own cost and discretion, shall have the right to subcontract the work performed under Section 2.1(i) through Section 2.1(iv) to Affiliates without the prior approval of Regeneron.

Roche Basel, at its own cost and discretion, shall have the right to subcontract the work performed under Section 2.1(i) to CMOs or other Third Parties in the Territory only with the prior approval of Regeneron; provide that Roche Basel may subcontract the work performed under Section 2.1(i) to CMOs with respect to Finished Product or the conversion of Drug Substance to Drug Product or Finished Product or Drug Product to Finished Product (but not with respect to the manufacture of Drug Substance) without the prior approval of Regeneron; provided further that Roche shall notify Regeneron in writing of such subcontracting in sufficient time for Regeneron to update its applicable regulatory filings for the applicable Product and shall use diligent efforts to ensure that there is no interruption for supply of such Product in the Regeneron Territory as a result of such subcontracting.

Roche Basel, at its own cost and discretion, shall have the right to subcontract the work performed under Section 2.1(ii) through Section 2.1(iv) to Third Parties in the Territory without the prior approval of Regeneron.

Each permitted subcontract shall be consistent in all material respects with the terms and conditions of this Agreement and Roche Basel shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable subcontractor to the same extent as they apply to Roche Basel for all purposes. Roche Basel assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such subcontractor and shall itself account to Regeneron for all payments due under this Agreement by reason of such subcontract.

2.4 Licenses granted by Roche

Roche hereby grants to Regeneron under the Roche Patent Rights and Roche Know-How and Roche Independent IP and Roche's interest in the Joint Patent Rights and Joint Know-How (and in the case of clause (v) below, under Roche's rights in the Global Trademarks):

(i) a non-exclusive right and license to make, have made, import, have imported, export and have exported Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.5;

(ii) a non-exclusive right and license to research, have researched, develop, have developed, seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.5;

(iii) an exclusive (even as to Roche) right and license to seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, Compounds and Products in the Regeneron Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.5;

(iv) an exclusive (even as to Roche) right and license to market, have marketed, commercially distribute, have commercially distributed, sell and have sold Products in the Field in the Regeneron Territory and to use, have used, import and have imported Products in the Regeneron Territory in connection with such marketing, commercial distribution and sale, including the right to sublicense pursuant to Section 2.5;

(v) subject to Section 14.3, a non-exclusive, royalty-free, fully paid-up, license to use the Global Trademarks owned by Roche in the Roche Territory to (i) conduct activities with respect to the Products in the Field in the Roche Territory solely to support the marketing, commercial distribution and sale of the Products in the Field in the Regeneron Territory, if applicable and (ii) supply Products to Roche pursuant to this Agreement or the Supply Agreement.

2.5 Regeneron's Right to Sublicense

Regeneron shall have the right to grant written sublicenses to its Affiliates (through multiple tiers) and Third Parties under its rights granted under Section 2.4 without prior approval of Roche; provided that, (a) with respect to any rights granted under Sections 2.4(i), Regeneron and its Affiliates shall not grant a sublicense (other than to a [* * *]) to a CMO or another Third Party to manufacture Drug Substance without Roche's prior written consent (other than sublicensing manufacture of Drug Substance to CMOs in the Territory up to the Minimum Committed Regeneron Capacity, which may be without the prior approval of Roche); and (b) Regeneron and its Affiliates shall not grant a sublicense (other than to a [* * *]) under Section 2.4(ii) with respect to Roche Independent IP to a Third Party without Roche's prior written consent, not to be unreasonably withheld, conditioned, or delayed. Regeneron must provide Roche reasonable notice before granting any [* * *], and upon Roche's request the Parties shall discuss in good faith options to avoid the grant of any [* * *] and Regeneron shall use diligent efforts to avoid having to grant any [* * *].

If Regeneron licenses a Third Party in the Regeneron Territory under the rights granted to Roche under Section 2.1(iv) in the Roche Territory (whether or not Regeneron sublicenses the rights granted to Regeneron by Roche under Section 2.4(iv) to such Third Party), then, unless otherwise agreed by Roche in writing in its sole discretion, such Third Party will be considered a Sublicensee of Regeneron.

[* * *]

Each permitted sublicense shall be consistent in all material respects with the terms and conditions of this Agreement and Regeneron shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable Affiliate or Sublicensee to the same extent as they apply to Regeneron for all purposes; provided that a separate written sublicense shall not be required for Affiliates or distributors who have existing agreements with Regeneron or its Affiliates that are consistent with the terms and conditions of this Agreement. Regeneron assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Affiliate or Sublicensee, as applicable, and shall itself account to Roche for all payments due under this Agreement by reason of such sublicense. Regeneron shall inform Roche promptly after having granted a sublicense pursuant to this Section 2.5.

2.6 Regeneron Right to Subcontract

Regeneron, at its own cost and discretion, shall have the right to subcontract any work performed under this Agreement to Third Parties in the Territory without the prior approval of Roche, except that Regeneron shall not have the right to subcontract manufacture of Drug Substance to CMOs or other Third Parties in the Territory without the prior approval of Roche; provided that Regeneron may subcontract manufacture of Drug Substance to CMOs in the Territory up to the Minimum Committed Regeneron Capacity without the prior approval of Roche. Unless otherwise agreed by the Parties, any grant of rights by Regeneron to a CMO or Third Party under the rights granted to Roche Basel pursuant to Section 2.1(i) shall be considered a "subcontract" for purposes of restrictions under this Section 2.6, regardless of the structure of such arrangement with the CMO or Third Party.

Each permitted subcontract shall be consistent in all material respects with the terms and conditions of this Agreement and Regeneron shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable subcontractor to the same extent as they apply to Regeneron for all purposes. Regeneron assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such subcontractor and shall itself account to Roche for all payments due under this Agreement by reason of such subcontract.

2.7 Combination Products and Companion Diagnostics

Each Party shall not, and shall cause its Affiliates not to develop, have developed, seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, commercially distribute, have commercially distributed, sell or have sold any Combination Product or Companion Diagnostic, unless and until the Parties have agreed in writing on the terms and conditions with respect thereto.

2.8 Back-Up Compounds

[* * *].

2.9 Antibody Conjugates

During the Agreement Term, Regeneron will not, and will cause its Affiliates not to, clinically develop or commercialize an Antibody Conjugate that contains the Lead Compound or any Antibody in the Lead Compound, or grant a license to a Third Party to do so.

3. Research and Development

3.1 Responsibilities

Regeneron shall, at its own cost and expense, use Commercially Reasonable Efforts to conduct the Ongoing Regeneron Studies and shall have the right to pursue Third Party funding for the Ongoing Regeneron Studies. Regeneron shall provide Roche Basel periodic updates at interim analysis points regarding the progress and status of the Ongoing Regeneron Studies, including a high-level summary of any available data from the Ongoing Regeneron Studies.

The JOC will discuss and align on a strategy for investigator-sponsored studies with respect to the Compounds and the Products in the Territory (for example key clinical questions of interest, areas that the Parties do not wish to address, and any potential supply constraint) (the "**ISS Strategy**"). Regeneron shall have the right, but not the obligation, to provide support for any investigator-sponsored studies with respect to the Compounds and the Products in the Regeneron Territory, consistent with the ISS Strategy, and will consult with Roche Basel regarding such studies and consider Roche Basel's comments in good faith. Roche shall have the right, but not the obligation, to provide support for any investigator-sponsored studies with respect to the Compounds and the Products in the Roche Territory, consistent with the ISS Strategy, and will consult with Regeneron regarding such studies and consider Regeneron's comments in good faith. Unless otherwise agreed by the Parties, each Party will provide support for any investigator-sponsored studies for the Compounds and the Products [* * *].

Prior to initiating a new Clinical Study that is not an Ongoing Regeneron Study and is not included in the then-current Co-Funded Development Plan and is not an ongoing Unilateral Study, the Party that desires to conduct such Clinical Study (the "**Proposing Party**") shall propose such Clinical Study to the JOC, which proposal shall include a synopsis of the protocol for such Clinical Study and an estimated budget for such Clinical Study. The JOC shall review and submit such Clinical Study to the JSC for approval. If the JSC agrees that the Parties shall share the [* * *] with respect to such Clinical Study, then the Parties shall amend the Co-Funded Development Plan to include such Clinical Study and such Clinical Study shall be a Co-Funded Study. With respect to each Co-Funded Study, the Party conducting such Co-Funded Study shall provide the other Party periodic updates at least once a Calendar Quarter regarding the progress and status of such Co-Funded Study, including a high-level summary of any available data from such Co-Funded Study.

If the JSC does not agree [* * *] with respect to such Clinical Study, then the Proposing Party shall have the right, but not the obligation, to conduct such Clinical Study [* * *] (each such Clinical Study, a "**Unilateral Study**"). [* * *].

Each Party shall use Commercially Reasonable Efforts to perform the development activities with respect to the Co-Funded Studies that are assigned to such Party in the Co-Funded Development Plan and shall do so in accordance with the Co-Funded Development Plan. The Parties acknowledge and agree that Regeneron is responsible for conducting the Additional Regeneron Studies, and Regeneron shall provide Roche Basel periodic updates at interim analysis points regarding the progress and status of the Additional Regeneron Studies, including a high-level summary of any available data from the Additional Regeneron Studies. Each Party will be responsible for its own internal costs associated with development activities for the Co-Funded Studies. [* * *] by or on behalf of either Party or any of its Affiliates in connection with the Co-Funded Studies (including, for clarity, such [* * *] incurred by or on behalf of Regeneron or any of its Affiliates with respect to the Additional Regeneron Studies prior to the Effective Date) that are not reimbursed by a Third Party shall be [* * *]. [* * *].

Each Party shall [* * *] be responsible for all development activities with respect to each Unilateral Study conducted by such Party. For clarity, neither Party shall have the obligation to conduct or, except as may be required by Applicable Law or ethical requirements, complete any Unilateral Study.

Prior to initiating any development activities with respect to any delivery device for the Products (e.g., pre-filled syringe) (the "**Device Development Activities**"), the Party that desires to conduct such Device Development Activities shall provide a proposed development plan for such delivery device to the JOC (the "**Device Development Plan**"), which Device Development Plan will include an estimated budget for such Device Development Activities. The JOC shall review and submit such Device Development Plan to the JSC for approval. If the JSC agrees [* * *] with respect to such Device Development Activities, then the Parties will agree to a final Device Development Plan and such Device Development Activities shall be "**Co-Funded Device Development Activities**". With respect to Co-Funded Device Development Activities, the Party conducting such Co-Funded Device Development Activities shall provide the other Party periodic updates regarding the progress and status of such Co-Funded Device-Development Activities.

If the other Party does not agree [* * *] with respect to proposed Device Development Activities, then the Party proposing such Device Development Activities shall have the right, but not the obligation, to conduct such Device Development Activities [* * *] (such Device Development Activities, "**Unilateral Device Development Activities**"). [* * *].

Each Party shall use Commercially Reasonable Efforts to perform the Device Development Activities with respect to Co-Funded Device Development Activities that are assigned to such Party in the final agreed Device Development Plan for such Co-Funded Device Development Activities and shall do so in accordance with such final agreed Device Development Plan. Each Party will be responsible for its own internal costs associated with the Co-Funded Device Development Activities and the [* * *] incurred by or on behalf of either Party or any of its Affiliates in connection with the Device Development Activities under the Device Development Plan shall be [* * *]. [* * *].

Each Party shall, [* * *], be responsible for all Unilateral Device Development Activities conducted by such Party. For clarity, neither Party shall have the obligation to conduct or, except as may be required by Applicable Law or ethical requirements, complete any Unilateral Device Development Activities.

[* * *]

Notwithstanding anything to the contrary in the foregoing, unless otherwise agreed by the Parties, Regeneron shall have the sole right, but not the obligation, to conduct any clinical assay that is designed to measure [* * *]. Regeneron shall use Commercially Reasonable Efforts to perform or have performed any [* * *] on biological samples collected in connection with any Clinical Study with respect to the Product conducted by or on behalf of Roche or its Affiliates or Sublicensees.

Each Party shall conduct its development activities with respect to the Compounds and Products in accordance with Applicable Law and the terms of this Agreement.

3.2 Co-Funded Development Plan

The Parties shall conduct the Co-Funded Studies in accordance with the Co-Funded Development Plan.

Any proposed modifications to the Co-Funded Development Plan to include any additional Co-Funded Studies or to modify any existing Co-Funded Studies shall be made pursuant to Article 8.

3.3 Exchange of Information

Each Party shall disclose and make available to the other Party all data and information necessary for such other Party to conduct the development activities under this Agreement. Each Party shall answer any questions reasonably posed by the other Party with respect to the development activities under this Agreement and provide any information reasonably requested by the other Party with respect thereto that is in the possession of such first Party.

Without limiting reporting obligations under Section 3.1, each Party shall provide to the other Party (a) headline data on each Clinical Study with respect to a Product conducted by such Party as soon as possible after such data or results become available and before the final report(s) are written and (b) final reports of each Clinical Study with respect to a Product conducted by such Party promptly after such reports become available. The data exchanged between the Parties under this Section 3.3 shall be delivered in an electronic format that is appropriate for purposes of submission to Regulatory Authorities in support of Regulatory Approval.

3.4 Development Records

Each Party shall maintain records of its development activities under this Agreement (or cause such records to be maintained) in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of such Party in the performance of the development.

3.5 PII/Samples

In connection with Clinical Studies or other activities associated with the development and commercialization of Products, the Parties may collect (i) personally identifiable information about individual human subjects or (ii) human biological samples (collectively, "**PII/Samples**"). Each Party shall collect the PII/Samples in compliance with Applicable Law and Roche shall use Commercially Reasonable Efforts to obtain all consents necessary for such PII/Samples to be transferred to Regeneron upon expiration or termination of this Agreement.

4. Manufacturing

4.1 Manufacturing Responsibility

4.1.1 Shared Responsibility during the Agreement Term

Each Party shall use diligent efforts to promptly complete those activities assigned to it pursuant to the Transfer Plan (as defined in the Technology Transfer Agreement) pursuant to the Technology Transfer Agreement. Notwithstanding Section 7 of the Technology Transfer Agreement, the Parties agree (a) they shall not terminate the Technology Transfer Agreement separate from this Agreement and (b) if either Party breaches the Technology Transfer Agreement, such breach shall be deemed to be a breach by such Party under this Agreement. Upon the Manufacturing Collaboration Timepoint, Roche shall, at its own cost, (i) dedicate and

utilize the equivalent of at least 100,000 liters of annualized bioreactor capacity on a full-time campaign basis [* * *] for the manufacture of Drug Substance at the Roche Manufacturing Facilities or at CMOs (subject to Section 2.3) ("**Minimum Committed Roche Capacity**"), unless the JMC decides a Minimum Committed Capacity Reduction pursuant to Section 8.2.3(g) and (ii) reserve sufficient capacity to fill, finish, pack and label, at its discretion, at Roche facilities or CMOs (subject to Section 2.3) the Drug Substance it manufactures.

Unless otherwise agreed by the Parties in writing, any Product supplied by Roche to Regeneron under this Agreement or the Supply Agreement shall be Finished Product. Prior to beginning to manufacture Drug Substance at a Roche Manufacturing Facility other than the Roche Manufacturing Facility in Vacaville, California, Roche will notify the JMC for review and discussion of the Roche Manufacturing Facility pursuant to Section 8.2.3(i); provided that the JMC shall not have an approval right over use of such Roche Manufacturing Facility and Roche may determine to use such Roche Manufacturing Facility in its discretion.

Upon the Manufacturing Collaboration Timepoint, Regeneron shall at its own cost, dedicate and utilize the equivalent of at least 40,000 liters of annualized bioreactor capacity on a full-time campaign basis [* * *] for the manufacture of Drug Substance at Regeneron's facilities or at CMOs (subject to Section 2.6) ("**Minimum Committed Regeneron Capacity**"), unless the JMC decides a Minimum Committed Capacity Reduction pursuant to Section 8.2.3(g). Unless otherwise agreed by the Parties in writing, any Products supplied by Regeneron to Roche Basel under this Agreement or the Supply Agreement shall be Drug Substance.

If the JMC decides to reduce the Minimum Committed Roche Capacity and Minimum Committed Regeneron Capacity because the demand in the Territory drops below 140,000 liters of bioreactor capacity on an annualized basis for commercial manufacture of the Drug Substance for the Lead Product, then, unless the JSC decides by mutual consent on a different proportion, the Minimum Committed Roche Capacity shall be reduced at the same proportion as the Minimum Committed Regeneron Capacity.

4.1.2 Excess Capacity

In addition to its responsibilities set forth in Section 4.1.1 each Party shall have the right to make available bioreactor capacity for Drug Substance at its own facilities consistent with the terms of this Agreement, in excess of, respectively, the Minimum Committed Roche Capacity and the Minimum Committed Regeneron Capacity.

Roche Basel shall consider in good faith any request by Regeneron to convert Drug Substance which Regeneron manufactures to Drug Product or Finished Product. For the avoidance of doubt, if Roche Basel determines that it does not or will not have sufficient excess capacity to accommodate Regeneron's request, that shall be a sufficient good faith reason for denying such request. [* * *].

4.1.3 Specifications

Regeneron shall be solely responsible for establishing the specifications for each Drug Substance and Drug Product. Prior to Regeneron finalizing any specifications, Regeneron will provide Roche with the proposed specifications and provide Roche with a reasonable opportunity to provide comments thereto, which Regeneron will consider in good faith. Each

Party shall be solely responsible for establishing the specifications for packaging and labeling of the Finished Product in its respective territory.

4.2 Standard Costs

(a) The Parties, through the JMC (in consultation with the FWG), shall determine each Party's Standard Cost for each Drug Substance, Drug Product (which shall be on a Presentation-by-Presentation and Permutation-by-Permutation basis) and Finished Product (which shall be on a Presentation-by-Presentation and Permutation-by-Permutation basis), and any manufacturing services (i.e., filing, finishing, packaging and labelling) to be performed by or on behalf of such Party for the other Party, in each case prior to the [* * *] and prior to each October 31 thereafter; provided that, with respect to each Presentation of Drug Product or Finished Product, the manufacturing Party may use a blended Standard Cost based on the weighted average of the Fully Burdened Manufacturing Costs for all applicable Permutations of such Presentation. Prior to each such date, each Party shall provide to the JMC, with such supporting cost breakout information as determined by the JMC, (i) the Fully Burdened Manufacturing Costs for each Drug Substance, Drug Product or Finished Product, for each applicable Presentation, manufactured by or on behalf of such Party or its Affiliates in the prior Calendar Year and any manufacturing services (i.e., filling, finishing, packaging and labelling) performed by or on behalf of such Party or any of its Affiliates for the other Party in the prior Calendar Year, (ii) its reasonable best estimate of its Fully Burdened Manufacturing Costs for each Drug Substance, Drug Product or Finished Product, including for each applicable Presentation, to be manufactured by or on behalf of such Party or its Affiliates in such Calendar Year and any manufacturing services (i.e., filling, finishing, packaging and labelling) to be performed by or on behalf of such Party or any of its Affiliates for the other Party in such Calendar Year, in each case, taking into account any anticipated changes in Fully Burdened Manufacturing Costs for such Calendar Year (e.g., manufacturing efficiencies, changes in cost of raw materials), and (iii) for any Presentation of Drug Product or Finished Product for which the manufacturing Party elects to use one blended Standard Cost, the information used by such Party to determine the weighted average of the Fully Burdened Manufacturing Costs for the various Permutations of such Presentation.

