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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2022
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

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

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

The number of shares outstanding of each of the registrant's classes of common stock as of July 25, 2022:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,818,146
Common Stock, $.001 par value	107,190,176

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

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,395.1	$ 2,885.6
Marketable securities	4,171.3	2,809.1
Accounts receivable, net	5,161.4	6,036.5
Inventories	2,218.5	1,951.3
Prepaid expenses and other current assets	583.6	332.4
Total current assets	15,529.9	14,014.9
Marketable securities	6,415.9	6,838.0
Property, plant, and equipment, net	3,637.7	3,482.2
Deferred tax assets	1,352.4	876.9
Other noncurrent assets	269.9	222.8
Total assets	$ 27,205.8	$ 25,434.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 534.2	$ 564.0
Accrued expenses and other current liabilities	1,933.4	2,206.8
Finance lease liabilities	—	719.7
Deferred revenue	566.3	442.0
Total current liabilities	3,033.9	3,932.5
Long-term debt	1,980.7	1,980.0
Finance lease liabilities	720.0	—
Deferred revenue	58.7	73.3
Other noncurrent liabilities	724.7	680.2
Total liabilities	6,518.0	6,666.0
Stockholders' equity:		
Preferred Stock, par value $.01 per share; 30.0 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, par value $.001 per share; 40.0 shares authorized; shares issued and outstanding - 1.8 in 2022 and 2021	—	—
Common Stock, par value $.001 per share; 320.0 shares authorized; shares issued - 128.3 in 2022 and 126.2 in 2021	0.1	0.1
Additional paid-in capital	9,120.2	8,087.5
Retained earnings	20,793.9	18,968.3
Accumulated other comprehensive loss	(223.8)	(26.2)
Treasury Stock, at cost; 20.6 shares in 2022 and 19.4 shares in 2021	(9,002.6)	(8,260.9)
Total stockholders' equity	20,687.8	18,768.8
Total liabilities and stockholders' equity	$ 27,205.8	$ 25,434.8

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Statements of Operations				
Revenues:				
Net product sales	$ 1,754.4	$ 4,137.8	$ 3,393.0	$ 5,862.1
Collaboration revenue	1,043.6	954.7	2,276.1	1,709.1
Other revenue	59.2	46.0	153.2	96.0
	2,857.2	5,138.5	5,822.3	7,667.2
Expenses:				
Research and development	794.3	714.2	1,638.1	1,457.1
Acquired in-process research and development	197.0	—	225.1	—
Selling, general, and administrative	476.3	414.7	926.3	820.3
Cost of goods sold	149.2	539.4	356.5	722.6
Cost of collaboration and contract manufacturing	147.9	154.3	345.5	279.1
Other operating (income) expense, net	(17.4)	(31.3)	(37.6)	(71.8)
	1,747.3	1,791.3	3,453.9	3,207.3
Income from operations	1,109.9	3,347.2	2,368.4	4,459.9
Other income (expense):				
Other (expense) income, net	(133.6)	420.0	(317.4)	574.9
Interest expense	(13.1)	(14.4)	(26.7)	(29.0)
	(146.7)	405.6	(344.1)	545.9
Income before income taxes	963.2	3,752.8	2,024.3	5,005.8
Income tax expense	111.1	653.9	198.7	791.7
Net income	$ 852.1	$ 3,098.9	$ 1,825.6	$ 4,214.1
Net income per share - basic	$ 7.90	$ 29.51	$ 17.01	$ 40.06
Net income per share - diluted	$ 7.47	$ 27.97	$ 16.07	$ 38.07
Weighted average shares outstanding - basic	107.9	105.0	107.3	105.2
Weighted average shares outstanding - diluted	114.0	110.8	113.6	110.7
Statements of Comprehensive Income				
Net income	$ 852.1	$ 3,098.9	$ 1,825.6	$ 4,214.1
Other comprehensive income (loss), net of tax:				
Unrealized loss on debt securities	(53.7)	(0.8)	(198.6)	(14.1)
Unrealized gain on cash flow hedges	—	0.3	1.0	0.5
Comprehensive income	$ 798.4	$ 3,098.4	$ 1,628.0	$ 4,200.5