(b) The Parties shall discuss and agree on, through the JMC (in consultation with the FWG), the Standard Costs for each Party with respect to each Drug Substance, Drug Product or Finished Product, including for each applicable Presentation to be manufactured by or on behalf of such Party or its Affiliates for the coming Calendar Year and for any manufacturing services (i.e., filling, finishing, packaging and labelling) to be performed by or on behalf of a Party or any of its Affiliates for the other Party, in each case, based on the information provided by each Party in accordance with Section 4.2(a).

(c) [* * *].

(d) Within [* * *] after the end of each of Calendar Year, with respect to each Presentation for which the manufacturing Party used one blended Standard Cost for all Permutations of such Presentation, such manufacturing Party shall report to the JMC such manufacturing Party's actual Fully Burdened Manufacturing Costs for each Permutation and the quantity of each such Permutation that was manufactured during such Calendar Year. [* * *].

4.3 Regeneron Cell Banks and Cell Media.

4.3.1 Regeneron Cell Banks

In connection with the technology transfer under the Technology Transfer Agreement and for the sole purposes of enabling Roche or its Affiliates to manufacture the Product(s) pursuant to this Agreement, Regeneron will, upon Roche's request, supply to Roche [* * *] of vials of the working cell bank for the manufacture of Drug Substance (the "**Working Cell Bank**"), subject to the terms and conditions herein and in the Technology Transfer Agreement.

Roche shall pay [* * *] in connection with the supply of any quantity of Working Cell Bank requested by Roche after completion of the technology transfer pursuant to the Technology Transfer Agreement.

Roche shall not, and shall cause its Affiliates not to, (i) use or duplicate any Working Cell Bank (or any component thereof) for any purpose other than to manufacture the Drug Substance for purposes of manufacturing the Product(s), or (ii) transfer any Working Cell Bank (or any component thereof) to any Third Party, other than a CMO approved by Regeneron.

4.3.2 Regeneron Cell Media

The Roche Group shall only purchase Regeneron Cell Media from Regeneron or its Affiliates, or from any Third Party that Regeneron has authorized to manufacture Regeneron Cell Media, in each case, solely to enable Roche to manufacture the Product(s) pursuant to this Agreement, and upon Roche's reasonable request, Regeneron shall provide a letter of authorization to any such Third Party in order to permit such Third Party to supply Regeneron Cell Media to Roche.

Regeneron shall not be required to disclose to Roche the composition, formula, properties or method of making any Regeneron Cell Media. Roche shall not, and shall cause its Affiliates not to, (a) use Regeneron Cell Media for any purpose other than to manufacture the Product(s) pursuant to this Agreement or (b) transfer Regeneron Cell Media to any Third Party other than a CMO approved by Regeneron.

Nothing in this Section 4.3.2 shall be deemed or construed to limit Roche or any of its Affiliates with respect to any cell culture media that Roche can demonstrate was in the possession of Roche or any of its Affiliates as of the Effective Date other than under this Agreement or the Technology Transfer Agreement.

4.3.3 Ownership and Restrictions

(a) Regeneron shall own exclusively the Working Cell Bank. Regeneron hereby grants to Roche Basel a non-exclusive, royalty-free, fully paid-up, non-sublicensable (other than to any of its Affiliates or CMO approved by Regeneron), non-transferable (except as permitted in Section 21.5) license to use the Working Cell Bank and Regeneron Cell Media solely for the purposes of manufacturing the Product(s) pursuant to this Agreement.

(b) Roche Basel shall not, and shall ensure that its Affiliates, and its and their permitted Sublicensees do not, reverse engineer any cell lines, media or feeds or any other proprietary materials in the Working Cell Bank or Regeneron Cell Media.

(c) Roche Basel shall destroy any quantities of Working Cell Bank and Regeneron Cell Media remaining upon expiration or termination of this Agreement within [* * *] following such expiration or termination. Roche shall provide written certification of such destruction to Regeneron.

5. Supply

5.1 Allocation

Until the [* * *], Regeneron, may sell Product manufactured by Regeneron in the Regeneron Territory or transfer such Product to Roche Basel for sale in the Roche Territory by Roche Basel, its Non-US Affiliates or Sublicensees in accordance with this Section 5.1 and Section 10.2 (a) – (c).

Until the [* * *], Roche may sell Product manufactured by Roche in the Roche Territory or transfer such Product to Regeneron for sale in the Regeneron Territory by Regeneron, its Affiliates or Sublicensees in accordance with this Section 5.1 and Section 10.2 (a) - (c).

Starting [* * *], the Parties shall manufacture Drug Substance for the Lead Product at the Minimum Committed Roche Capacity and the Minimum Committed Regeneron Capacity, respectively. For clarity, each Party may, at its discretion, prior to [* * *] manufacture Drug Substance for the Lead Product that counts towards the Minimum Committed Roche Capacity or the Minimum Committed Regeneron Capacity, as the case may be, for the year 2021.

[* * *]

[* * *]

For clarity, the actual amount of Product provided from one Party to the other Party pursuant to this Section 5.1 will be determined in accordance with the forecasting and ordering process set forth in the Supply Agreement.

Notwithstanding anything to the contrary in this Agreement, Regeneron shall not be required to sell any Product to any US Affiliate of Roche.

5.2 Supply Price

If one Party supplies to the other Party Drug Substance, Drug Product or Finished Product, as the case may be, such supply shall be [* * *].

5.3 Supply Agreement

Unless otherwise agreed by the Parties, no later than [* * *] following the Effective Date, the Parties will negotiate in good faith and enter into a supply agreement on reasonable and customary terms for the process of ordering and supply of Products among the Parties, with a related quality agreement (collectively, the "**Supply Agreement**"). The principles set forth in Sections 5.1 and 5.2 shall be further detailed in the Supply Agreement. The Supply Agreement shall also encompass precise descriptions of Drug Product manufacturing and labeling and packaging.

6. Regulatory

6.1 Responsibility

6.1.1 Regeneron's Responsibilities.

Regeneron shall be solely responsible [* * *] for all regulatory affairs specifically with respect to any Product in the Regeneron Territory, including pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities including the preparation and filing of applications for any or all Regulatory Approvals, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Products in the Regeneron Territory. Regeneron or its Affiliates shall own, maintain and file in their discretion all regulatory filings and Regulatory Approvals for all Products throughout the Regeneron Territory. Roche shall, upon Regeneron's reasonable request and [* * *], provide assistance with respect to any such regulatory activities conducted by Regeneron, including that Roche shall prepare the portions of any regulatory filing documentation in the Regeneron Territory to the extent relating to Roche's manufacture of Drug Substance, Drug Product or Finished Product, as applicable. Notwithstanding the foregoing, Roche shall be responsible for the Roche Regulatory Activities (including any such activities in the Regeneron Territory), and to the extent permitted by Applicable Law, Roche and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Roche Regulatory Activities in the Regeneron Territory. To the extent permitted by Applicable Law, Regeneron shall (a) provide Roche reasonable advance notice of any meeting with any Regulatory Authority in the Regeneron Territory related to the preparation or filing of such applications, and Roche may appoint up to [* * *] Roche employees to attend any such meeting with Regulatory Authorities in the Regeneron Territory; and (b) upon Roche's request, Regeneron shall provide Roche with copies of all material filings and submissions prepared and exchanged with Regulatory Authorities in support of obtaining or maintaining Regulatory Approval for the Products in the Regeneron Territory.

Regeneron shall also be solely responsible [* * *] for all regulatory affairs related to (a) (i) the conduct of the Ongoing Regeneron Studies and (ii) any Co-Funded Study or Unilateral Study, in either case, conducted by or on behalf of Regeneron and (b) Regeneron's manufacture of the Products, in each case ((a) or (b)), anywhere in the Territory (collectively, the "**Regeneron Regulatory Responsibilities**"), including pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities including the preparation and filing of applications for any or all Regulatory Approvals, as well as any or all governmental approvals with respect to the Regeneron Regulatory Responsibilities ("**Regeneron Regulatory Activities**"); provided, that the Parties shall [* * *] Regeneron's [* * *] for all regulatory affairs related to any Co-Funded Study. Regeneron and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Regeneron Regulatory Activities in the Territory (but not, for clarity, any Regulatory Approval for commercialization of any Product in the Roche Territory except as provided in the next paragraph). Regeneron shall (A) provide reasonable advance notice of any meeting with any Regulatory Authority in the Roche Territory related to any Regeneron Regulatory Responsibilities, and, to the extent permitted by Applicable Law, Roche may appoint up to [* * *] Roche employees to attend any such meeting with Regulatory Authorities in the Roche Territory; and (B) consider in good faith any input from Roche in preparing such regulatory materials and interactions. Roche shall, upon Regeneron's

reasonable request, provide assistance with respect to any such regulatory activities conducted by Regeneron, subject to the following paragraph with respect to the First Approval Activities.

Regeneron shall, in coordination with Roche, be responsible, [* * *], for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities (including the preparation and filing of applications) for the first MAA for the Lead Product in the EU (the "**First EU Approval**") and the first Regulatory Approval for the Lead Product in the United Kingdom (the "**First UK Approval**"), in each case, as determined by the JOC, either (A) in the name of Regeneron, or (B) in the name of Roche (in which case, Regeneron shall act as an agent of Roche) (collectively, the "**First Approval Activities**"). If Regeneron acts as an agent of Roche and file the application for the First EU Approval or for the First UK Approval, as applicable, in the name of Roche, then upon Regeneron's reasonable request, Roche shall execute any documentation necessary to enable Regeneron to act as Roche's agent with respect to the applicable First Approval Activities. Roche shall, upon Regeneron's reasonable request and [* * *], provide assistance with respect to the First Approval Activities, including that Roche shall prepare the portions of the application for the First EU Approval or the First UK Approval, as applicable, to the extent relating to Roche's manufacture of Drug Substance, Drug Product or Finished Product, as applicable. To the extent permitted by Applicable Law, (i) Regeneron shall provide Roche reasonable advance notice of any meeting with any Regulatory Authority in the EU or the United Kingdom, as applicable, related to the preparation or filing of such application, and Roche may appoint [* * *] Roche employees to attend any such meeting with Regulatory Authorities in the EU or the United Kingdom, as applicable; and (ii) Regeneron shall seek input from Roche in preparing such regulatory materials and interactions, and Roche at its own discretion shall have the right to review and approve all documentation prepared and exchanged with Regulatory Authorities in support of filing for such First EU Approval or First UK Approval, as applicable, related to manufacturing sites and manufacturing specifications, label wording and claims (summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), primary/secondary packaging text) and negotiation of pediatric investigational plans or post-approval commitments. If Regeneron files the application for the First EU Approval or for the First UK Approval, as applicable, in the name of Regeneron, then, as soon as practicable after obtaining the First EU Approval or the First UK Approval, as applicable, Regeneron shall undertake all actions necessary to transfer to Roche such First EU Approval or First UK Approval, as applicable, and any regulatory filings in Regeneron's possession with respect thereto (but excluding, for clarity, any CTA for the Lead Product) and, Regeneron shall, at Roche's reasonable request, cooperate as necessary for such First EU Approval or First UK Approval, as applicable, to be transferred to Roche.

Promptly after the Effective Date, Regeneron shall coordinate and cooperate with Roche to share with Roche, upon Roche's reasonable request, (i) relevant historical clinical safety data, copies of all material correspondence with the Regulatory Authorities of the Roche Territory, (ii) electronic Clinical Study data (including Clinical Study reports, datasets, summaries, overviews and other relevant documentation) in an appropriate format and (iii) regulatory dossiers containing information necessary or useful to Roche in connection with its regulatory filings for any Products in the Roche Territory, including clinical trial dossiers, material regulatory correspondence, and study reports from completed non-clinical studies, in each case, ((i) - (iii)) to the extent in the possession of Regeneron or any of its Affiliates. Regeneron shall, upon Roche's request and at Roche's cost, assist Roche in conducting any required GCP audit related to the above-mentioned documentation.

Regeneron shall maintain the company core data sheet for each Product (the "**CCDS**") for purposes of enabling commercialization of such Product throughout the Territory. Either Party may propose modifications to the CCDS and the Parties shall then discuss whether to modify the CCDS, with each Party considering the other Party's comments with respect thereto in good faith; provided, however, that Regeneron shall have the final decision-making authority with respect to any update to the CCDS.

6.1.2 Roche's Responsibilities.

From and after the Effective Date, subject to the remainder of this paragraph and Regeneron's obligations in Section 6.1.1, Roche shall be solely responsible [* * *] for all regulatory affairs specifically with respect to any Product in the Roche Territory, including the preparation and filing of applications for Regulatory Approval, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Products in the Roche Territory. Roche shall be responsible for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with regulatory agencies, for all Products throughout the Roche Territory. To the extent permitted by Applicable Law, (i) Roche shall provide Regeneron reasonable advance notice of any meeting with any Regulatory Authority in a Major Country related to the preparation or filing of such applications, and Regeneron may appoint [* * *] Regeneron employees to attend any such meeting with Regulatory Authorities in such Major Country; and (ii) Roche shall seek input from Regeneron in preparing such regulatory materials and interactions, and Regeneron shall have the right to review and comment on all material filings and submissions prepared and exchanged with Regulatory Authorities in support of obtaining or maintaining Regulatory Approval for the Products in each Major Country, and Roche shall consider such comments in good faith. Without limiting the foregoing, in preparing regulatory filings with Regulatory Authorities with respect to the Products in the Roche Territory, Roche shall not disclose any Sensitive Information to any Regulatory Authority without Regeneron's prior written approval, [* * *]. Roche shall not submit to a Regulatory Authority, or otherwise agree to any Product labeling (or any modification thereto) that is not consistent with the CCDS, without the prior written consent of Regeneron. During the Agreement Term, Roche or its Affiliates shall own, maintain and file in their discretion all regulatory filings and Regulatory Approvals for all Products throughout the Roche Territory. Notwithstanding the foregoing, Regeneron shall be responsible for the First Approval Activities and the Regeneron Regulatory Responsibilities, in each case, as described in Section 6.1.1 and Regeneron and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Regeneron Regulatory Activities in the Roche Territory.

Roche shall also be solely responsible [* * *] for all regulatory affairs related to (a) the conduct of any Co-Funded Study or Unilateral Study conducted by or on behalf of Roche and (b) Roche's manufacture of the Products anywhere in the Territory (the "**Roche Regulatory Responsibilities**"), including pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities including the preparation and filing of applications for any or all Regulatory Approvals, as well as any or all governmental approvals with respect to the Roche Regulatory Responsibilities ("**Roche Regulatory Activities**"); provided, that the Parties shall [* * *] Roche's [* * *] for all regulatory affairs related to any Co-Funded Study. Roche and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Roche Regulatory Activities in the Territory (but not, for clarity, any BLA for a Product in the Regeneron Territory).

In the event Roche cannot conduct regulatory activities independent of Regeneron which would be needed to pursue Roche Regulatory Responsibilities, including for Regulatory Approval of a Product in the Roche Territory, Regeneron shall use Commercially Reasonable Efforts to assist Roche [* * *], subject to Section 16.1(c). In addition, Regeneron shall prepare the portions of any regulatory filing documentation in the Roche Territory to the extent relating to Regeneron's manufacture of Drug Substance, Drug Product or Finished Product, as applicable.

6.2 Regulatory Diligence Obligation

Regeneron shall use Commercially Reasonable Efforts to obtain (subject to Roche's responsibilities pursuant to Section 6.1) and maintain Regulatory Approval for the Product in the Regeneron Territory; and to obtain the First EU Approval and First UK Approval, as applicable; provided, however, that Regeneron shall not be obligated to conduct any Clinical Studies other than the Ongoing Regeneron Studies and Additional Regeneron Studies to obtain such Regulatory Approval in the EU and the United Kingdom, as applicable.

[* * *].

In the case of multiple Products, then the Parties' diligence obligations under this Section 6.2 shall be with respect to all such Products, taken as a whole.

6.3 Pharmacovigilance and Global Safety Database

The Parties mutually agree to execute a separate safety data exchange agreement as deemed applicable but no later than the initiation of the first Clinical Study for a Product by Roche or the first Regulatory Approval in the Roche Territory (whichever comes first) (the "**Safety Data Exchange Agreement**"). Such Safety Data Exchange Agreement shall set forth the responsibilities and obligations of the Parties with respect to the procedures and timeframes for compliance with the Applicable Law pertaining to safety reporting of the Product(s) and their related activities.

Regeneron shall be responsible for the establishment, holding and maintenance of the global safety database with respect to any Product at its expense.

7. Commercialization

7.1 Responsibility

Regeneron, [* * *], shall have sole responsibility and decision-making authority for all activities associated with marketing, promotion, sale, medical affairs and distribution of Products in the Regeneron Territory.

Roche Basel, [* * *], shall have sole responsibility and decision-making authority for all activities associated with marketing, promotion, sale, medical affairs and distribution of Products in the Roche Territory.

Notwithstanding the foregoing, in no event shall either Party or any of its Affiliates (a) if such Party or its Affiliates sell a Product in the Field in their Respective Territory to a customer who also purchases other products or services from any such entity, such Party shall not, and shall cause its Affiliates not to, bundle or include any Product as part of any multiple product offering

or discount or price the Products in a manner that is reasonably likely to disadvantage a Product in order to benefit sales or prices of other products offered for sale by such Party or its Affiliates to such customer or (b) accept funding from a Third Party for any other products of services for such Party or any of its Affiliates that is reasonably likely to disadvantage the pricing of a Product.

7.2 Pricing

All decisions for each Product related to any pricing matter, including list price, targeted net pricing, sales-weighted average discounts and rebates, pricing strategy (including the approach to pricing with different types of accounts and plans, including types of discounts and rebates), and modifications to any of the foregoing, will be solely made by (a) Regeneron for the Regeneron Territory and (b) Roche Basel for the Roche Territory; [* * *].

7.3 Commercialization Diligence Obligation

Following receipt of Regulatory Approval in the US, Regeneron shall use Commercially Reasonable Efforts to commercialize the Product in the US.

With respect to each Roche Major Country, following receipt of Regulatory Approval in such Roche Major Country, Roche Basel shall use Commercially Reasonable Efforts to commercialize the Product in such Roche Major Country.

Roche Basel shall use Commercially Reasonable Efforts to commercialize the Product in the ROW. Roche (and its Affiliates) shall [* * *].

[* * *].

In the case of multiple Products, then the Parties' diligence obligations under this Section 7.3 shall be with respect to all such Products, taken as a whole.

7.4 [* * *]

[* * *].

7.5 Distribution of Products

Each Party shall manage its Finished Product inventory in the ordinary course of business consistent with its regular practices without regard to the calculation of the Global Gross Profit sharing. [* * *].

7.6 Distribution Audit

If, for a given period (but in no event shorter than [* * *]), one Party has a reasonable inquiry about the other Party's distribution of any Product (including both sales of the Product and distribution of the Product as [* * *]) in such other Party's Respective Territory [* * *], then, upon request by the first Party, the Parties shall discuss such inquiry in good faith through the JMC. Without limiting a Party's right to conduct financial audit pursuant to Section 13.1, each Party shall have the right to audit the applicable books and records of the other Party (or, where applicable, its Affiliates and Sublicensees) relating to distribution of the Product by such other

Party, its Affiliates and Sublicensees, or its or their Third Party logistics service providers, including, to the extent permitted under the applicable agreements between such other Party (or, where applicable, its Affiliates and Sublicensees) and its or their Third Party logistics service providers, the distribution records furnished by such Third Party logistics service providers, for the sole purposes of confirming such other Party's compliance with Section 7.5 (each such audit, a "**Product Distribution Audit**"). The terms and conditions set forth in Section 13.1 with respect to the confidentiality obligations, and the auditing process, limitations, and expenses shall apply, *mutatis mutandis*, to a Product Distribution Audit.

Notwithstanding the foregoing, Regeneron shall not have the right under this Section 7.6 to conduct a Product Distribution Audit with respect to any period for which Roche elects to determine in accordance with Appendix 1.106 the total number of units of all applicable Presentations of the Product that constituted Net Sales [* * *] for each applicable Calendar Quarter [* * *].

8. Governance

8.1 Joint Steering Committee

8.1.1 Formation

Promptly after the Effective Date, the Parties shall establish a joint steering committee ("**JSC**") to oversee the development, manufacturing and commercialization activities under this Agreement.

8.1.2 Members

The JSC shall be composed of six (6) persons ("**Members**"). Roche and Regeneron each shall be entitled to appoint three (3) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement upon written notice to the other Party; provided, that a Party that replaces a Member shall notify the other Party at least [* * *] prior to the next scheduled meeting of the JSC. Each Party may invite a reasonable number of additional experts or advisors to attend part or the whole JSC meeting with prior notification to the JSC; provided that any such expert or advisor who is not an employee of the applicable Party must be approved in advance by the other Party and bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 18. The JSC shall be co-chaired by a Member from Regeneron and a Member from Roche.

8.1.3 Responsibilities of the JSC

The JSC shall have the responsibility and authority to:

(a) review and discuss the development, commercialization and manufacturing activities of both Parties;

(b) approve the Co-Funded Development Plan (including any Clinical Study for which the Parties will share [* * *] as a Co-Funded Study) and any material amendment to the Co-Funded Development Plan submitted by the JOC, including provisions regarding the

responsibility for the performance of the respective development activities with respect to any additional Co-Funded Studies, provided that, (i) with respect to an Additional Regeneron Study any portion of the initial Co-Funded Development Plan with respect to such Additional Regeneron Study that is consistent with the protocol existing as of the Effective Date for such Additional Regeneron Study shall be deemed to have been approved by the JSC; and (ii) with respect to any amendment to the Co-Funded Development Plan for an Additional Regeneron Study, only such amendment that involves [* * *] (each, a "**Material Additional Study Change**") shall be subject to the JSC's approval;

(c) discuss the progress and status of each Unilateral Study;

(d) approve the initial Device Development Plan submitted by the JMC and any material amendment thereto;

(e) [* * *];

(f) review all commercialization activities for the Products in the Territory;

(g) facilitate the exchange of information between the Parties with respect to the development, seeking and obtain Regulatory Approval and commercialization of the Compounds and Products in the Territory;

(h) establish and delegate specifically defined duties to the JMC and JOC;

(i) establish additional subcommittees or operational teams as deemed appropriate and delegate specifically defined duties to them;

(j) attempt to resolve any matters escalated to the JSC by the JMC or JOC; and

(k) perform such other tasks as set forth in this Agreement or as otherwise agreed by the Parties in writing.

The JSC shall have no responsibility and authority other than that expressly set forth in this Section 8.1.3.

8.1.4 Meetings

The Alliance Directors will be responsible for sending invitations and agendas for all JSC meetings to all Members at least [* * *] before the next scheduled meeting of the JSC, provided that the Alliance Director from either Party may request a JSC meeting under exigent circumstances by providing [* * *] prior notice. The JSC shall hold meetings no less than twice each Calendar Year during the Agreement Term, either in person or by tele-/video-conference, and in any case as frequently as the Members of the JSC agree is necessary. The Alliance Director of each Party may attend the JSC meetings as a permanent participant.

8.1.5 Minutes

The Alliance Directors shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JSC meetings, and shall circulate draft minutes of JSC meetings to all members of the JSC for comment and review within [* * *] after the relevant meeting. The Members of the JSC shall have [* * *] to provide comments. The Alliance Directors shall incorporate timely received comments and distribute finalized minutes to all Members of the JSC within [* * *] of the relevant meeting. Both co-chairpersons of the JSC must approve the final version of the minutes before its distribution.

8.1.6 Decisions

8.1.6.1 Decision Making Authority

The JSC shall decide matters within its responsibilities set forth in Section 8.1.3.

8.1.6.2 Consensus; Good Faith

The Members of the JSC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JSC. The Parties shall endeavor to make decisions by consensus with the Members of the JSC from each Party collectively having one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a Member from each Party is present and participating in the vote.

8.1.6.3 Failure to Reach Consensus, Escalation

If the JSC is unable to decide a matter by consensus, then:

(a) Roche shall have final decision authority on any matter relating to (i) the commercialization of Product in the Roche Territory, subject to Regeneron's performance of the First Approval Activities pursuant to Section 6.1.1,; and (ii) selection of Alternative Product Trademarks;

(b) Regeneron shall have final decision authority on any matter relating to (i) the commercialization of Product in the Regeneron Territory; (ii) [* * *]; (iii) any Material Additional Study Change; and (iv) the Global Trademarks;

(c) If the JSC is unable to resolve any other matters not addressed in the foregoing clauses (a) - (b), including any matter escalated to the JSC by the JMC or the JOC, then such matter shall be referred to the CEO of Regeneron and the CEO of Roche Pharmaceuticals for resolution, who shall use reasonable and good faith efforts to reach a decision by consensus within [* * *] after the date such matter is referred to them. If the CEOs of both Parties are unable to reach a decision within such [* * *] period, then unless otherwise agreed by the Parties, [* * *].

8.2 Joint Manufacturing Committee

8.2.1 Formation

Promptly after the Effective Date, the Parties shall establish a joint manufacturing committee ("***JMC***"), which will be a subcommittee of the JSC, to oversee the manufacturing activities under this Agreement.

8.2.2 Members

The JMC shall be composed of four (4) Members. Roche and Regeneron each shall be entitled to appoint two (2) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement upon written notice to the other Party; provided, that a Party that replaces a Member shall notify the other Party at least [* * *] prior to the next scheduled meeting of the JMC. Each Party may invite a reasonable number of additional experts or advisors to attend part or the whole JMC meeting with prior notification to the JMC; provided that any such expert or advisor who is not an employee of the applicable Party must be approved in advance by the other Party and bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 18. The JMC shall be co-chaired by a Member from Regeneron and a Member from Roche.

8.2.3 Responsibilities of the JMC

The JMC shall have the responsibility and authority to:

(a) Discuss, review and approve a rolling, 12-month production forecast for Drug Substance of each Product for each Party (the "**Production Forecast**") and an Alternative Supply Allocation plan (as the case may be pursuant to Section 8.2.3(b)) to be used under the Supply Agreement. [* * *];

(b) decide on changing the allocation of the total Drug Substance of Product produced between the Regeneron Territory and the Roche Territory as foreseen in Section 5.1, including in accordance with demand for the Product in each Respective Territory ("**Alternative Supply Allocation**");

(c) determine each Party's Standard Cost for Drug Substance, Drug Product or Finished Product, including for each applicable Presentation or Permutation, in accordance with Section 4.2;

(d) oversee all aspects of the manufacture of Products under the Supply Agreement, including product specifications and quality;

(e) discuss and approve any transfer of Drug Substance, Drug Product or Finished Product between Parties not included in the Supply Agreement;

(f) discuss and approve any request for one Party to convert the other Party's Drug Substance or Drug Product to Drug Product or Finished Product respectively;

(g) decide on appropriate reductions to the Minimum Committed Roche Capacity or Minimum Committed Regeneron Capacity, including, in light of a decrease in demand such that there is no longer a demand for the equivalent of at least 140,000 liters of bioreactor capacity on an annualized basis for the manufacture of Drug Substance in the Territory;

(h) discuss any disproportional distribution by either Party of Product containing Drug Substance manufactured and supplied by the other Party;

(i) discuss and review use by Roche of an additional Roche Manufacturing Facility, as provided in Section 4.1.1;

(j) report on a regular basis to the JSC; and

(k) escalate to the JSC as required.

The JMC shall have no responsibility and authority other than that expressly set forth in this Section 8.2.3, except if the JSC decides to delegate specifically defined duties to the JMC pursuant to Section 8.1.3(h).

8.2.4 Meetings

The co-chairpersons of the JMC will be responsible for sending invitations and agendas for all JMC meetings to all Members at least [* * *] before the next scheduled meeting of the JMC. The JMC shall hold meetings either in person or by tele-/video-conference, and in any case as frequently as the Members of the JMC agree is necessary. The Alliance Director of each Party may attend the JMC meetings as a permanent participant.

8.2.5 Minutes

The co-chairpersons of the JMC will be responsible for designating a Member to record in reasonable detail and circulate draft minutes of JMC meetings to all members of the JMC for comment and review within [* * *] after the relevant meeting. The Members of the JMC shall have [* * *] to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the JMC within [* * *] of the relevant meeting. Both co-chairpersons of the JMC must approve the final version of the minutes before its distribution.

8.2.6 Decisions

8.2.6.1 Decision Making Authority

The JMC shall decide matters within its responsibilities set forth in Section 8.2.3.

8.2.6.2 Consensus; Good Faith

The Members of the JMC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JMC. The Parties shall endeavor to make decisions by consensus with the Members of the JMC from each Party collectively having one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a Member from each Party is present and participating in the vote.

8.2.6.3 Failure to Reach Consensus

If the JMC is unable to decide a matter by consensus, then such matter shall be referred to the JSC for resolution.

8.3 Joint Operations Committee

8.3.1 Formation

Promptly after the Effective Date, the Parties shall establish a joint operations committee ("**JOC**"), which will be a subcommittee of the JSC, to oversee the development and commercialization activities under this Agreement.

8.3.2 Members

The JOC shall be composed of six (6) Members. Roche and Regeneron each shall be entitled to appoint three (3) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement upon written notice to the other Party; provided, that a Party that replaces a Member shall notify the other Party at least [* * *] prior to the next scheduled meeting of the JOC. Each Party may invite a reasonable number of additional experts or advisors to attend part or the whole JOC meeting with prior notification to the JOC; provided that any such expert or advisor who is not an employee of the applicable Party must be approved in advance by the other Party and bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 18. The JOC shall be co-chaired by a Member from Regeneron and a Member from Roche.

8.3.3 Responsibilities of the JOC

The JOC shall have the responsibility and authority to:

(a) submit to the JSC the Co-Funded Development Plan and any material amendment to the Co-Funded Development Plan, including any proposal to add any Clinical Study for which the Parties will share [* * *] as a Co-Funded Study, and any proposal regarding the responsibility for the performance of the respective development activities with respect to any additional Co-Funded Studies; provided that, (i) with respect to any amendment to the Co-Funded Development Plan for an Additional Regeneron Study, only a Material Additional Study Change requires the JSC's approval, and (ii) Regeneron may submit any Material Additional Study Change directly to the JSC without first submitting to the JOC;

(b) determine the ISS Strategy;

(c) submit to the JSC the initial Device Development Plan and any material amendment thereto;

(d) review and monitor the development activities for the Products, including regulatory activities undertaken pursuant to this Agreement;

(e) submit to the JSC for approval proposals to pursue Third Party funding for either Party for Co-Funded Studies [* * *];

(f) discuss and review all commercialization activities for the Products in the Territory;

(g) discuss and approve [* * *] in the Roche Territory and the Regeneron Territory;

(h) align on global guidelines and strategy for pricing for the Products;

(i) align on global contracting and communications strategy; including strategies for interactions with governments, media, international institutions and stakeholders;

(j) [* * *];

(k) select the Global Trademarks and, if applicable, Alternative Product Trademarks, and establish any applicable rules regarding the use of Global Trademarks or Alternative Product Trademarks;

(l) [* * *];

(m) discuss and determine whether the regulatory filing for the First EU Approval or the First UK Approval will be made in Regeneron's name or in Roche's name with Regeneron acting as agent (provided that notwithstanding anything to the contrary in this Agreement, Regeneron will have the final decision making authority with respect to either filing being made in Regeneron's name);

(n) discuss each Party's plan for publication;

(o) discuss and approve the Other Chugai Asset Activities;

(p) report on a regular basis to the JSC;

(q) oversee the operation and activities of the FWG and approve any matter submitted by the FWG;

(r) discuss updates provided by Regeneron pursuant to Section 2.8 and discuss any progress made on Additional Compounds, if any;

(s) escalate to the JSC as required.

The JOC shall have no responsibility and authority other than that expressly set forth in this Section 8.3.3, except if the JSC decides to delegate specifically defined duties to the JOC pursuant to Section 8.1.3(h).

8.3.4 Meetings

The co-chairpersons of the JOC will be responsible for sending invitations and agendas for all JOC meetings to all Members at least [* * *] before the next scheduled meeting of the JOC. The JOC shall hold meetings either in person or by tele-/video-conference and in any case as frequently as the Members of the JOC agree is necessary. The Alliance Director of each Party may attend the JOC meetings as a permanent participant.

8.3.5 Minutes

The co-chairpersons of the JOC will be responsible for designating a Member to record in reasonable detail and circulate draft minutes of JOC meetings to all members of the JOC for comment and review within [* * *] after the relevant meeting. The Members of the JOC shall have [* * *] to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the JOC within [* * *] of the relevant meeting. Both co-chairpersons of the JOC must approve the final version of the minutes before its distribution.

8.3.6 Decisions

8.3.6.1 Decision Making Authority

The JOC shall decide matters within its responsibilities set forth in Section 8.3.3.

8.3.6.2 Consensus; Good Faith

The Members of the JOC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JOC. The Parties shall endeavor to make decisions by consensus with the Members of the JOC from each Party collectively having one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a Member from each Party is present and participating in the vote.

8.3.6.3 Failure to Reach Consensus

If the JOC is unable to decide a matter by consensus, such matter shall be referred to the JSC.

8.4 Financial Working Group

8.4.1 Formation.

Promptly after the Effective Date, the Parties will establish a financial working group (the "**FWG**") to oversee the accounting, financial (including planning, reporting and controls) and funds flow matters related to this Agreement.

8.4.2 Operation of the FWG.

Promptly following the Effective Date, each Party shall designate its respective initial representatives to the FWG to allow such FWG to begin operating under the direction of the JOC. The FWG shall have no decision-making authority and shall report to the JOC.

9. Exclusivity

9.1 Non-Compete Obligation

Roche and its Affiliates shall not, directly or indirectly, whether alone or with or through any Third Party, (a) prior to the first approval of the first MAA for a Product in the EU, clinically develop or (b) at any time during the Agreement Term, manufacture (other than for purposes of research and development activities of Roche and its Affiliates permitted hereunder), have manufactured (other than for purposes of research and development activities of Roche and its Affiliates permitted hereunder), sell, distribute or otherwise commercialize, in each case ((a) and (b)), any

product containing Antibody(ies) [* * *] other than the Products (each, a "**Competing Product**"), or directly or indirectly assist any Third Party to do so. [* * *].

For clarity, prior to the first approval of the first MAA for a Product in the EU, Roche and its Affiliates may conduct pre-clinical or non-clinical research and development activities (including technology transfer activities and preclinical evaluation of Third Party assets) on any Competing Product.

9.2 Regeneron Right of First Negotiation to Chugai Asset

As of the Effective Date, Chugai has [* * *] (the "**Chugai Asset**"). Roche may enter into an agreement with Chugai for an option for an exclusive right and license under any Patent Rights and know-how owned or controlled by Chugai to develop, register, use, sell, market and import the Chugai Asset in [* * *] (such countries of the world, the "**Chugai Asset Territory**"; and such option, the "**Roche Chugai Option**"). Prior to Roche's exercise of the Roche Chugai Option, Roche shall have the right to [* * *] (the "**Permitted Chugai Activities**"). Regeneron acknowledges and agrees that is it not a breach of Section 9.1 by Roche for Chugai to [* * *] conduct the Permitted Chugai Activities. Roche shall have the right to [* * *] Roche shall not [* * *] without the agreement of the Parties through the JOC ("**Other Chugai Asset Activities**") (disputes with respect to which, for clarity, shall be subject to Section 8.1.6.3(c)).

Roche hereby grants Regeneron an exclusive option to obtain the right and sublicense under any Patent Rights and know-how owned or controlled by Chugai that Roche obtains through the exercise of the Roche Chugai Option to [* * *] and a financial interest in the commercialization of the Chugai Asset in the entire Territory, in each case, in accordance with this Section 9.2 (the "**Chugai Asset Option**").

Roche shall provide Regeneron periodic updates regarding the development and characteristics of the Chugai Asset at each JOC meeting.

Without Regeneron's consent in its discretion, Roche will not enter into any agreement with a Third Party (including, for clarity, Chugai) that would conflict with the rights that Regeneron would have with respect to the Chugai Asset if Regeneron exercises the Chugai Asset Option.

9.2.1 Chugai Asset Data Package

If Roche desires to exercise the Roche Chugai Option, then after [* * *] Roche shall provide, or cause Chugai to provide, Regeneron a complete data package with respect to the Chugai Asset, including all data, reports, documentation and other information relating to the Chugai Asset, necessary or reasonably useful for the Parties to determine whether the Chugai Asset has satisfied the Chugai Asset Criteria, including the results of such Clinical Study and any other clinical or non-clinical data, all information regarding the manufacturing process (including yields), route or frequency of administration, and the proprietary position of the Chugai Asset (the "**Chugai Asset Data Package**").

Within [* * *] after Regeneron receives the Chugai Asset Data Package, the Parties shall discuss in good faith and endeavor to mutually agree (a) whether or not the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria and (b) if the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, then whether or not the Chugai Asset satisfies the Chugai Asset Criteria. If the Parties cannot agree within [* * *] following Regeneron's receipt

of the Chugai Asset Data Package (x) whether or not the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, or (y) whether or not the Chugai Asset satisfies the Chugai Asset Criteria, then, in either case ((x) or (y)), such dispute shall be determined in accordance with Section 21.2, and if still not resolved, then decided by an Expert Committee pursuant to Section 21.4.

If both Parties agree, or the Executive Officers or Expert Committee, as applicable, determines that the Chugai Asset Data Package does not satisfy the Chugai Asset Data Package Criteria or that the Chugai Asset has not satisfied the Chugai Asset Criteria, then, in either case, Roche shall not exercise the Roche Chugai Option and the Chugai Asset shall remain a Competing Product for purposes of this Agreement, and the obligations set forth in Section 9.1 shall continue to apply to Roche with respect to the Chugai Asset.

Thereafter, if Roche receives any additional data or information with respect to the Chugai Asset and desires to exercise the Roche Chugai Option, Roche shall deliver to Regeneron an updated Chugai Asset Data Package, and the process set forth in this Section 9.2.1 shall apply to determine whether the updated Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, and whether the Chugai Asset satisfies the Chugai Asset Criteria.

9.2.2 Chugai Asset Agreement

If both Parties agree, or the Executive Officers or Expert Committee determines that the Chugai Asset satisfies the Chugai Asset Criteria (such agreement or determination, "**Chugai Asset Positive Determination**"), then Regeneron shall have the right, within [* * *] following the date on which the Chugai Asset Positive Determination is made (the "**Exercise Period**"), to exercise the Chugai Asset Option by providing written notice to Roche ("**Exercise Notice**").

Roche shall not exercise the Roche Chugai Option until the Chugai Asset Positive Determination has been made, and either (a) Regeneron exercises the Chugai Asset Option by providing the Exercise Notice, or (b) Regeneron notifies Roche in writing that Regeneron will not exercise the Chugai Asset Option or fails to provide the Exercise Notice during the Exercise Period.