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

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

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2021	1.8	$ —	126.2	$ 0.1	$ 8,087.5	$18,968.3	$ (26.2)	(19.4)	$(8,260.9)	$ 18,768.8
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	1.6	—	593.7	—	—	—	—	593.7
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.2)	—	(105.8)	—	—	—	—	(105.8)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	12.8	—	—	—	1.7	14.5
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.5)	(352.0)	(352.0)
Stock-based compensation charges	—	—	—	—	165.9	—	—	—	—	165.9
Net income	—	—	—	—	—	973.5	—	—	—	973.5
Other comprehensive loss, net of tax	—	—	—	—	—	—	(143.9)	—	—	(143.9)
Balance, March 31, 2022	1.8	—	127.6	0.1	8,754.1	19,941.8	(170.1)	(19.9)	(8,611.2)	19,914.7
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.8	—	228.0	—	—	—	—	228.0
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(41.9)	—	—	—	—	(41.9)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	14.0	—	—	—	2.2	16.2
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.7)	(393.6)	(393.6)
Stock-based compensation charges	—	—	—	—	166.0	—	—	—	—	166.0
Net income	—	—	—	—	—	852.1	—	—	—	852.1
Other comprehensive loss, net of tax	—	—	—	—	—	—	(53.7)	—	—	(53.7)
Balance, June 30, 2022	1.8	$ —	128.3	$ 0.1	$ 9,120.2	$20,793.9	$ (223.8)	(20.6)	$(9,002.6)	$ 20,687.8

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, 2020	1.8	$ —	121.5	$ 0.1	$ 6,716.2	$10,893.0	$ 29.3	(16.4)	$(6,613.3)	$ 11,025.3
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.5	—	93.9	—	—	—	—	93.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(66.4)	—	—	—	—	(66.4)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	8.5	—	—	—	1.5	10.0
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.7)	(323.5)	(323.5)
Stock-based compensation charges	—	—	—	—	135.6	—	—	—	—	135.6
Net income	—	—	—	—	—	1,115.2	—	—	—	1,115.2
Other comprehensive loss, net of tax	—	—	—	—	—	—	(13.1)	—	—	(13.1)
Balance, March 31, 2021	1.8	—	121.9	0.1	6,887.8	12,008.2	16.2	(17.1)	(6,935.3)	11,977.0
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.7	—	216.6	—	—	—	—	216.6
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(26.1)	—	—	—	—	(26.1)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	11.6	—	—	—	2.5	14.1
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.6)	(288.6)	(288.6)
Stock-based compensation charges	—	—	—	—	135.9	—	—	—	—	135.9
Net income	—	—	—	—	—	3,098.9	—	—	—	3,098.9
Other comprehensive loss, net of tax	—	—	—	—	—	—	(0.5)	—	—	(0.5)
Balance, June 30, 2021	1.8	$ —	122.5	$ 0.1	$ 7,225.8	$15,107.1	$ 15.7	(17.7)	$(7,221.4)	$ 15,127.3

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

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

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net income	$ 1,825.6	$ 4,214.1
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	148.7	138.5
Stock-based compensation expense	326.7	276.4
Losses (gains) on marketable and other securities, net	370.9	(553.9)
Other non-cash items, net	138.3	192.6
Deferred taxes	(381.0)	51.8
Acquired in-process research and development in connection with asset acquisition	195.0	—
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	875.1	(2,883.9)
Increase in inventories	(328.7)	(221.5)
Increase in prepaid expenses and other assets	(288.5)	(277.8)
Increase (decrease) in deferred revenue	109.7	(64.8)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(325.7)	423.7
Total adjustments	840.5	(2,918.9)
Net cash provided by operating activities	2,666.1	1,295.2
Cash flows from investing activities:		
Purchases of marketable and other securities	(3,774.9)	(1,886.5)
Sales or maturities of marketable and other securities	2,181.4	1,217.1
Capital expenditures	(295.4)	(263.8)
Asset acquisition, net of cash acquired	(230.3)	—
Net cash used in investing activities	(2,119.2)	(933.2)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	828.4	308.2
Payments in connection with Common Stock tendered for employee tax obligations	(147.7)	(180.7)
Repurchases of Common Stock	(717.1)	(612.1)
Net cash used in financing activities	(36.4)	(484.6)
Net increase (decrease) in cash, cash equivalents, and restricted cash	510.5	(122.6)
Cash, cash equivalents, and restricted cash at beginning of period	2,898.1	2,207.3
Cash, cash equivalents, and restricted cash at end of period	$ 3,408.6	$ 2,084.7

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

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

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, 2021 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, 2021.

Beginning with the first quarter of 2022, the Company added a new line item, Acquired in-process research and development, to its Condensed Consolidated Statements of Operations and Comprehensive Income. This line item includes in-process research and development acquired in connection with asset acquisitions as well as up-front/opt-in payments related to license and collaboration agreements. Amounts recorded in this line item for the three and six months ended June 30, 2022 would have historically been recorded to Research and development expenses. No such amounts were recorded for the three and six months ended June 30, 2021.

2. Product Sales

Net product sales consist of the following:

(In millions)	Three Months Ended June 30,		Six Months Ended June 30,	
Net Product Sales in the United States	**2022**	**2021**	**2022**	**2021**
EYLEA®	$ 1,621.2	$ 1,424.7	$ 3,138.8	$ 2,771.7
Libtayo®*	90.9	78.0	169.8	147.1
Praluent®	31.2	41.9	64.8	85.2
REGEN-COV®**	—	2,591.2	—	2,853.4
Evkeeza®	11.1	2.0	19.6	2.5
ARCALYST®***	—	—	—	2.2
	$ 1,754.4	$ 4,137.8	$ 3,393.0	$ 5,862.1

** Net product sales of REGEN-COV in the United States relate to product sold in connection with our agreements with the U.S. government. See Note 3 for further details.

*** Effective April 1, 2021, Kiniksa records net product sales of ARCALYST in the United States. Previously, the Company recorded net product sales of ARCALYST in the United States.

* Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. Effective July 1, 2022, the Company will record global net product sales of Libtayo. See Note 3 for further details.

As of June 30, 2022 and December 31, 2021, the Company had $3.888 billion and $5.059 billion, respectively, of trade accounts receivable that were recorded within Accounts receivable, net.

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for the three and six months ended June 30, 2022 and 2021. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	57 %	22 %	56 %	30 %
McKesson Corporation	28 %	14 %	29 %	19 %
U.S. government	— %	57 %	— %	43 %

3. Collaboration, License, and Other Agreements

a. Sanofi

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

(In millions)	Statement of Operations Classification	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Antibody:					
Regeneron's share of profits in connection with commercialization of antibodies	Collaboration revenue	$ 496.6	$ 327.6	$ 911.9	$ 588.2
Sales-based milestone earned	Collaboration revenue	$ —	$ —	$ 50.0	$ —
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	$ 145.5	$ 110.9	$ 306.3	$ 216.5
Other	Collaboration revenue	$ 28.9	$ —	$ 28.9	$ —
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 52.7	$ 46.5	$ 89.2	$ 77.1
Regeneron's obligation for its share of Sanofi research and development expenses	Research and development expense	$ (15.6)	$ (10.6)	$ (25.3)	$ (22.5)
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 110.8	$ 78.3	$ 202.5	$ 137.9
Immuno-oncology:					
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	Collaboration revenue	$ 3.9	$ (3.5)	$ 6.7	$ (9.6)
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ 2.6	$ 2.7	$ 4.6	$ 7.4
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 21.2	$ 22.5	$ 42.7	$ 44.4
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 22.4	$ 20.7	$ 41.4	$ 39.2
Regeneron's obligation for its share of Sanofi commercial expenses	Selling, general, and administrative expense	$ (10.7)	$ (10.9)	$ (19.9)	$ (18.6)
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ (37.8)	$ (34.4)	$ (70.1)	$ (64.8)
Amounts recognized in connection with up-front payments received	Other operating income	$ 17.0	$ 20.7	$ 35.1	$ 43.6

Antibody

The Company is party to a global, strategic collaboration with Sanofi to research, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"), which currently consists of Dupixent® (dupilumab), Kevzara® (sarilumab), and itepekimab.

Under the terms of the Antibody License and Collaboration Agreement, Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on our share of collaboration profits from commercialization of collaboration products. Under the terms of the Antibody License and Collaboration Agreement, we were 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. On July 1, 2022, an amendment to the Antibody License and Collaboration Agreement became effective, pursuant to which the percentage of Regeneron’s share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%.

Sanofi leads commercialization activities for products under the Antibody Collaboration, subject to the Company's right to co-commercialize such products. In addition to profit and loss sharing, the Company is entitled to receive sales milestone payments

from Sanofi. During the three months ended March 31, 2022, the Company earned a $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $2.0 billion on a rolling twelve-month basis. We are entitled to receive up to an aggregate of $100.0 million in additional sales milestone payments from Sanofi, which includes the next sales milestone payment of $50.0 million that would be earned when such sales outside the United States exceed $2.5 billion on a rolling twelve-month basis.