If Regeneron exercises the Chugai Asset Option by providing the Exercise Notice within the Exercise Period, then Regeneron and Roche shall, and Roche shall cause Chugai to, promptly negotiate and execute a separate license agreement (the "**Chugai Asset Agreement**") or an amendment to this Agreement (the "**Chugai Asset Amendment**") that is consistent with the terms and conditions set forth on Appendix 9.2 and on other terms mutually acceptable to Regeneron, Roche and Chugai, which the Parties anticipate will be substantially similar to the terms of this Agreement except as set forth on Appendix 9.2.

If (A) Regeneron notifies Roche in writing that Regeneron will not exercise the Chugai Asset Option or (B) Regeneron fails to provide the Exercise Notice during the Exercise Period, then the Chugai Asset Option shall expire. If thereafter Roche exercises the Roche Chugai Option or otherwise obtains any right to develop or commercialize the Chugai Asset, then (X) Roche shall promptly notify Regeneron of such exercise or receipt of such other right, and (Y) Regeneron shall have the right to terminate this Agreement upon [* * *] prior written notice to Roche, which right must be exercised within [* * *] after notice from Roche of the first commercial sale of the

Chugai Asset, and such termination by Regeneron shall be deemed to be a termination by Roche pursuant to Section 19.2.5 for purposes of post-termination effect and obligations.

Additionally, if the Chugai Asset receives Regulatory Approval in Japan, and the Parties have not entered into the Chugai Asset Agreement or Chugai Asset Amendment, as applicable, then upon Regeneron's request, Roche shall immediately terminate Chugai's sublicense with respect to the Products in Japan.

During the Agreement Term, neither Party shall have the right to develop or commercialize the Chugai Asset until the Chugai Asset Agreement or Chugai Asset Amendment is executed by the Parties and Chugai, except that (i) Roche shall have the right to conduct the Permitted Chugai Activities and Other Chugai Asset Activities approved by the JOC; (ii) if (A) Regeneron notifies Roche in writing that Regeneron will not exercise the Chugai Asset Option or (B) Regeneron fails to provide the Exercise Notice during the Exercise Period, then Roche shall thereafter have the right to develop and commercialize the Chugai Asset, and (iii) if Regeneron exercises the Chugai Asset Option by providing the Exercise Notice within the Exercise Period, then, for clarity, the last sentence of the first paragraph of Section 9.2 shall remain in effect while the Parties and Chugai are negotiating the Chugai Asset Agreement or Chugai Asset Amendment, [* * *].

10. Payment

10.1 Reimbursement [* * *] for Development Activities

With respect to each Co-Funded Study, the Party not performing such Co-Funded Study shall reimburse the Party performing such Co-Funded Study for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with performing such Co-Funded Study (including, for clarity, such [* * *] incurred by or on behalf of Regeneron or any of its Affiliates with respect to the Additional Regeneron Studies prior to the Effective Date) to the extent such [* * *] are not funded by a Third Party. For clarity, each Party shall bear its internal costs with respect to performing any Co-Funded Study.

With respect to Co-Funded Device Development Activities, the Party not performing such Co-Funded Device Development Activities shall reimburse the Party performing such Co-Funded Device Development Activities for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with performing such Device Development Activities to the extent such [* * *] are not funded by a Third Party. [* * *]

With respect to each Unilateral Study, if the Party not performing such Unilateral Study uses any data or results from such Unilateral Study to obtain, maintain or expand any Regulatory Approval or any pricing or reimbursement for, otherwise includes such data or results in the label for, or uses such data and results to commercialize, a Product in its Respective Territory, then such non-performing Party shall reimburse the Party that performed such Unilateral Study for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with such Unilateral Study to the extent such [* * *] are not funded by a Third Party. For clarity, the submission of data and results from a Unilateral Study to a Regulatory Authority only for safety reporting purposes in connection with periodic safety reporting or as a courtesy copy shall not result in a reimbursement obligation under this paragraph. The Party not performing the applicable Unilateral Study shall promptly notify the performing Party of any use of the data or

results of such Unilateral Study that would result in a reimbursement obligation under this paragraph.

With respect to Unilateral Device Development Activities, if the Party not performing such Unilateral Device Development Activities wishes to use the delivery device or other results of such Unilateral Device Development Activities for a Product in its Respective Territory, then such non-performing Party shall reimburse the Party that performed such Unilateral Device Development Activities for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with such Unilateral Device Development Activities to the extent such [* * *] are not funded by a Third Party, and the performing Party shall provide the results of the Unilateral Device Development Activities to the non-performing Party and such other information and assistance as is required for the non-performing Party to manufacture and use the delivery device resulting from such Unilateral Device Development Activities.

10.2 Global Gross Profit Sharing

Beginning with the Calendar Quarter in which the Collaboration Timepoint occurs, with respect to each Presentation of Product, Roche Basel shall be entitled to the product of (i) [* * *] of the Global Gross Profit for such Presentation in such Calendar Quarter, multiplied by the Roche Production Contribution for such Presentation in such Calendar Quarter ("**Roche Global Gross Profit**") and (ii) Regeneron will be entitled to the remainder of the Global Gross Profit; provided, that for the Calendar Quarter in which the Collaboration Timepoint occurs, for purposes of this Section 10.2 the amount of the Global Gross Profit for such Calendar Quarter shall be prorated based on the ratio of the number of days in such Calendar Quarter from and after the Collaboration Timepoint and the total number of days in such Calendar Quarter.

Example:

[* * *]

Notwithstanding the foregoing:

(a) if prior to the [* * *], Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use in the EU but not the Regeneron Territory, Roche Basel may sell Product in the Roche Territory and, in the case of such sales, may retain [* * *] of the Global Gross Profit for the Roche Territory prior to the [* * *] (and shall provide [* * *] of such Global Gross Profits to Regeneron), [* * *]. For clarity, Roche Basel shall not be entitled to share any of the Global Gross Profit in the Regeneron Territory until Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use in the Regeneron Territory; or

(b) if prior to the [* * *], Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use in the Regeneron Territory, but not the EU, [* * *], then (i) Roche shall transfer such Product to Regeneron for sale in the Regeneron Territory by Regeneron in accordance with the allocation provided in Section 5.1 following the [* * *], and Roche may, upon mutual agreement of the Parties, transfer additional Product to Regeneron for sale in the Regeneron Territory by Regeneron; and (ii) the Parties shall share the Global Gross Profits for the Regeneron Territory as provided in the first paragraph of this Section 10.2; or

(c) if prior to the [* * *], Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use (X) in the EU and the Regeneron Territory, or (Y) in the Regeneron Territory but not the EU, and in either case ((X) or (Y)), [* * *], then Roche shall transfer such Product to Regeneron for sale in the Regeneron Territory by Regeneron in accordance with the allocation provided in Section 5.1 following the [* * *], and in the case of clause (Y), Roche may, upon mutual agreement of the Parties, transfer additional Product to Regeneron for sale in the Regeneron Territory by Regeneron; provided that, in either case ((X) or (Y)), [* * *], (A) Regeneron may retain [* * *] of the Global Gross Profit for the sales of Products supplied by Roche in the Regeneron Territory [* * *] and (B) [* * *].

[* * *]

[* * *]

[* * *]

10.3 Disclosure of Payments

Each Party acknowledges that the other Party may be obligated to disclose this financial arrangement, including all fees, payments and transfers of value, as required under Applicable Law; provided, however, that any such disclosure shall be subject to the provisions of Section 18.2.

11. Accounting and Reporting

11.1 Mechanics and Timing of Payments

For Global Gross Profit payments, on a Presentation-by-Presentation basis, commencing with the first Calendar Quarter after the Collaboration Timepoint or any Interim Collaboration Timepoint in which a Party incurs Net Sales (a) within [* * *] after the end of each Calendar Quarter, such Party shall share with the other Party a good faith estimate of (i) such Party's Net Sales of such Presentation, (ii) the units of such Presentation sold by or on behalf of such Party, its Affiliates and Sublicensees in such Calendar Quarter, (iii) the units of such Presentation sold by or on behalf of such Party, its Affiliates and Sublicensees in such Calendar Quarter for which the Drug Substance was manufactured by the Roche Group (which may be determined in accordance with Appendix 1.106, if applicable), (iv) [* * *], and (v) the units of such Presentation distributed as [* * *], in each case, by or on behalf of such Party, its Affiliates and Sublicensees in such Calendar Quarter; and (b) as soon as practicable after the end of each such Calendar Quarter, but in any event no later than [* * *] after the end of each such Calendar Quarter, such Party shall share with the other Party the actual Net Sales in accordance with the foregoing subclause (i) and units dispersed in accordance with the foregoing subclauses (ii) - (v) of such Presentation, together with a calculation of such Party's Gross Profit for such Presentation for such Calendar Quarter (each report described in this clause (b), a "**Gross Profit Interim Report**"). Each Party shall have [* * *] after the delivery of the other Party's Gross Profit Interim Report to review and ask questions. Within [* * *] following the end of such Calendar Quarter, each Party shall update its Gross Profit Interim Report to reflect the final amounts and the Parties shall coordinate to aggregate the final reports to calculate the total Global Gross Profit and Roche Global Gross Profit (**"Global Gross Profit Final Report"**). The Party that owes

payment to the other Party pursuant to the Global Gross Profit Final Report shall pay such amount within [* * *] after receipt of an invoice from the Party that is due payment.

For Co-Funded Study reimbursement and Co-Funded Device Development Activities reimbursement, respectively, the Parties shall share a good faith estimate of the applicable costs incurred, within [* * *] after the end of each Calendar Quarter in which such costs are incurred. As soon as practicable after the end of each such Calendar Quarter, but in any event no later than [* * *] after the end of each such Calendar Quarter, each Party shall share with the other Party [* * *] incurred by such Party (each, a **"Reconciliation Interim Report"**), together with reasonable supporting documentation for such [* * *]. Each Party shall have [* * *] after the delivery of the other Party's Reconciliation Interim Report to review and ask questions. Within [* * *] following the end of such Calendar Quarter, each Party shall update its Reconciliation Interim Report to reflect the final amounts and the Parties shall coordinate to aggregate the reports to calculate the total amount to be reimbursed under this Agreement (**"Reconciliation Final Report"**). The Party that owes payment to the other Party pursuant to the Reconciliation Final Report shall pay such amount within [* * *] after receipt of an invoice from the Party that is due payment.

With respect to each Unilateral Study for which reimbursement becomes due, within [* * *] after the Party that performed such Unilateral Study becomes aware that such reimbursement is due, such performing Party shall share with the other Party the [* * *] incurred by such conducting Party for such Unilateral Study (a "**Unilateral Study Costs Report**"), together with reasonable supporting documentation for such [* * *]. The non-performing Party shall have [* * *] after the delivery of the Unilateral Study Costs Report to review and ask questions. If the non-performing Party raises any questions to be addressed, the performing Party shall update its Unilateral Study Costs Report to reflect the final amounts within [* * *] after the delivery of the initial Unilateral Study Costs Report. The non-performing Party shall pay the performing Party the applicable amount within [* * *] after receipt of an invoice from the performing Party.

Any payments of Standard Costs for Product supplied by one Party to the other Party or for manufacturing services performed by one Party to the other Party under this Agreement shall be paid in accordance with Section 11.5.

Any payment required to be made to Regeneron by Roche pursuant to this Section 11.1 or Section 11.5 shall be made by Roche Basel.

11.2 Late Payment

Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at a rate equal to [* * *] points above the average one-month Euro Interbank Offered Rate (EURIBOR), as reported by Reuters from time to time, calculated on the number of days such payment is overdue, unless such payment amount is reasonably disputed in good faith, in which case the amount payable after such dispute is resolved shall start to earn interest hereunder on the date such dispute is resolved.

11.3 Method of Payment

All amounts payable by one Party hereunder shall be paid by the other Party in Dollars (the "**Payment Currency**") by bank wire transfer in immediately available funds to account(s) designated by the other Party.

11.4 Currency Conversion

In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, the Party converting such amounts to Dollars shall use their respective then-current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements. As of the Effective Date, the internal foreign currency translation method (a) for Roche, is to convert currencies other than Dollars or Swiss Francs to Swiss Francs and then to Dollars at the year-to-date average rate as reported by Reuters (or any successor thereto), and (b) for Regeneron, is to convert currencies other than Dollars to Dollars using the average of the daily spot rates (the Mid Price Close) found on Bloomberg (or any successor thereto). Each Party shall promptly notify the other Party if there is any change to its then-current internal foreign currency translation method.

11.5 Reimbursement

For all amounts for which a Party (the "**Owing Party**") is obligated to reimburse or pay the other Party (the "**Owed Party**") pursuant to this Agreement or the Technology Transfer Agreement, for which no specific provision is provided hereunder or thereunder regarding how such payment shall be made, or any payments under Section 4.2(c), the Owed Party shall send to the Owing Party an invoice for such amount within [* * *] 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 [* * *] after receipt by the Owing Party thereof and shall be made in accordance with Section 11.3 and Section 11.4.

11.6 Payment Disputes

With respect to any payment obligations under this Agreement, if the Owing Party in good faith disputes any portion of any such payment, 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.

12. Taxes

12.1 Certain Taxes

Regeneron shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Regeneron under this Agreement.

Roche shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Roche under this Agreement.

12.2 Withholding Taxes

If provision is made in law or regulation of any country for withholding or deduction of taxes of any type, levies or other charges with respect to any amounts payable under this Agreement to Regeneron or Roche, then Roche or Regeneron (as applicable) shall be entitled to withhold or deduct the amount of such taxes, levies, or other charges from such amount payable and shall promptly pay such tax, levy or charge for and on behalf of Regeneron or Roche (as applicable) to the proper governmental authority, and shall promptly furnish Regeneron or Roche (as applicable) with receipt of payment. Roche or Regeneron (as applicable) shall be entitled to deduct any such tax, levy or charge actually paid from payment due Regeneron or Roche (as applicable) or be promptly reimbursed by Regeneron or Roche (as applicable) if no further payments are due to Regeneron or Roche (as applicable). Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted. Any amounts deducted and withheld from any payment to a Party pursuant to this Section 12.2 shall be treated as having been paid to such Party.

12.3 FDII Documentation

To the extent applicable and reasonably requested by Regeneron, Roche 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 Roche for all reasonable out-of-pocket costs incurred by Roche in connection with providing such documentation or other certification to Regeneron. The Parties intend that Regeneron shall be entitled to any deduction under Section 250(b) of the Code for which Regeneron is eligible with respect to the remainder of the Global Gross Profit under Section 10.2, and this Agreement shall be interpreted accordingly.

13. Auditing

13.1 Right to Audit

Each Party shall keep, and shall require its Affiliates and its and their Sublicensees, if any, to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all payments payable under this Agreement (e.g. the Parties' calculation of Standard Costs). Such books of accounts shall be kept at such Party's, Affiliate's or Sublicensee's, as applicable, principal place of business. At the expense of the auditing Party, the auditing Party shall have the right, in accordance with the remainder of this Section 13.1, Section 13.2 and Section 13.3, to engage an internationally recognized independent public accountant reasonably acceptable to the audited Party to perform, on behalf of the auditing Party, an audit of such books and records of the audited Party and its Affiliates and its and their Sublicensees that are deemed necessary by the independent public accountant to report on the correctness of any financial report or payments made under this Agreement for the period or

periods requested by the auditing Party. The Parties shall cause such accountant to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such accountant to retain all such financial information in confidence pursuant to terms no less stringent than those set forth in Article 18.

Upon timely request and at least [* * *] prior written notice from the auditing Party, such audit shall be conducted for those countries the auditing Party has specifically requested, during regular business hours in such a manner as to not unnecessarily interfere with the audited Party's normal business activities. Such audit shall be limited to books and records with respect to the [* * *] Calendar Years prior to audit notification, and if the auditing Party requests an audit for a country for a given Calendar Year, no additional audits may be conducted for such country for such Calendar Year unless a material discrepancy is found in such audit. If auditing Party does not request an audit for a given Calendar Year on or before the [* * *] anniversary of the end of such Calendar Year, then the auditing Party shall no longer have the right to conduct an audit for such Calendar Year under this Section 13.1.

Such audit for a country shall not be performed more frequently than once per Calendar Year nor more frequently than once with respect to records covering any specific country for any specific period of time unless a material discrepancy is found in such audit.

All books of accounts herein referred and any information contained therein shall be (a) used by the auditing Party only for the purpose of verifying payments and reports hereunder and (b) treated as the audited Party's Confidential Information subject to the obligations of this Agreement.

13.2 Audit Reports

The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The auditors shall share all draft audit findings with the audited Party before sharing such findings with the auditing Party and before the final audit report is issued and shall remove any information reasonably identified by the audited Party as being confidential or competitively sensitive or proprietary information. The final audit report shall be shared with the audited Party at the same time it is shared with the auditing Party. The auditors shall not reveal to the auditing Party the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement. The results of any such audit shall be final and binding upon the Parties, unless disputed by a Party within [* * *] of delivery. Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any amount based on a disputed audit shall not be deemed to have been triggered until such dispute is resolved hereunder; provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

13.3 Over-or Underpayment

If the audit reveals an overpayment, the overpaid Party shall reimburse the other Party for the amount of the overpayment within [* * *] (and, if such overpayment was made due to an error in an invoice or report provided by such overpaid Party, with interest thereon as provided in Section 11.2). If the audit reveals an underpayment, the underpaying Party shall reimburse the other Party for the amount of the underpayment within [* * *] (and, if such additional amounts are owed due to an error in an invoice or report provided by such underpaying Party, with interest

thereon as provided in Section 11.2). The audited Party shall reimburse the auditing Party for the audit costs if the cumulative discrepancy of amounts reported or paid during the applicable audited period exceeds [* * *].

14. Intellectual Property

14.1 Ownership of Intellectual Property

Nothing in this Agreement shall affect the ownership of any Patent Rights, know-how or other intellectual property, in each case, developed prior to the Effective Date or independent of this Agreement, including, for clarity, Roche Independent IP. Regeneron shall own all Regeneron Inventions and all Patent Rights and other intellectual property rights that Cover the Regeneron Inventions. Roche shall own all Roche Inventions and all Patent Rights and other intellectual property rights that Cover the Roche Inventions. Regeneron and Roche shall jointly own all Joint Inventions and Joint Patent Rights. Regeneron and Roche each shall require, and shall cause its respective Affiliates to require (a) all of its (or its Affiliates') employees and consultants to assign all inventions related to Compounds or Products made by them to Roche or Regeneron (or such Affiliate), as the case may be and (b) all other persons or entities who perform any activities for or on behalf of such Party to assign (or, if such Party is unable to cause such person or entity to agree to such assignment obligation despite such Party's using Commercially Reasonable Efforts to negotiate such assignment obligation, provide an exclusive license under) their rights in any such Inventions or Patent Rights to such Party.

Each Party shall promptly disclose to the other Party in writing, the discovery, development or creation of any Invention made solely or jointly by or on behalf of such Party, any of its Affiliates, or, if applicable, Sublicensees in connection with the performance of obligations under this Agreement. Each Party shall promptly disclose to the other and shall cause its Affiliates and Sublicensees to disclose any Know-How made solely or jointly by or on behalf of such Party or any of its Affiliates or Sublicensees in connection with the performance of obligations under this Agreement that constitutes an improvement to the process of manufacturing the Compounds or Products.

The determination of inventorship for Inventions shall be in accordance with US inventorship laws as if such Inventions were made in the US.

Subject to the licenses granted under this Agreement and Roche's obligation under Article 9, Regeneron and Roche will each have an equal undivided share in the Joint Patent Rights, without obligation to account to the other for exploitation thereof, or to seek consent of the other Party for the grant of any license thereunder.

Except as specifically set forth herein, this Agreement shall not be construed as (i) giving either of the Parties any license, right, title, interest in or ownership to the Confidential Information of the other Party; (ii) granting any license or right under any intellectual property rights; or (iii) representing any commitment by either Party to enter into any additional agreement, by implication or otherwise.

With respect to Know-How (other than Inventions) generated pursuant to this Agreement, (a) Regeneron shall own such Know-How (i) generated by or on behalf of Regeneron or any of its Affiliates or Sublicensees solely or jointly with a Third Party or (ii) generated by or on behalf of

the Roche Group solely or jointly with Regeneron or any of its Affiliates or a Third Party that is specifically related to any Product (including the composition of, formulations containing, any methods of using, or the manufacture of, a Product) ((i) and (ii) together, "**Arising Regeneron Know-How**"), (b) Roche shall own such Know-How generated by or on behalf of the Roche Group solely or jointly with a Third Party, excluding any Arising Regeneron Know-How, and (c) the Parties shall jointly own any Joint Know-How. For clarity, Arising Regeneron Know-How shall not include any Roche Independent IP or any Know-How of general applicability to antibody products and not specific to the Product. For example, Know-How that can be applied to purification of antibodies generally but not specific to manufacturing of a Compound or Product shall not be considered Arising Regeneron Know-How.

Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their Sublicensees, as applicable, to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions, Know-How, Patent Rights or other intellectual property rights as is necessary to fully effect, as applicable, the sole or joint ownership provided for in this Section 14.1. Pursuant to Section 21.18, each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such applications, approvals, assignments, agreements, documents, and instruments, and shall provide any additional consents, as may be necessary or as the other Party may reasonably request for a Party to perfect or exercise its rights provided for in this Section 14.1.

Roche here grants Regeneron a non-exclusive, worldwide, royalty-free, perpetual, irrevocable, transferable, sublicensable (through multiple tiers) license under any Arising Roche Manufacturing IP for any and all purposes. "**Arising Roche Manufacturing IP**" shall mean any Inventions, Know-How, Patent Rights and other intellectual property rights arising under this Agreement generated by or on behalf of the Roche Group solely or jointly with Regeneron or any of its Affiliates or a Third Party that is related to Regeneron's manufacturing process for a Product and that does not constitute Arising Regeneron Invention, Arising Regeneron Know-How or a Patent Right that Covers any Arising Regeneron Invention or Arising Regeneron Know-How (which Patent Rights, for clarity, shall be owned by Regeneron). For clarity, Roche shall own any Arising Roche Manufacturing IP.

14.2 Inventions Made by Employees, Subcontractors and Services Providers

In accordance with any Applicable Law regarding employee's inventions, each Party agrees to claim the ownership or exclusive and unlimited use of any Invention conceived, reduced to practice, developed, made or created in the performance of, or as a result of, any activities under or in connection with this Agreement by employees of such Party or its applicable Affiliates. For the avoidance of doubt, each Party, or its Affiliates (as applicable) is responsible for fulfilling the obligations towards its or their respective employees under any Applicable Law providing for compensation to employees for inventions.

Each Party shall, and shall cause its Affiliates and Sublicensees to, obtain an assignment from subcontractors or service providers to such Party or its applicable Affiliates or Sublicensees of all Inventions related to a Product made by such individuals during the course of and as a result of their performance under this Agreement.

14.3 Trademarks and Labeling

Regeneron shall have the right and responsibility to create, select and obtain the International Non-proprietary Name (INN) from the World Health Organization and the US Adopted Name (USAN) from the US Adopted Names Council (USANC) as the generic name(s) for the Products.

The JOC shall select one or more global trademark(s) for use on the Product in the Territory, including any accompanying logos, slogans, trade names, domain names, trade dress or other indicia of origin, excluding the corporate names and logos of either Party (the "**Global Trademarks**"). If, under Applicable Law, none of the Global Trademarks for a Product can be used for the commercialization of such Product in a country in the Roche Territory, the JOC shall discuss and select one (1) or more alternative trademarks, including any accompanying logos, slogans, trade names, domain names, trade dress or other indicia of origin, for the commercialization of such Product in such country (each, an "**Alternative Product Trademark**"); provided, that if the Parties are unable to agree on such Alternative Product Trademarks, the JOC shall have the right to select such Alternative Product Trademarks.

Regeneron shall own all Global Trademarks in the Regeneron Territory, and shall, at its sole cost, be responsible for procurement, maintenance, enforcement and defense of all Global Trademarks in the Regeneron Territory.

Roche shall own all Global Trademarks and, if applicable, Alternative Product Trademarks, in the Roche Territory, and shall, at its sole cost, be responsible for procurement, maintenance, enforcement and defense of Global Trademarks and if applicable, Alternative Product Trademarks, in the Roche Territory.

Each Party shall keep the other Party reasonably informed regarding any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for a Global Trademark, or, with respect to Roche if applicable, Alternative Product Trademark in its Respective Territory.

Each Party and its Affiliates and its and their Sublicensees shall not license (or, as applicable, sublicense) rights to use, or otherwise transfer ownership of the Global Trademark(s) or, if applicable with respect to Roche, Alternative Product Trademarks, without the prior written consent of the other Party except with respect to any manufacturing or development activities permitted hereunder. Each Party and its Affiliates and its and their Sublicensees shall only utilize the Global Trademark(s) or, if applicable with respect to Roche, Alternative Product Trademarks, on materials related to the Products in its Respective Territory (including package inserts, packaging, trade packaging, internet pages, social media, advertising and promotional materials used or distributed in connection with the Products).

Each Party agrees that at no time during the Agreement Term will it or any of its Affiliates attempt to use or register in its Respective Territory any trademarks, trade dress, service marks, trade names or domain names confusingly similar to any Global Trademark or, if applicable with respect to Roche, any Alternative Product Trademark, in relation to a product that is not a Product, or take any other action that damages or dilutes the rights to, or goodwill associated with, any Global Trademark or, if applicable with respect to Roche, any Alternative Product Trademark.

All use of the Global Trademarks and Alternative Product Trademarks, as applicable, by a Party or its Affiliates or Sublicensees, or, where applicable, its or their distributors, shall be in accordance with (a) rules established by the JOC, if any, and (b) quality standards established by the respective trademark owner, in each case ((a) or (b)), that are reasonably necessary in order to preserve the validity and enforceability of the Global Trademarks and Alternative Product Trademarks, as applicable.

14.4 Use of Corporate Names.

Roche shall not, and shall cause its Affiliates and Sublicensees not to, include Regeneron's name on materials related to the Products in the Roche Territory (including package inserts, packaging, trade packaging, internet pages, social media, advertising and promotional materials used or distributed in connection with the Products), unless (a) with respect to packaging for the Products (including package inserts, packaging and trade packaging for the Products) requested by Regeneron in writing (unless it is commercially unreasonable to do so, or prohibited by Applicable Law) or required under Applicable Law, or (b) with respect to other materials related to the Products (including internet pages, social media, advertising and promotional materials used or distributed in connection with the Products) upon mutual agreement by the Parties or required under Applicable Law, in which case ((a) or (b)), Regeneron's name shall have equal prominence with Roche's name on such materials. Regeneron hereby grants to Roche Basel the right (which right may be sublicensed to Roche Basel's Affiliates and Sublicensees), free of charge, to use Regeneron's name and logo on package inserts, packaging, trade packaging, internet pages, social media and all promotional materials used or distributed in connection with the Products in the Roche Territory during the Agreement Term, in each case, only to the extent pursuant to subclause (a) or (b) in this paragraph. During the Agreement Term, Roche shall submit samples of each such package inserts, packaging, trade packaging, internet pages, social media and all promotional materials using Regeneron's name or logo to Regeneron for approval in accordance with the review and approval process established below.

Regeneron shall not, and shall cause its Affiliates and Sublicensees not to, include Roche's name on materials related to the Products in the Regeneron Territory (including package inserts, packaging, trade packaging, internet pages, social media, advertising and promotional materials used or distributed in connection with the Products), unless (i) with respect to packaging for the Products (including package inserts, packaging and trade packaging for the Products) requested by Roche in writing (unless it is commercially unreasonable to do so, or prohibited by Applicable Law) or required under Applicable Law, or (ii) with respect to other materials related to the Products (including internet pages, social media, advertising and promotional materials used or distributed in connection with the Products) upon mutual agreement by the Parties or required under Applicable Law, in which case ((i) or (ii)), Roche's name shall have equal prominence with Regeneron's name on such materials. Roche hereby grants to Regeneron the right (which right may be sublicensed to Regeneron's Affiliates and Sublicensees), free of charge, to use Roche's name and logo on package inserts, packaging, trade packaging, internet pages, social media and all promotional materials used or distributed in connection with the Products in the Regeneron Territory during the Agreement Term, in each case, only to the extent pursuant to subclause (i) or (ii) in this paragraph. During the Agreement Term, Regeneron shall submit samples of each such package inserts, packaging and trade packaging, internet pages, social media and all promotional materials using Roche's name or logo to Roche for approval in accordance with the review and approval process established below.

Promptly following the Effective Date, the Parties shall discuss in good faith and establish guidelines and an expedited review and approval process regarding the use of each Party's name on material related to the Products. During the Agreement Term, if a Party's name is included on materials related to the Product in the other Party's Respective Territory in accordance with the terms hereunder, the other Party shall comply with the applicable use guideline with respect thereto.

Except as expressly provided herein, no right, express or implied, is granted by this Agreement to use in any manner the name of the other Party or its Affiliates or any other trade name, symbol, logo or trademark of the other Party or its Affiliates.

14.5 Prosecution of Product Patent Rights in the Regeneron Patent Territory

Regeneron shall have the sole right, but not the obligation, to Handle all Product Patent Rights in the Regeneron Patent Territory. The Parties shall share [* * *] all of Regeneron's [* * *] incurred with respect to Handling the Product Patent Rights in the Regeneron Patent Territory. Regeneron shall use good faith efforts to notify Roche Basel of filing of any provisional or utility application for any Product Patent Right in the Regeneron Patent Territory, if practicable, and shall notify Roche Basel of filing of any application under the Patent Cooperation Treaty for any Product Patent Right. At Regeneron's reasonable request, Roche Basel shall cooperate, in all reasonable ways with the Handling of all Product Patent Rights in the Regeneron Patent Territory.

14.6 Prosecution of Product Patent Rights in the Roche Territory and Joint Patent Rights in the Territory

Regeneron shall have the first right, but not the obligation, to Handle all Product Patent Rights in the Roche Territory and all Joint Patent Rights in the Territory. Regeneron shall promptly inform Roche Basel of all material steps with regard to the Handling of such Patent Rights, including by providing Roche Basel with a copy of material communications to and from the applicable patent authorities regarding such Patent Rights. Regeneron shall provide Roche Basel drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Roche Basel to review and comment thereon, and Regeneron shall consider in good faith the requests and suggestions of Roche Basel with respect to such drafts and with respect to strategies for filing and prosecuting such Patent Rights. At Regeneron's reasonable request, Roche Basel shall cooperate, in all reasonable ways with the Handling of all Product Patent Rights in the Regeneron Patent Territory.

If Regeneron determines to abandon any Product Patent Right in the Roche Territory or Joint Patent Right in the Territory then, prior to such abandonment, Regeneron shall offer such Patent Right to Roche Basel to Handle, subject to the following: Roche Basel's Handling of such Patent Right must be consistent with Regeneron's global patent strategy for the Products. Roche Basel shall promptly inform Regeneron of all material steps with regard to the Handling of such Patent Rights, including by providing Regeneron with a copy of material communications to and from the applicable patent authorities regarding such Patent Right. Roche Basel shall provide Regeneron drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Regeneron to review and comment thereon, and Roche Basel shall consider in

good faith the requests and suggestions of Regeneron with respect to such drafts and with respect to strategies for filing and prosecuting any such Patent Right; provided that if Regeneron determines that any proposed actions by Roche Basel with respect to any such Patent Right would reasonably be expected to have a negative impact on the global patent portfolio for the Products, then Roche Basel must implement Regeneron's comments with respect to any such actions.

The Parties shall share [* * *] all of the Handling Party's [* * *] incurred with respect to Handling the Product Patent Rights in the Roche Territory and the Joint Patent Rights in the Territory; provided that, with respect to each Joint Patent Right, the non-Handling Party for such Joint Patent Right may elect, upon written notice to the Handling Party for such Joint Patent Right to no longer share the Handling Party's [* * *] and expenses incurred for such Joint Patent Right, in which case the non-Handling Party shall assign all of its right, title and interest in and to such Joint Patent Right to the Handling Party.

14.7 Handling of Other Patent Rights.

Roche Basel shall, at its own expense and discretion, have the sole right, but not the obligation, to Handle (including abandon) all Roche Patent Rights and Regeneron, shall, at its own expense and discretion, have the sole right, but not the obligation, to Handle (including abandon) all Regeneron Patent Rights that are not Product Patent Rights, in each case, without any coordination with, or notice to, the other Party. At the Handling Party's reasonable request, the other Party shall cooperate, in all reasonable ways, with the Handling of the Patent Rights described in this Section 14.7.

14.8 Coordination; No Invention Overlap

If the Parties need to consult with each other on the Handling of Patent Rights, the Parties may establish a patent coordination team by mutual agreement and shall adopt procedures for interacting on patent matters.

The Party Handling the Regeneron Patent Rights shall ensure that, unless otherwise agreed by the Parties in writing, no Patent Right that Covers a Regeneron Invention also Covers a Roche Invention or a Joint Invention. The Party Handling the Roche Patent Patents shall ensure that, unless otherwise agreed by the Parties in writing, no Patent Right that Covers a Roche Invention also Covers a Regeneron Invention or a Joint Invention. The Party Handling the Joint Patent Rights shall ensure that, unless otherwise agreed by the Parties in writing, no Patent Right that Covers a Joint Invention also Covers a Regeneron Invention or a Roche Invention.

14.9 Unified Patent Court (Europe)

At any time prior to the end of the "transitional period" as such term is used in Article 83 of the Agreement on a Unified Patent Court between the participating Member States of the European Union, Regeneron shall have the sole right to make decisions regarding whether, for a given relevant Product Patent Right or Joint Patent Right in the European Union, to (i) opt out from the exclusive competence of the Unified Patent Court or (ii) if applicable, withdraw a previously-registered opt-out, and Regeneron shall so notify the Registry of the Unified Patent Court in the manner specified by Rule 5 of the Rules of Procedure of the Unified Patent Court, pay any such registry fee and take such other action as may be necessary to effect the opt-out or opt-out

withdrawal ("**Register**"). The costs to Register shall be shared in the same manner as the Handling costs are shared for the applicable Patent Right.

14.10 CREATE Act

In the event that either Party to this Agreement intends to overcome a rejection of a claimed Invention pursuant to the provisions of 35 USC §§ 102(a)-(d), such Party shall first obtain the prior written consent of the other Party.

14.11 Infringement of Product Patent Rights and Joint Patent Rights

Each Party shall promptly provide written notice to the other Party during the Agreement Term of any (i) known infringement or suspected infringement by a Third Party of any Product Patent Right or Joint Patent Rights, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any Product Know-How or Joint Know-How ((i) and (ii) collectively, "**Infringement**"), and shall provide the other Party with all information in its possession supporting such Infringement.

Regeneron shall have the sole right, but not the obligation, to initiate a suit or action regarding any Regeneron Controlled Infringement, including to settle any such suit or action. Regeneron shall use good faith efforts to notify Roche Basel of any material progress in connection with any such suit or action. At Regeneron's written request, Roche Basel shall offer reasonable assistance to Regeneron in connection any such suit or action at no charge to Regeneron except for reimbursement [* * *] incurred by Roche in rendering such assistance ([* * *]). The Parties will [* * *] of Regeneron's [* * *] in connection with any suit or action with respect to any Regeneron Controlled Infringement as follows: [* * *].

Regeneron shall have the first right, but not the obligation, to initiate a suit or action regarding any Roche Shared Infringement. Within[* * *] after Regeneron provides or receives written notice of any Roche Shared Infringement (such [* * *] period, the "**Enforcement Decision Period**"), Regeneron, in its sole discretion, shall decide whether or not to initiate a suit or action regarding such Roche Shared Infringement and shall notify Roche of its decision in writing ("**Enforcement Suit Notice**"). If Regeneron decides to bring a suit or take action with respect to any Roche Shared Infringement, once Regeneron provides the applicable Enforcement Suit Notice, Regeneron may immediately commence such suit or take such action. In the event that Regeneron (i) does not in writing advise Roche Basel within the Enforcement Decision Period that Regeneron will commence suit or take action with respect to a Roche Shared Infringement, or (ii) fails to commence suit or take action within a reasonable time after providing the applicable Enforcement Suit Notice, Roche shall thereafter have the right (subject to Regeneron's written consent, not to be unreasonably conditioned, withheld or delayed) to commence suit or take action with respect to such Roche Shared Infringement and shall provide written notice to Regeneron of any such suit commenced or action taken by Roche.

The Party bringing suit or taking action with respect to any Roche Shared Infringement (the "**Initiating Party**") shall keep the other Party reasonably informed of the progress of such suit or action and shall provide the other Party with advance copies, to the extent the Initiating Party is lawfully permitted to do so, of all material documents or communications to be filed or positions to be taken in such suit or action and will consider the other Party's comments with respect

thereto in good faith. The Initiating Party shall have the sole and exclusive right to select counsel for any such suit or action.

If Regeneron is the Initiating Party with respect to any suit or action with respect to any Roche Shared Infringement, the Parties will [* * *] of Regeneron's [* * *] in connection with such suit or action [* * *]. If Roche Basel is the Initiating Party with respect to any suit or action with respect to any Roche Shared Infringement, the Parties will [* * *] of Roche Basel's [* * *] in connection with such suit or action as follows: [* * *].

Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action with respect to any Regeneron Controlled Infringement or Roche Shared Infringement shall be used as follows:

(a) First, (i) with respect any Regeneron Controlled Infringement, to reimburse each Party for its share of Regeneron's [* * *] associated with such action and (ii) with respect to any Roche Shared Infringement, to reimburse each Party for its share of the Initiating Party's [* * *] associated with such action; and

(b) Second, any remaining amount shall be retained by or paid to (i) with respect any Regeneron Controlled Infringement, Regeneron and (ii) with respect to any Roche Shared Infringement, the Initiating Party; provided, however, any such amount shall constitute Global Gross Profit.

If the Initiating Party believes it is reasonably necessary or desirable to obtain an effective remedy for the other Party to be joined as a party to the applicable suit or action, upon written request the other Party agrees to be joined as a party to such suit or action but shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to the suit or action. At the Initiating Party's written request, the other Party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance (which shall then be subject to same reimbursement provisions as the out-of-pocket costs of the Initiating Party). The other Party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.

The Initiating Party may settle, consent to a judgment or otherwise voluntarily dispose of any Roche Shared Infringement suit or action ("**Settlement**") without the written consent of the other Party; provided, that, Roche, as the Initiating Party, shall not admit non-infringement or grant a license or other right, including any covenant not to sue, with respect to any Product Patent Right, Product Know-How, Joint Patent Rights or Joint Know-How or otherwise settle in a manner that would reasonably be expected to have a negative impact on a Product or the global patent portfolio for the Products, or on the employees of Regeneron or on Regeneron's reputation, in each case, without Regeneron's consent.

Roche shall, at its own cost and expense, have the sole right, but not the obligation, to decide whether or not to initiate (or settle) any suit or action in the Territory with respect to any (i) known infringement or suspected infringement by a Third Party of any Roche Patent Right, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any Roche Know-How in each case, without any coordination with, or notice to, Regeneron. Regeneron, shall, at its own

costs and expense, have the sole right, to decide whether or not to initiate (or settle) any suit or action in the Territory with respect to any (iii) known infringement or suspected infringement by a Third Party of any Regeneron Patent Rights that are not Product Patent Rights, or (iv) known or suspected unauthorized use or misappropriation by a Third Party of any Regeneron Know-How that is not Product Know-How, in each case, without any coordination with, or notice to, Roche. Each Party, shall, at its own costs and expense, have the sole right, to decide whether or not to initiate (or settle) any suit or action in the Territory with respect to any (v) known infringement or suspected infringement by a Third Party of any Joint Patent Rights, or (vi) known or suspected unauthorized use or misappropriation by a Third Party of any Joint Know-How, in each case ((v) and (vi)), that is not Competitive Infringement, without any coordination with, or notice to, the other Party. The Party initiating any suit or action pursuant to this paragraph shall retain all monies recovered upon the final judgment or settlement of any action. With respect to any suit or action initiated pursuant to this paragraph, at the acting Party's written request, the other Party shall offer reasonable assistance to the acting Party in connection therewith at no charge to the acting Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance.

14.12 Invalidity or Unenforceability Defenses or Actions

Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Product Patent Rights or Joint Patents Rights by a Third Party of which such Party becomes aware.

Regeneron shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Product Patent Rights in the Regeneron Patent Territory. The Parties shall share [* * *] all of Regeneron's [* * *] incurred with respect to defending the Product Patent Rights in the Regeneron Patent Territory. Regeneron shall use good faith efforts to notify Roche of any material steps taken in connection with defending the Product Patent Rights in the Regeneron Patent Territory. At Regeneron's written request, Roche shall offer reasonable assistance to Regeneron in connection with defending the Product Patent Rights in the Regeneron Patent Territory at no charge to Regeneron except for reimbursement of reasonable out-of-pocket expenses incurred by Roche in rendering such assistance (which shall then be subject to same reimbursement provisions as the out-of-pocket costs of Regeneron).

Regeneron shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Product Patent Rights in the Roche Territory and the Joint Patent Rights in the Territory (such Patent Rights, the "**Roche-Shared Defense Patents**"). Within [* * *] after Regeneron provides or receives written notice of any alleged or threatened assertion of invalidity or unenforceability of any of the Roche-Shared Defense Patents (such [* * *] period, the "**Defense Decision Period**"), Regeneron, in its sole discretion, shall decide whether or not to defend and control the defense of the validity and enforceability of such Roche-Shared Defense Patents and shall notify Roche of its decision in writing ("**Defense Suit Notice**"). If Regeneron decides to defend and control the defense of the validity and enforceability of such Roche- Shared Defense Patents, once Regeneron provides the applicable Defense Suit Notice, Regeneron may immediately commence such defense. In the event that Regeneron (i) does not in writing advise Roche within the Defense Decision Period that Regeneron will defend and control the defense of an Roche-Shared Defense Patent, or (ii) fails to commence the defense of such Roche-Shared Defense Patent within a reasonable time after providing the applicable Defense Suit Notice, Roche shall thereafter have the right (subject to

Regeneron's written consent, not to be unreasonably conditioned, withheld or delayed) to defend and control the defense of such Roche-Shared Defense Patent and shall provide written notice to Regeneron of any such defense taken by Roche.

The Party defending and controlling the defense with respect to any Roche-Shared Defense Patent (the "**Defending Party**") shall keep the other Party reasonably informed of the progress of such suit or action and shall provide the other Party with advance copies, to the extent the Defending Party is lawfully permitted to do so, of all material documents or communications to be filed or positions to be taken in such suit or action and will consider the other Party's comments with respect thereto in good faith; provided, that, with respect to Roche as the Defending Party, if Regeneron determines that any proposed actions by Roche with respect to such defense would reasonably be expected to have a negative impact on the global patent portfolio for the Products, then Roche must implement Regeneron's comments with respect to any such actions. The Defending Party shall have the sole and exclusive right to select counsel for any such suit or action. At the Defending Party's written request, the other Party shall offer reasonable assistance to the Defending Party in connection with defending the Roche-Shared Defense Patents at no charge to the Defending Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance (which shall then be subject to same reimbursement provisions as the out-of-pocket costs of the Defending Party).

If Regeneron is the Defending Party with respect to any Roche-Shared Defense Patent, the Parties will share all of Regeneron's [* * *] in connection with such defense [* * *]. If Roche is the Defending Party with respect to any Roche-Shared Defense Patent, the Parties will share all of Roche's [* * *] in connection with such suit or action as follows: [* * *].

14.13 Defense

If an action for infringement is commenced against either Party, its Affiliates or its licensees or its sublicensees (including Sublicensees) related to the discovery, development (including the conduct of the Co-Funded Development Plan), manufacture, use or sale of a Product (a "**Third Party Infringement Action**"), then, subject to Article 16, the following shall apply:

(a) The Party (or its Affiliate, licensee or sublicensee, as applicable) who is named as the defendant shall have the right (but not the obligation) to defend such Third Party Infringement Action at its own expense; provided, however, that if a Third Party Infringement Action is commenced against both Regeneron (or any of its Affiliates, licensees or sublicensees), on the one hand, and Roche (or any of its Affiliates, licensees or Sublicensees), on the other hand (a "**Joint Infringement Action**"), then Regeneron shall have the first right, but not the obligation, to conduct and control the defense of such Third Party Infringement Action, using counsel of its own choice. Roche shall assist and cooperate with Regeneron, at Regeneron's expense, to the extent necessary in the defense of such suit. If Regeneron elects not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such Joint Infringement Action, Regeneron shall notify Roche of such election within such time periods so Roche is not prejudiced by any delays, and Roche shall have the right (but not the obligation), to conduct and control the defense of such Joint Infringement Action using counsel of its own choice. The Parties will share the [* * *] of the controlling Party in defense of a Joint Infringement Action as follows: [* * *].

(b) The Party entitled to defend any Third Party Infringement Action shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion; provided, that Roche shall not enter into any settlement of any Third Party Infringement Action that [* * *] in each case ((i) - (iii)), without Regeneron's prior written consent in its sole discretion, and provided, that Regeneron shall not enter into any settlement of any Third Party Infringement Action that [* * *] in each case ((iv) and (v)), without Roche's prior written consent in its sole discretion. Unless otherwise agreed by the Parties, with respect any settlement of a Third Party Infringement Action, the Parties shall share responsibility for the payment of any award for damages, or any amount due pursuant to such settlement as follows: to the extent that such settlement is with respect to the Regeneron Territory, [* * *].

(c) Each Party will provide the other Party with prompt written notice of the commencement of any proceedings under this Section 14.13 and such Party will keep the other Party reasonably informed of all material developments in connection with any such Third Party Infringement Action, including by promptly furnish the other Party with a copy of all documents or communications filed in such action.

14.14 Common Interest Disclosures

The Parties have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Co-Funded Development Plan or Compounds or Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the Co-Funded Development Plan or Compounds or Products. Accordingly, any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property or technology owned by Third Parties will be used solely for purposes of the Parties' common legal interests with respect to the conduct of this Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party. Notwithstanding the foregoing, neither Party's attorney represents the other Party.

14.15 Biosimilars

Notwithstanding anything herein to the contrary, if either Party receives notice or a copy of an application submitted to a Regulatory Authority in the Territory for a Biosimilar Product or similar notice or communication pursuant to which a product is claimed to be interchangeable with a Product, whether or not such notice or copy is provided under any Applicable Law, or otherwise becomes aware that such an application, notice or communication has been submitted to a Regulatory Authority in the Territory for approval, such Party shall notify and provide the other Party copies of such application, notice, communication and any other relevant information to the extent permitted by Applicable Law. The Parties shall cooperate in good faith with one another with respect to the foregoing, including with respect to proceedings related thereto, in a manner consistent with the rights and obligations of the Parties set forth in Section 14.11, Section 14.12 or Section 14.13, as applicable.

14.16 Patent Term Extensions

"**Patent Term Extensions**" shall mean all available patent term extensions, adjustments or restorations, or supplementary protection certificates.

Regeneron shall have the sole right, but not the obligation, to file for Patent Term Extensions with respect to the Products in the Regeneron Patent Territory. The Parties will share all of Regeneron's [* * *] for such Patent Term Extensions [* * *]. Roche shall have the sole right, but not the obligation, to file for Patent Term Extensions, including Supplementary Protection Certifications, with respect to the Products in the Roche Territory; provided, that if filing for any such Patent Term Extension would reasonably be expected to have a negative impact on the Product in the US then Regeneron's prior approval, in its sole discretion, shall be required for such Patent Term Extension. The Parties will share all of Roche's [* * *] for such Patent Term Extensions [* * *].

With respect to Patent Term Extensions with respect to the Products in the Roche Territory, subject to Roche obtaining Regeneron's approval if necessary, Regeneron shall (a) grant Roche the right to file for such Patent Term Extension and (b) execute such authorizations and other documents and take such other actions as may be reasonably requested by Roche to obtain such Patent Term Extensions. Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such Patent Term Extensions. The Parties shall cooperate with each other in gaining Patent Term Extensions with respect to the Products.

With respect to any filings made to Regulatory Authorities with respect to any Compounds or Products, including, as required or allowed in the US, the FDA's Purple Book, if applicable, or outside the US, other international equivalents, Regeneron will have the sole right to make any such decision whether to list Regeneron Patent Rights, but in all events will comply with Applicable Law, provided that Regeneron will consider in good faith any timely comments received from on behalf of Roche with respect to such filings in the Roche Territory prior to submission. Upon Regeneron's request, Roche will reasonably cooperate in the implementation of Regeneron's decision made under this Section 14.16.

14.17 Interference, Opposition and Reissue of Third Party Patents

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 Right of a Third Party in furtherance of a Product in the Territory, 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 discuss the appropriate course of action with respect to such proposed interference, opposition, post-grant review, reissue or reexamination proceeding; provided, that after such discussion either Party may initiate any interference, opposition, post-grant review, reissue or reexamination proceeding relating to a Patent Right of a Third Party in furtherance of a Product in the Territory, except that Roche may not initiation any such interference, opposition, post-grant review, reissue or reexamination proceeding in the US without Regeneron's prior written consent in its sole discretion.

14.18 Third Party IP Licenses

With respect to any Patent Right or other intellectual property right of a Third Party that is necessary or reasonably useful for the development, manufacture or commercialization of the Products, (a) Regeneron shall have the exclusive right to negotiate and enter into any such license or other agreement with a Third Party to obtain rights to any such Patent Right or other intellectual property right solely in the Regeneron Patent Territory, (b) Roche Basel shall have the exclusive right to negotiate and enter into any such license or other agreement with a Third Party to obtain rights to any such Patent Right or other intellectual property right solely in the Roche Territory and (c) the Parties must mutually agree on the terms and conditions of any license or other agreement with a Third Party to obtain rights to any such Patent Right or other intellectual property right in both (i) some or all of the Regeneron Patent Territory and (ii) some or all of the Roche Territory.

15. Representations and Warranties

15.1 Regeneron Representations and Warranties

Regeneron represents and warrants to Roche, as of the Effective Date:

(a) Product Data

The data, results, reports, and other documentation disclosed by Regeneron to Roche, either via the electronic data room or direct communication in writing between the business representatives of the Parties, in each case, to the extent related to any Compound or Product, are true and accurate.

(b) Ownership of Patent Rights

Regeneron owns all of the Regeneron Base Patent Rights. Appendix 1.90 contains a complete and accurate list of all patents and patent applications included in the Regeneron Base Patent Rights.

(c) Inventors

The inventors of the inventions disclosed or claimed in the Regeneron Base Patent Rights have transferred full ownership of such inventions to Regeneron, or are under an obligation to transfer the full ownership of such inventions to Regeneron.

(d) Grants

To Regeneron's Knowledge, Regeneron has the lawful right to grant Roche the rights and licenses described in this Agreement.

(e) Validity of Patent Rights; Inventorship Disputes

To Regeneron's Knowledge, the claims in the Regeneron Base Patent Rights are valid and enforceable. Regeneron has no Knowledge of any inventorship disputes concerning any Regeneron Base Patent Rights.

(f) Ownership and Validity of Know-How

To Regeneron's Knowledge, Regeneron's Know-How has not been misappropriated from any Third Party. Regeneron has taken reasonable measures to protect the confidentiality of its Know-How.

(g) No Limitations on Manufacturing

Without limiting Regeneron's representation and warranty in Section 15.3(a), neither [* * *] nor any other indenture, mortgage, deed of trust, lease, agreement, or other instrument to which Regeneron is a party or by which Regeneron or any of its property is bound, contains a term that would restrict Roche from using any of the Roche Manufacturing Facilities to supply Regeneron with Products for the Regeneron Territory or to otherwise fulfill any of Roche's manufacturing and supply obligations under this Agreement.

(h) Regeneron and its Affiliates have not clinically developed or commercialized or granted a license to a Third Party to clinically develop or commercialize an Antibody Conjugate that contains any Antibody in the Lead Compound.

15.2 Roche Representations and Warranties

Roche represents and warrants to Regeneron that, as of the Effective Date:

All written information disclosed by Roche to Regeneron regarding Roche's and its Affiliates' manufacturing or organization manufacturing capabilities and compliance history is true and accurate.

15.3 Mutual Representations and Warranties

Each Party represents and warrants to the other Party as of the Effective Date, and covenants, as follows:

(a) Authorization

The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder: (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the organization documents of such Party; (iv) to the Knowledge of such Party, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a party or by which such Party or any of its property is bound, which violation would have an adverse effect on the financial condition of such Party or on the ability of such Party to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained previously (other than Regulatory Approvals required for the sale of Products and filings with Regulatory Authorities required in connection with Products).

Without limiting the foregoing, (A) such Party is duly organized and validly existing under the Applicable Laws of its jurisdiction of incorporation; (B) such Party has full corporate power and

authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement; (C) 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); and (D) the individuals executing this Agreement for such Party have been duly authorized to execute and deliver this Agreement on behalf of such Party.

(b) No Claims

There are no claims or investigations pending or, to such Party's Knowledge, threatened against such Party or any of its Affiliates, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially impair, prevent or delay such Party's ability to perform its obligations hereunder. During the Agreement Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

(c) Insurance

During the Agreement Term and for a minimum period of [* * *] thereafter and for an otherwise longer period as may be required by Applicable Law, each of Regeneron and Roche will procure and maintain insurance consistent with industry practice or required by Applicable Law, which may be through self-insurance. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Roche, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed by such Party or its Affiliates in connection with this Agreement. Any insurance proceeds received by a Party in connection with any indemnified claim shall be retained by such Party and shall not reduce any obligation of the other Party under Article 16 with respect to such claim.

(d) Debarment

Each Party covenants that it and its Affiliates and, to the best of such Party's knowledge, its and their respective employees who are involved in the development or commercialization of the Compounds or the Products will not be debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar federal or state agency or program in the United States or any other country ("**Debarred**"). In the event a Party receives notice of, or becomes aware that any of its Affiliates or any employee of such Party or any of its Affiliates receives notice of, in either case, debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes or any other similar federal or state agency or program in the United States or any other country, such Party shall promptly notify the other Party in writing.

Each Party has adopted and implemented compliance policies that conform to industry standards. Each Party will use commercially reasonable efforts to ensure that no employees of such Party or its Affiliates who are involved in the development or commercialization of the Compounds or the Products are Debarred.

(e) No Force Majeure Event

Each Party represents and warrants that as of the Effective Date it is not currently under the effects of a force majeure event as contemplated by Section 21.9 such as would prevent or materially hinder or delay its performance hereunder.

15.4 No Other Representations and Warranties

EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE.

16. Indemnification

16.1 Indemnification by Roche

Roche shall indemnify, hold harmless and defend Regeneron, Regeneron's Affiliates and its and their respective directors, officers, employees and agents ("**Regeneron Indemnitees**") from and against any and all losses, expenses, cost of defense (including reasonable attorneys' fees, witness fees, damages, taxes, judgments, fines and amounts paid in settlement) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Claims**") arising from or occurring as a result of (a) the breach of this Agreement or the Supply Agreement by Roche or any of its Affiliates, if applicable, (b) the negligence or willful misconduct of any Roche Indemnitee or a Sublicensee of Roche in performing its or their obligations under this Agreement, (c) any regulatory activities conducted by Regeneron or its Affiliates to assist Roche to obtain Regulatory Approval for a Product (other than the First Approval Activities) in the Roche Territory pursuant to Section 6.1.2, or (d) any employee of Roche or its Affiliates who is involved in the development or commercialization of the Compounds or the Products being Debarred, except, in the case of (a) and (b), to the extent Regeneron has an obligation to indemnify Roche for Losses pursuant to Section 16.2, as to which Losses each Party shall indemnify the other Party to the extent of their respective liability for such Losses.

16.2 Indemnification by Regeneron

Regeneron shall indemnify, hold harmless and defend Roche, Roche's Affiliates and its and their respective directors, officers, employees and agents ("**Roche Indemnitees**") from and against any and all Losses in connection with any and all Claims arising from or occurring as a result of (a) the breach of this Agreement or the Supply Agreement by Regeneron or any of its Affiliates, if applicable, (b) the negligence or willful misconduct of any Regeneron Indemnitee or a Sublicensee of Regeneron in performing its or their obligations under this Agreement, or (c) any employee of Regeneron or its Affiliates who is involved in the development or commercialization of the Compounds or the Products being Debarred, except, in each case ((a) and (b)), to the extent Roche has an obligation to indemnify Regeneron for Losses pursuant to Section 16.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

16.3 No Fault Claims

With respect to any Claim arising out of or related to the research, development, seeking and obtaining Regulatory Approval for, making, using, importing or exporting of the Compounds or Products under this Agreement that is not subject to indemnification under Section 16.1 or Section 16.2 and is not subject to Section 14.13 (each, a "**No Fault Claim**"), (a) the provisions of Section 16.4 shall not apply with respect to the defense of such No Fault Claim and the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending such No Fault Claim, including whether to settle any such No Fault Claim and (b) [* * *]. For clarity, neither Party shall settle any No Fault Claim without the other Party's consent, not to be unreasonably withheld, conditioned or delayed.

16.4 Indemnification Procedure

All indemnification claims in respect of a Regeneron Indemnitee or a Roche Indemnitee shall be made solely by Regeneron or Roche, as applicable (each of Regeneron or Roche in such capacity, the "**Indemnified Party**"). The Indemnified Party shall promptly notify the other Party ("**Indemnifying Party**") in writing of the Claim, and any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 16.1 or Section 16.2 (an "**Indemnification Claim Notice**").

With respect to each Claim, the obligations of the Indemnifying Party shall be governed by and contingent upon the following:

(a) At its option, the Indemnifying Party may assume the defense of any Claim by notifying the Indemnified Party in writing within [* * *] after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party or its Indemnitees, in respect of such Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's or its Indemnitees' claim for indemnification. Upon assuming the defense of a Claim, the Indemnifying Party may appoint the lead counsel in the defense of such Claim. If the Indemnifying Party assumes the defense of a Claim, the Indemnified Party shall promptly deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party or any of its Indemnitees in connection with the Claim. If the Indemnifying Party assumes the defense of a Claim, except as provided in subsection (b) below, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party or any of its Indemnitees in connection with the analysis, defense or settlement of such Claim unless specifically requested in writing by the Indemnifying Party. If it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party or its Indemnitees from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any Losses incurred by the Indemnifying Party in its defense of the Claim.

(b) The Indemnified Party shall be entitled to participate in, but not control, the defense of a Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof, and the assumption by the Indemnifying Party of such cost and expense, have been specifically requested in writing by the Indemnifying Party, (ii) the Indemnifying Party

has failed to assume the defense and employ counsel in accordance with Section 16.4(a) (in which case the Indemnified Party shall control the defense) or (iii) the interests of the applicable Indemnitees and the Indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both entities under Applicable Law, ethical rules or equitable principles (in which case the Indemnified Party shall control its defense).

(c) With respect to any Losses relating solely to the payment of money damages in connection with a Claim and that shall not result in the applicable Indemnitee becoming subject to injunctive or other relief or otherwise adversely affecting the business of the applicable Indemnitee in any manner and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with any Claim, if the Indemnifying Party has assumed the defense of the Claim in accordance with Section 16.3, the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the Indemnifying Party controls the defense of a Claim as provided above, the Indemnified Party shall not settle such Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(d) Regardless of whether the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party and Indemnitees of, records and information that are reasonably relevant to such Claim and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the Indemnifying Party shall reimburse the Indemnified Party for all its out-of-pocket expenses in connection therewith.

(e) Except as provided above, the Losses incurred by the Indemnified Party in connection with any Claim shall be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party or its Indemnitees.

17. Liability

EXCEPT FOR INDEMNIFICATION OBLIGATIONS OF A PARTY UNDER ARTICLE 16, BREACHES OF CONFIDENTIALITY IN ARTICLE 18, BREACHES OF ARTICLE 9, GRANT BY EITHER PARTY OF A LICENSE IN BREACH OF THE Exclusive license granted BY IT under Section 2.1(IV) or Section 2.4(IV), GROSS NEGLIGENCE, WILLFUL MISCONDUCT, AND ANY OTHER LIABILITY TO THE EXTENT SUCH LIABILITY CANNOT BE LIMITED UNDER APPLICABLE LAW, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE

OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, DAMAGES FOR LOSS OF PROFIT, LOSS OF REVENUE, OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES.

18. Obligation Not to Disclose Confidential Information

18.1 Non-Use and Non-Disclosure

During the Agreement Term and for [* * *] thereafter, a Receiving Party shall (a) treat Confidential Information of the Disclosing Party as strictly confidential and with similar care as it would treat its own information of a similar nature, and (b) not use such Confidential Information other than for fulfilling its obligations or exercising its rights under this Agreement; provided that with respect to any Confidential Information that is specifically identified as a trade secret, or that the other Party has reason to know is a trade secret under Applicable Law, such obligations shall survive until such Confidential Information is no longer a trade secret under Applicable Law.

The Receiving Party covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party (or its Affiliates) to any Third Party except (i) to its employees, agents, consultants or any other person under its authorization; provided that 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, (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory; provided that such Third Parties are subject in writing to substantially the same confidentiality obligations as the Parties under this Agreement, (iv) to permitted potential and actual Sublicensees or subcontractors; provided that such permitted potential and actual Sublicensees or subcontractors are subject in writing to substantially the same confidentiality obligations as the Parties under this Agreement, or (v) as set forth elsewhere in this Agreement; provided that the exceptions in clauses (iii), (iv) and (v) shall not apply with respect to Proprietary Manufacturing Information.

18.2 Permitted Disclosure

Notwithstanding the obligation of confidentiality, non-use and non-disclosure set forth in Section 18.1 but subject to Section 18.3, the Parties recognize the need for certain exceptions to this obligation, and each Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment; provided, further, that the Confidential Information disclosed in response to such order or as required by Applicable Law shall be limited to that information that is legally required to be disclosed in response to such order or by such Applicable Law;

(b) made by or on behalf of the Receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval pursuant to the terms of 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;

(c) made to a US government agency or contractor in connection with performance of a US government agreement or sub-agreement (provided that appropriate markings to protect Confidential Information pursuant to US government regulations are applied to Confidential Information to the extent applicable); provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law; or

(d) with respect to Joint Know-How, made by either Party or its Affiliates as may be necessary or useful in connection with the exploitation of any product that is not a Competing Product in the Territory.

18.3 Proprietary Manufacturing Information

Without limitation of any of the foregoing, Roche shall adopt and implement reasonable firewall procedures to prevent the disclosure of and use of Proprietary Manufacturing Information beyond the persons who are required to receive such information in order to manufacture the Products or to prepare, submit, obtain or maintain Regulatory Approvals for the Products in the Field in the Roche Territory in accordance with this Agreement (and who are bound by confidentiality obligations no less stringent than those provided in this Agreement), including by establishing reasonable physical and electronic safeguards, segregating all Proprietary Manufacturing Information from its own information or materials or that of others (including Affiliates) in order to prevent commingling; not copying or otherwise duplicating any embodiments of the Proprietary Manufacturing Information, except as necessary to manufacture the Products or to prepare, submit, obtain or maintain Regulatory Approvals for the Products in the Field in the Roche Territory in accordance with this Agreement (provided that any such copies or duplications of such Proprietary Manufacturing Information shall be marked “confidential,” “proprietary”, or the like); and notifying Regeneron immediately, and cooperating with Regeneron as Regeneron may reasonably request, upon any discovery of any loss or compromise of Proprietary Manufacturing Information.

[* * *]

Notwithstanding anything else in this Agreement to the contrary, if Roche or any of its Affiliates receives a request for any Proprietary Manufacturing Information 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 Roche shall (i) notify Regeneron of such request within [* * *], (ii) permit Regeneron 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 Regeneron with reasonable assistance in opposing such request or seeking such limitations. Roche shall not, and shall cause its Affiliates not to, disclose any Proprietary Manufacturing Information to any governmental authority in response to a request under any freedom of information law without Regeneron’s prior written consent, not to be unreasonably withheld, conditioned or delayed;

provided that Regeneron acknowledges and agrees that it would be unreasonable for it to not consent to any disclosure if such lack of disclosure would cause Roche or any of its Affiliates to violate Applicable Law.

Any Regeneron Confidential Information (as the term is defined in the Technology Transfer Agreement) that constitutes Proprietary Manufacturing Information shall be governed by the applicable terms under this Agreement.

18.4 Press Releases; Use of Name

The Parties shall mutually agree on the content of any press releases, and shall coordinate on the initial press release promptly after the Effective Date. Except as otherwise expressly provided herein or for any such disclosure that is, in the opinion of the issuing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the issuing Party (or any parent entity thereof) are listed, neither Party shall issue any other public announcement or press release or make any other public disclosure regarding this Agreement, its terms or its subject matter without the other Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, Regeneron shall be responsible for, and shall have the final decision-making authority on any press releases for any Ongoing Regeneron Studies.

The restrictions imposed by this Section 18.4 shall not prohibit either Party from making any disclosure if, in the opinion of the counsel of the Party making such disclosure, such disclosure is required by Applicable Law or the rules of a stock exchange on which the securities of the first Party, provided, that such Party shall submit the proposed disclosure to the other Party in advance (and in no event less than [* * *] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon, and shall consider the other Party's comments in good faith.

Except as expressly provided herein or required by Applicable Law, neither Party shall use the name, logo or trademark of the other Party or any of its Affiliates or any of its or their Sublicensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party.

18.5 Publications

During the Agreement Term, the following restrictions shall apply with respect to disclosure by any Party of Confidential Information relating to the Compounds or Products in any publication or presentation:

(a) With respect to publications or presentations relating to Co-Funded Studies where Roche is involved in operationalizing the Co-Funded Study and for other joint publications or presentations, the Parties will work together in good faith to co-author such publication or presentation, and will mutually agree in good faith on all aspects of such publication or presentation, including without limitation the content of the publication or presentation and the timing and manner of its publication or presentation. If the Parties cannot reach agreement, then the Party that sponsors, or is primarily responsible for operationalizing, the Co-Funded Study will make the final determination on all aspects of such publication or presentation except with respect to disclosure of an invention, solely or jointly conceived or

reduced to practice by the other Party, or the Confidential Information of the other Party (other than the results of the Co-Funded Study).

(b) With respect to publications or presentations relating to Co-Funded Studies where Roche is not involved in operationalizing the Co-Funded Study (including, for clarity, the Additional Regeneron Studies), Regeneron shall provide Roche with a copy of such proposed publication or presentation at least [* * *] (or at least [* * *] in the case of oral presentations) prior to submission for publication so as to provide Roche with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by Roche to Regeneron in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if Roche notifies ("**Roche Publishing Notice**") Regeneron in writing, within [* * *] after receipt of the copy of the proposed publication or presentation (or at least [* * *] in the case of oral presentations), that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived or reduced to practice by Roche, for which Roche reasonably desires to obtain patent protection, in which case Regeneron shall delay such publication for a mutually agreeable period of time not to exceed [* * *] from the date of the Roche Publishing Notice; or (ii) contains Confidential Information of Roche (other than the results of any Co-Funded Study), in which case, Regeneron shall, upon Roche's request, remove from the publication such information.

(c) With respect to publications or presentations related to Unilateral Studies or other unilateral publications or presentations by a Party relating to the Compounds or Products, subject to Section 18.5(d), the Party proposing such publication or presentation ("**Publishing Party**") shall provide the other Party with a copy of such proposed publication or presentation at least [* * *] (or at least [* * *] in the case of oral presentations) prior to submission for publication so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies ("**Publishing Notice**") the Publishing Party in writing, within [* * *] after receipt of the copy of the proposed publication or presentation (or at least [* * *] in the case of oral presentations), that such publication or presentation in its reasonable judgment; (i) contains an invention, solely or jointly conceived or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection, in which case the Publishing Party shall delay such publication for a mutually agreeable period of time not to exceed [* * *] from the date of the Publishing Notice; or (ii) contains Confidential Information of such other Party (other than the results of any Clinical Study conducted under this Agreement, if applicable), in which case, the Publishing Party shall, upon the other Party's request, remove from the publication such information. In the case of publications or presentations by Roche relating to a Roche Unilateral Study, Roche agrees to include authors from Regeneron in such publication or presentation.

(d) The obligations under Section 18.5(c) shall not apply to any publications or presentations by Regeneron or any of its Affiliates related to activities conducted with respect to the Compounds or Products prior to the Effective Date, and Regeneron shall provide Roche an advance copy of any such publications or presentations.

19. Term and Termination

19.1 Commencement and Term

This Agreement shall commence upon the Effective Date and continue for the Agreement Term (which, for clarity, includes any extension agreed by the Parties).

19.2 Termination

19.2.1 Termination for Breach

A Party ("**Non-Breaching Party**") shall have the right to terminate this Agreement in its entirety in the event the other Party ("**Breaching Party**") is in breach of any of its material obligations under this Agreement. The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify in reasonable detail the facts underlying or constituting the alleged breach. The Breaching Party shall have a period of [* * *] after such written notice is provided ("**Peremptory Notice Period**") to cure such breach. If the Breaching Party has a bona fide dispute as to whether such breach occurred or has been cured, it will so notify the Non-Breaching Party, and the expiration of the Peremptory Notice Period shall be tolled until such bona fide dispute is resolved pursuant to Section 21.2. Upon a determination of breach or failure to cure, the Breaching Party may have the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in its entirety effective as of the expiration of the Peremptory Notice Period. A Party's failure to meet the Minimum Committed Regeneron Capacity or the Minimum Committed Roche Capacity, as the case may be, shall be considered a breach of a material obligation by such Party. Notwithstanding the foregoing, Regeneron's rights with respect to Roche's breach of its diligence obligations set forth in Section 6.2 or Section 7.3 shall be subject to Section 19.2.2(a) and Section 19.2.2(b).

19.2.2 Termination for Roche Diligence Breach or Failure to Commercialize

Notwithstanding any provision to the contrary set forth in this Agreement,

(a) Roche's breach of its regulatory diligence obligation set forth in Section 6.2 or its commercialization diligence obligations set forth in Section 7.3 with respect to a Roche Major Country will not give Regeneron the right to terminate this Agreement in its entirety and will give Regeneron the right to terminate this Agreement solely with respect to such Roche Major Country.

(b) Roche's breach of its regulatory diligence obligation set forth in Section 6.2 or its commercialization diligence obligations set forth in Section 7.3 with respect to the ROW, taken as a whole, will not give Regeneron the right to terminate this Agreement in its entirety and will give Regeneron the right to terminate this Agreement solely with respect to the ROW.

(c) If, after [* * *] following the First Commercial Sale of the Lead Product in any country in the EU or the United Kingdom, Roche is not commercializing any Product in a country in the Roche Territory, and upon Regeneron's written inquiry to the Roche Chair of the JOC, confirms in writing that it has no plans to commercialize any Product in such country, or

does not provide Regeneron within [* * *] after receiving such inquiry from Regeneron with a reasonable written plan to commercialize a Product in such country during the Agreement Term, and Regeneron in good faith plans to commercialize the Product in such country, then Regeneron shall have the right to terminate this Agreement solely with respect to such country immediately upon written notice to Roche.

The notice requirement and opportunity to dispute and cure a breach as set forth in the second through fifth sentences of Section 19.2.1 above shall apply to any termination pursuant to clauses (a) or (b) of this Section 19.2.2, provided that Regeneron's right to terminate will be limited as set forth in this Section.

19.2.3 Insolvency

A Party shall have the right to terminate this Agreement, if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within [* * *] after the filing thereof.

19.2.4 Termination by Roche for Technical Failure

If (i) both of the first two Ongoing Regeneron Studies listed in Appendix 1.73 are placed on clinical hold by the FDA or EMA that continues for thirty (30) days, unless Regeneron is undertaking reasonable actions to have either such clinical hold removed, in which case if such hold continues for ninety (90) days, (ii) the Lead Product has not received an Emergency Use Authorization prior to May 31, 2021, (iii) Regeneron has not filed for full Regulatory Approval of the Lead Product in the US prior to May 31, 2021, or (iv) Regeneron terminates further development of the Lead Product, then Roche shall have the right to terminate this Agreement in its entirety upon thirty (30) days' prior written notice, provided in each case, such notice of termination is delivered by Roche within thirty (30) days after the occurrence of the condition giving rise to the right of termination.

19.2.5 Termination by Roche due to [* * *] Third Party Product

If a Third Party Antibody product targeting SARS-CoV-2 in form of a single Antibody or a cocktail of at least two Antibodies is [* * *] the safety and efficacy profile of such Third Party Antibody product confers a substantial public health benefit over the Lead Product [* * *] (an "**Alternative Third Party Product**"), then Roche shall have the right to terminate this Agreement in its entirety upon (a) sixty (60) days prior written notice at any time if such notice is given prior the First Commercial Sale of the Lead Product in the Territory; or (b) six (6) months prior written notice at any time if such notice is given after First Commercial Sale of the Lead Product in the Territory; provided, that, with respect to the Chugai Asset as the Alternative Product, Roche shall not have the right to terminate this Agreement pursuant to this Section 19.2.5 unless Regeneron has notified Roche in writing that Regeneron will not exercise the Chugai Asset Option or Regeneron does not provide the Exercise Notice during the Exercise Period.

If the Parties cannot agree on whether the safety and efficacy profile of an Alternative Third Party Product confers a substantial public health benefit over the Lead Product in either treatment or prophylactic use, such matter shall be determined in accordance with Section 21.2, and if still not resolved, then decided by an Expert Committee pursuant to Section 21.4, and

Roche shall not have the right to terminate this Agreement pursuant to this Section 19.2.5 unless and until such Expert Committee determines that the safety and efficacy profile of such Alternative Third Party Product confers a substantial public health benefit over the Lead Product in either treatment or prophylactic use.

19.3 Consequences of Expiration or Termination

19.3.1 Transfer of Products

Upon the expiration or earlier termination for any reason of this Agreement, the rights and licenses granted by each Party to the other under this Agreement shall terminate in their entirety, on the effective date of expiration or termination, as applicable, subject to Regeneron's rights in Section 19.3.1(c).

Upon any termination or expiration of this Agreement, if Regeneron desires to continue development or commercialization of Product(s), Regeneron shall give a Continuation Election Notice to Roche within [* * *] of Regeneron's notice of termination (in the event of termination by Regeneron) or receipt of Roche's notice of termination (in the event of termination by Roche). If Roche receives such a timely Continuation Election Notice, and to the extent requested by Regeneron and consistent with ensuring a smooth and orderly transition to Regeneron or its designee, Roche shall perform the following activities (the "**Roche Transfer Activities**"):

(a) Roche shall assign and transfer to Regeneron or its designee all regulatory filings and approvals, regulatory communications, all final pre-clinical and Clinical Study reports and Clinical Study protocols, Product Trademarks and all data, including clinical data, in Roche's possession or control related to all Product(s). All data shall be transferred in the form and format in which it is maintained by Roche or otherwise reasonably requested by Regeneron. Original paper copies shall also be transferred. Roche shall not be required to prepare or finalize any new data, reports or information solely for purposes of transfer to Regeneron.

(b) Roche shall assign to Regeneron or its designee agreements between Roche or any of its Affiliates on the one hand, and any Third Party on the other hand (including such agreements with CROs, CMOs or distributors) to the extent relating to the Product(s), provided that, with respect to any such Third Party agreement entered into by Roche or any of its Affiliates prior to the Effective Date, to the extent that the assignment by Roche requires any notice to or consent of the relevant Third Party counterparty to such agreement, or requires the separation of such agreement into an agreement that is retained by Roche or any of its Affiliates and an agreement that is assignable to (or entered into by) Regeneron, as applicable, (i) Roche shall use reasonable efforts to give such notice, or (ii) the Parties will reasonably cooperate to (A) obtain such consent or (B) at the request and with the reasonable assistance of Roche, negotiate such separation, in each case ((i) and (ii)), as soon as practicable, provided that neither Roche nor any of its Affiliates shall agree to any material undertakings in connection therewith, and until such assignment is executed, the Parties will reasonably cooperate to provide Regeneron the benefits under such agreement to the extent applicable to the rights to be assigned to Regeneron, provided further that Regeneron will be responsible for all payments under such agreement to the extent applicable to the benefits provided to Regeneron with respect to the Product(s), and any payments required by such Third Party as pursuant to any such agreement to secure such consent.

(c) Roche shall grant and hereby grants (effective as of expiration or termination of this Agreement) to Regeneron a non-exclusive, worldwide, sublicenseable (through multiple tiers) license under the Roche Independent IP, Roche Patent Rights, Roche Know-How, and Roche's interest in the Joint Patent Rights and Joint Know-How, to the extent necessary or reasonably useful to allow Regeneron, its Affiliates or licensees to develop, manufacture, have manufactured, use, offer to sell, sell, promote, export and import the applicable Product(s) in the Territory, provided that, if Roche identifies in writing to Regeneron that any Roche Independent IP, Roche Patent Rights or Roche Know-How granted to Regeneron under this Section 19.3.1(c) is under a Third Party agreement between Roche or any of its Affiliates on the one hand, and any Third Party on the other hand, and if such Third Party agreement is not assigned to Regeneron pursuant to Section 19.3.1(b), then Regeneron shall be responsible for the payment obligations under such Third Party agreement to the extent related to any Product(s) sold on or after the expiration or termination of this Agreement; provided, that the Parties shall negotiate in good faith the financials terms for any such license under the Roche Independent IP, taking into account the value of such Roche Independent IP. If the Parties are unable to agree on such financial terms, such dispute shall be submitted for resolution by a Third Party expert jointly selected by the Parties.

(d) Roche shall, and shall cause its Affiliates and subcontractors to conduct such other actions as are reasonably necessary to ensure a smooth and orderly transition without interruption.

19.3.2 Other Obligations

19.3.2.1 Obligations Related to Ongoing Activities

If Regeneron does not provide a timely Continuation Election Notice to Roche then Roche (a) shall have the right to cancel such ongoing obligations, and (b) shall complete all non-cancellable obligations at its own expense.

Subject to the foregoing, from the date of notice of termination until the effective date of termination, Roche shall continue activities, including preparatory activities, ongoing as of the date of notice of termination, but shall not be obliged to initiate any new activities not ongoing at the date of notice of termination. With respect to any Clinical Study or other development activities with respect to the Product that Regeneron does not elect to assume, unless the continued conduct of such Clinical Study or other development activity is required by the applicable Regulatory Authority or Applicable Law or the termination of such Clinical Study or other development activity would be inconsistent with standards of ethical conduct of human clinical trials, Roche shall wind-down such activities in a smooth, orderly and efficient manner in compliance with Applicable Law and with due regard for patient safety and the rights of any subjects that are participants in any such Clinical Studies, and take any actions that is reasonably necessary or appropriate to avoid any human health or safety problems or that is otherwise required by Applicable Law.

After the end of the effective date of termination, Roche shall have no obligation to perform or complete any activities or to make any payments for performing or completing any activities under this Agreement, except for the Roche Transfer Activities or as otherwise expressly stated herein.

19.3.2.2 Obligations Related to Manufacturing

If a Product is marketed in any country in the Territory on the date either Party provides a notice of termination of this Agreement (other than a termination pursuant to Section 19.2.4), then upon the request of Regeneron, Roche shall manufacture and supply such Product to Regeneron at the then-current Minimum Committed Roche Capacity prior to expiration or termination for a period that shall not exceed [* * *] from the end of the Agreement Term at [* * *], then [* * *]; (b) if this Agreement is terminated by Roche pursuant to Section 19.2.1, then Roche shall not be obligated to supply Product to Regeneron under this Section 19.3.2.2. Without limiting Roche's obligation under Section 19.3.1, Regeneron shall use Commercially Reasonable Efforts to take over the manufacturing as soon as practicable after termination of this Agreement; and (c) if this Agreement is terminated by Roche for an Alternative Third Party Product pursuant to Section 19.2.5, and, during the [* * *] post-termination supply period, Roche enters into an agreement with the applicable Third Party with respect to such Alternative Third Party Product and, as a result, will have insufficient capacity to manufacture such Alternative Third Party Product and the Product at the Roche Manufacturing Facilities, then Roche may reduce its supply of the Product to Regeneron as needed to manufacture such Alternative Third Party Product upon [* * *] prior written notice (which notice may be delivered at any time concurrently with or after Roche executing the agreement with the applicable Third Party with respect to such Alternative Third Party Product). During the post-termination supply period, Roche shall cooperate with Regeneron to facilitate a smooth and orderly transition of manufacturing of the Product to Regeneron or its designee. Upon expiration of the post-termination supply period, Roche shall, upon Regeneron's request, sell to Regeneron all or any requested portion of its inventory, if any, of Drug Substance, Drug Product and Finished Product remaining after fulfillment of Regeneron's orders during the post-termination supply period at Roche's Fully Burdened Manufacturing Cost.

19.3.2.3 Ancillary Agreements

Except as otherwise provided in this Agreement (including pursuant to Section 19.3.2.2), the termination of this Agreement shall cause the automatic termination of all ancillary agreements related hereto, if any.

19.3.2.4 Limitations on Grant-Backs; Transfer Expenses

For purposes of clarity, irrespective of anything to the contrary in this Agreement:

(a) Roche shall transfer to Regeneron all PII/Samples promptly following expiration or termination of this Agreement subject to compliance with applicable contractual restrictions, patient consents and Applicable Law. Roche shall not be obligated to transfer an PII/Samples that Roche in good faith believes would be prohibited or would subject Roche to potential liability by reason of Applicable Law, contractual restrictions or insufficient patient consent. Upon completion of such transfers, Regeneron shall use the transferred PII/Samples for the sole purpose of developing, manufacturing and commercializing the Product(s), and Regeneron shall be responsible for the correct use of the PII/Samples in line with the informed consent forms (including but not limited to potential re-consenting of the patients at Regeneron's costs).

(b) The costs and expenses incurred in connection with the Roche Transfer Activities shall be shared by the Parties as follows:

(i) if this Agreement is terminated by Regeneron pursuant to Section 19.2.1, Section 19.2.3 (or, with respect to a Terminated Country, pursuant to Section 19.2.2(a) or Section 19.2.2(b)), Roche shall be responsible for its own costs and expenses incurred for the Roche Transfer Activities, and shall reimburse Regeneron for all reasonable out-of-pocket costs and expenses incurred by or on behalf of Regeneron for the Roche Transfer Activities;

(ii) if this Agreement is terminated by Roche pursuant to Section 19.2.1 or Section 19.2.3, Regeneron shall be responsible for its own costs and expenses incurred for the Roche Transfer Activities, and shall reimburse Roche for all reasonable out-of-pocket and internal costs and expenses incurred by or on behalf of Roche for the Roche Transfer Activities;

(iii) if this Agreement is terminated pursuant to Section 19.2.4 or Section 19.2.5 (or, with respect to a Terminated Country, pursuant to Section 19.2.2(c)), Regeneron shall be responsible for its own costs and expenses incurred for the Roche Transfer Activities and shall reimburse Roche for all reasonable out-of-pocket costs and expenses incurred by or on behalf of Roche for the Roche Transfer Activities;

provided further that transfer activities corresponding to the return of material remains, data, reports, records, documents, regulatory filings and Regulatory Approvals originally provided by Regeneron to Roche no less than three (3) years from the effective date of termination or expiration shall be returned to Regeneron free of charge.

(c) Unless otherwise agreed to by the Parties, transfer of physical materials that are required under Roche Transfer Activities shall be delivered, at Roche's option, FCA international courier near location where materials stored at time of transfer (Incoterms 2010) or CPT Regeneron or Regeneron's designee (Incoterms 2010).

19.3.2.5 Payment Obligations

Termination of this Agreement by a Party, for any reason, shall not release either Party from any obligation to make any payments that are payable prior to the effective date of termination.

19.3.2.6 Return or Destruction of Confidential Information

Except as expressly permitted under this Agreement, including, with respect to Regeneron, for purposes of continuing development, manufacture and commercialization of the Product(s), following expiration or earlier termination of this Agreement and upon the written request from either Party, each Party shall promptly return to the other Party (or destroy) all Confidential Information of the other Party, including any copies thereof (except one (1) copy of such Confidential Information, which may be retained for archival purposes, solely to ensure compliance with the terms of this Agreement).

19.3.3 Termination with respect to a country.

If this Agreement is terminated by Regeneron with respect to a particular country, but not in its entirety, pursuant to Section 19.2.2 (each, a "**Terminated Country**"), then (a) the Terminated Country shall be excluded from the Roche Territory for purposes of this Agreement from and after the effective date of such termination, and Regeneron shall have the sole right, but not the obligation, to import, export, sell, offer to sell or otherwise commercialize or explore any Compound or Product in the Terminated Country, at its sole cost and expense, and any and all profits for any Compound or Product sold in the Terminated Country shall be retained by Regeneron and shall not be subject to the Global Gross Profits sharing under this Agreement; (b) the licenses granted by Regeneron to Roche under Section 2.1(iii) and Section 2.1(iv) shall terminate with respect to the Terminated Country; and (c) Section 19.3.1 and Section 19.3.2 (other than Section 19.3.2.2) shall apply *mutatis mutandis* with respect to such Terminated Country; provided that, (i) unless otherwise agreed by the Parties, removal of a Terminated Country from the Roche Territory shall not reduce the Minimum Committed Roche Capacity or increase the Minimum Committed Regeneron Capacity, (ii) Regeneron, any of its Affiliates or Sublicensees, shall have the right to sell in a Terminated Country any Product supplied by Roche, and, (iii) notwithstanding Section 19.3.1(c), with respect to any Product sold by Regeneron, any of its Affiliates or Sublicensees in a Terminated Country for which the Drug Substance is manufactured by Roche, Regeneron shall pay to Roche plus a five percent (5%) royalty on the Net Sales of such Product.

19.4 Survival

Article 1 (Definitions, to the extent necessary to interpret this Agreement), Section 4.3.1 3rd paragraph (Regeneron Cell Bank), Section 4.3.2 (Regeneron Cell Media) (second and third paragraphs), Section 4.3.3 other than the second sentence of subsection (a) thereof (Ownership and Restrictions), Section 15.4 (No Other Representations and Warranties), Section 19.3 (Consequences of Termination), Section 19.4 (Survival), Articles 10, 11 and 13 (Payment, Accounting and Reporting, and Auditing, each to the extent payment obligations exist at the time of termination), Article 12 (Taxes, to the extent such were incurred at the time of termination), Section 14.1 (Ownership of Intellectual Property); Article 16 (Indemnification), Article 17 (Liability), Article 18 other than Section 18.5 (Obligation Not to Disclose Confidential Information); Article 20 (Bankruptcy) and Article 21 other than Section 21.4 (Miscellaneous) shall survive any expiration or termination of this Agreement for any reason.

20. Bankruptcy

The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code (the "**Bankruptcy Code**") to the maximum extent permitted by Applicable Law. 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 Bankruptcy Code shall be deemed to be "intellectual property" for the purposes of Section 365(n). The Parties shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code, including the right to obtain the intellectual property from another entity.

21. Miscellaneous

21.1 Governing Law; Jurisdiction

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, United States, without reference to its conflict of law principles that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

Each Party (a) irrevocably submits to the exclusive jurisdiction of (i) the state courts of the State of New York in Manhattan, New York, and (ii) the United States District Court for the Southern District of New York, for the purposes of any suit, action, or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby, (b) waives any objections to such jurisdiction and venue and (c) agrees not to commence any suit, action or other proceeding arising out of or relating to this Agreement except in such courts.

Notwithstanding anything to the contrary in this Agreement, issues regarding the scope, construction, validity or enforceability of any Patent Rights shall be determined in a court of competent jurisdiction under the local patent laws of the jurisdictions that issued the Patent Rights in question.

21.2 Disputes

Unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below (the "**Executive Officers**") or their designees, for good faith negotiations attempting to resolve the dispute for a period of [* * *]. Such Executive Officers are as follows:

For Regeneron: [* * *]

For Roche: [* * *]

21.3 Equitable Relief

The Parties hereby acknowledge and agree that the restrictions on the Parties under Article 9 and Article 18 are special, unique and of extraordinary character, that the Parties would not have entered into this Agreement absent the restrictions set forth in Article 9 and Article 18, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of Article 9 or Article 18, such refusal or failure may 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 Article 9 or Article 18, then, in addition to any other remedy that may be available to the other Party at law or in equity, such other Party will be entitled to seek specific performance and injunctive relief. Nothing in this Section 21.3 or elsewhere in this Agreement is intended or should be construed to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

21.4 Expert Committee

If, after escalation to the Executive Officers in accordance with Section 21.2, the Parties are unable to agree on whether (a) the safety and efficacy profile of an Alternative Third Party Product confers a substantial public health benefit over the Lead Product in either treatment or prophylactic use settings, (b) whether or not the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, (c) if the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, then whether or not the Chugai Asset satisfies the Chugai Asset Criteria, (d) whether or not an Additional Compound Data Package satisfies the Additional Compound Data Package Criteria, or (e) whether or not an Additional Compound or a Back-Up Compound, as applicable, satisfies the Additional Compound Criteria (each of (a) - (e), an "**Expert Matter**"), then any such Expert Matter shall be decided by the following procedure. Roche will select one (1) individual who would qualify as an Expert, Regeneron will select (1) individual who would qualify as an Expert, and those two (2) individuals shall select one (1) individual who would qualify as an Expert and who shall be chairperson of a committee of the three Experts (the "**Expert Committee**"), each Expert with a single deciding vote. The Parties shall use good faith efforts to form the Expert Committee within [* * *] after expiration of the Executive Officers' negotiation period. The Expert Committee will promptly (but no more than [* * *] after the appointment of the third (3rd) Expert) hold a meeting to review the issue under review and will provide the Parties with at least [* * *] notice of such meeting. At such meeting, the Expert Committee will consider memoranda submitted by each Party at least [* * *] before the meeting, as well as reasonable presentations that each Party may present at the meeting. The Expert Committee may order the Parties to produce any additional documents or information that are relevant to the Expert Committee decision. The agreement of two (2) of the three (3) Experts on the Expert Committee shall be sufficient to render a decision. The Parties shall use diligent efforts to cause the completion of any such dispute resolution within [* * *] following expiration of the Executive Officers' negotiation period. The determination of the Expert Committee as to the issue under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide any issues other than the applicable Expert Matter.

21.5 Assignment

Except as otherwise expressly provided herein, neither Party shall have the right to assign this Agreement or any part hereof or any of the rights or obligations hereunder without the prior written approval of the other Party except (a) in whole or in part to an Affiliate of the assigning Party, or (b) in whole to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise; *provided* that the assigning Party shall remain primarily liable hereunder with respect to any assignment under this clause (b) with respect to obligations and liabilities relating to the period prior to such assignment, and in each case ((a) and (b)), so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. Notwithstanding the foregoing, Roche Basel shall not assign its rights under this Agreement or any part thereof to any US Person without the prior written consent of Regeneron. Any attempted assignment in violation hereof shall be void. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

21.6 Affiliates

Each Party may perform its obligations under this Agreement through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly.

21.7 Independent Contractor

No employee or representative of either 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 prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the Parties' legal relationship under this Agreement shall be that of independent contractors, and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties or any of their respective Affiliates. Nothing contained in this Agreement shall be deemed or construed by the Parties, any of their Affiliates, or any third party to treat the relationship between the Parties contemplated by this Agreement as a partnership, joint venture or other business entity under US federal, state, local, or non-US tax law, and the Parties shall not take any position, on a tax return or otherwise, inconsistent therewith. Each Party shall bear its own costs and expenses incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided for in this Agreement.

21.8 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be invalid, illegal or unenforceable at law or in equity, then such invalid, illegal or unenforceable provisions shall be enforced to the maximum extent permitted under Applicable Law, and the Parties shall consult and use all reasonable efforts to agree upon, and hereby agree and consent to, replacement legal, valid and enforceable provisions that will achieve as far as possible the intentions of the Parties (including the economic benefits and rights contemplated herein) while avoiding any unjust enrichment of either Party. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.9 Force Majeure

Except for payment obligations, each Party shall be excused from any failure or delay in performance required hereunder (and any liability or responsibility for such failure or delay) to the extent such failure or delay is caused by or results from any catastrophes or other major events beyond its reasonable control, including, embargoes, acts of terrorism, civil commotions, acts of God, disease, pandemics, lockouts or other labor disturbances, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, such Party's obligations hereunder will resume. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical and

will use commercially reasonable efforts to mitigate the effects of such force majeure circumstances.

21.10 Waiver

The failure by either Party to require strict performance or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition. 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.

21.11 Interpretation

Except where the context expressly requires otherwise:

(a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa),

(b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”,

(c) the word “will” shall be construed to have the same meaning and effect as the word “shall”,

(d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein),

(e) any reference herein to any Party or Third Party or person shall be construed to include the Party’s or Third Party’s or person’s permitted successors and assigns,

(f) any reference herein to a number of “days” shall be construed to refer to calendar days,

(g) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof,

(h) all references herein to Articles, Sections or Appendices shall be construed to refer to Articles, Sections or Appendices of this Agreement, and references to this Agreement include all Appendices hereto,

(i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof,

(j) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or”, and

(k) references to a decision that must be agreed by the Parties, such agreement must be evidenced in writing between the Parties, irrespective of whether the applicable provisions provides for such agreement to be in writing throughout this Agreement.

21.12 Entire Understanding

This Agreement (including all Appendices attached hereto), together with the Supply Agreement, and the Safety Data Exchange Agreement, constitute the entire understanding between the Parties with respect to the subject matter hereof and supersedes any and all prior agreements, understandings and arrangements, whether written or oral, other than the Technology Transfer Agreement.

21.13 Amendments

No amendments of the terms and conditions of this Agreement shall be binding upon either Party unless in writing and signed by both Parties.

21.14 Invoices

All invoices that are required or permitted hereunder shall be in writing and sent by the invoicing Party to the other Party at the following address or such other address as such other Party may later provide; provided that, with respect to Regeneron, all invoices to be submitted hereunder shall only be submitted in PDF format via email to the invoice email addresses indicated below and Roche may similarly request that invoices be submitted in PDF format via email and provide an email address for such submissions:

Roche:
[* * *]

Regeneron:

[* * *]

21.15 Notice

All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as set forth below. Any such notice shall be deemed to have been delivered (a) upon receipt if delivered by hand, (b) upon confirmation of transmission if transmitted by facsimile, (c) one (1) Business Day after it is sent via a nationally recognized overnight courier service or (d) upon receipt of proof of delivery if sent by registered or certified mail, postage prepaid, return receipt requested. Either Party

may change its address by giving notice to the other Party in the manner provided above. This Section 21.15 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

if to Regeneron, to: [* * *]

if to Roche, to: [* * *]

21.16 Counterparts

This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which 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.

21.17 Third Party Beneficiaries

Except as provided below in this Section 21.17, 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. Notwithstanding the foregoing, Article 16 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Roche Indemnitees as if they were parties hereto, but this Agreement is only enforceable by the Parties.

21.18 Further Assurances

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure such other Party its rights and remedies under this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

Regeneron Pharmaceuticals, Inc.

_/s/ Nouhad Husseini_____

Name: Nouhad Husseini

Title: SVP, Business Development

F. Hoffmann-La Roche Ltd

__/s/ James Sabry_____

Name: James Sabry

Title: SVP, Head of Partnering

__/s/ F. Bächler_____

Name: Dr. Franziska Bächler

Title: Attorney-at-Law

Genentech, Inc.

__/s/ Edward Harrington_____

Name: Edward Harrington

Title: CFO Genentech

Appendix 1.20(a)

Additional Regeneron Studies

[* * *]

Appendix 1.20(b)

Other Agreed Co-Funded Studies

[* * *]

Appendix 1.66

Lead Compound

[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]		
	[* * *]	[* * *]	[* * *]
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	[* * *]	[* * *]	[* * *]
	[* * *]	[* * *]	[* * *]
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	[* * *]	[* * *]	[* * *]
	[* * *]	[* * *]	[* * *]

Appendix 1.73

Ongoing Regeneron Studies

[* * *]

Appendix 1.106

Product Contribution Alternative Principles

“Roche Quarterly Distribution” shall mean, with respect to a Presentation and a [* * *].

With respect to each Presentation, the number of units of the Roche Quarterly Distribution for which the Drug Substance was manufactured by the Roche Group for inclusion in the numerator of the Roche Production Contribution shall be determined based on the following principles:

(a) With respect to the portion of the Roche Quarterly Distribution for a Presentation for a Calendar Quarter that is less than or equal to Roche’s [* * *].

(b) [* * *].

(c) [* * *].

An example of the application of such principles is attached as Exhibit A.

Exhibit A

[* * *]

Appendix 1.90
Regeneron Base Patent Rights

[* * *]

Appendix 1.104

Roche Manufacturing Facilities

[* * *]

Appendix 9.2

[* * *]

Exhibit 31.1

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

I, Leonard S. Schleifer, certify that:

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

Date: November 5, 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: November 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 September 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)
November 5, 2020

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