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

(In millions)	**June 30, 2022**	**December 31, 2021**
Accounts receivable, net	$ 751.5	$ 504.8
Deferred revenue	$ 457.5	$ 368.7

Immuno-oncology

The Company has been party to a collaboration with Sanofi for antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). Under the terms of the Immuno-oncology License and Collaboration Agreement, the parties were co-developing and co-commercializing Libtayo. The parties shared equally, on an ongoing basis, development and commercialization expenses for Libtayo. The Company had principal control over the development of Libtayo and led commercialization activities in the United States (see Note 2 for related product sales information), while Sanofi led commercialization activities outside of the United States. The parties shared equally in profits and losses in connection with the commercialization of Libtayo.

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA"). Consequently, in July 2022, the Company made a $900.0 million up-front payment to Sanofi, and Sanofi is eligible to receive a $100.0 million regulatory milestone and up to an aggregate of $100.0 million in sales-based milestones upon achieving certain amounts of worldwide net product sales of Libtayo through 2023. The Company will also pay Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. Amounts paid to Sanofi in connection with obtaining the worldwide rights to Libtayo, including the up-front payment and any contingent consideration, will be recorded as an intangible asset.

The Company was obligated to reimburse Sanofi for half of the development costs it funded that were attributable to clinical development of antibody product candidates under the Amended and Restated Immuno-oncology Discovery and Development Agreement from our share of profits from commercialized IO Collaboration products. Under the A&R IO LCA, the amount of development costs incurred under the IO Collaboration for which we are obligated to reimburse Sanofi is $35.0 million, and the Company will reimburse Sanofi for such development costs by paying Sanofi a 0.5% royalty on net product sales of Libtayo until all such development costs have been reimbursed by Regeneron.

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

(In millions)	**June 30, 2022**	**December 31, 2021**
Accounts receivable, net	$ 12.4	$ (22.5)
Deferred revenue	$ 33.8	$ 16.0
Other liabilities	$ 241.0	$ 276.1

Other liabilities include up-front payments received from Sanofi for which recognition had been deferred. During the third quarter of 2022, in connection with the A&R IO LCA, the remaining IO Collaboration Other liabilities balance will be recorded as a reduction to the intangible asset described above.

b. Bayer

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA (aflibercept) and aflibercept 8 mg outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally.

Bayer markets EYLEA outside the United States and the companies share equally in profits and losses from sales. In Japan, the Company was entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net product sales through 2021, and effective January 1, 2022, the companies share equally in profits and losses from sales.

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

(In millions)	Statement of Operations Classification	Three Months Ended June 30,		Six Months Ended June 30,	
		2022	2021	2022	2021
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	Collaboration revenue	$ 339.7	$ 335.4	$ 678.1	$ 644.3
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ 17.8	$ 13.7	$ 42.8	$ 27.6
One-time payment in connection with change in Japan arrangement	Collaboration revenue	$ —	$ —	$ 21.9	$ —
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 9.8	$ 9.9	$ 20.9	$ 20.7
Regeneron's obligation for its share of Bayer research and development expenses	Research and development expense	$ (6.9)	$ (10.9)	$ (17.7)	$ (23.4

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

(In millions)	June 30, 2022	December 31, 2021
Accounts receivable, net	$ 347.6	$ 355.5
Deferred revenue	$ 133.7	$ 129.4

c. U.S. Government

In 2020, we announced an expansion of our Other Transaction Agreement with the Biomedical Advanced Research Development Authority ("BARDA"), pursuant to which the U.S. Department of Health and Human Services ("HHS") was obligated to fund certain of our costs incurred for research and development activities related to COVID-19 treatments.

In 2020 and 2021, we entered into agreements to manufacture and deliver filled and finished drug product of REGEN-COV (casirivimab and imdevimab) to the U.S. government. In connection with one of our 2021 agreements, Roche supplied a portion of the doses to Regeneron to fulfill our agreement with the U.S. government (see "Roche" below for further details regarding our collaboration agreement with Roche).

As of December 31, 2021, the Company had completed its final deliveries of drug product under its agreements with the U.S. government. See Note 2 for REGEN-COV net product sales recognized during the three and six months ended June 30, 2021.

d. Roche

In 2020, we entered into a collaboration agreement (the "Roche Collaboration Agreement") with Roche to develop, manufacture, and distribute the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve™ in other countries). We lead global development activities for casirivimab and imdevimab, and the parties jointly fund certain studies.

Under the terms of the agreement, each party is obligated to dedicate a certain amount of manufacturing capacity to casirivimab and imdevimab each year. We distribute the product in the United States and Roche distributes the product outside of the United States. The parties share gross profits from worldwide sales based on a pre-specified formula, depending on the amount of manufactured product supplied by each party to the market. Each quarter, a single payment is due from one party to the other to true-up the global gross profits between the parties. If Regeneron is to receive a true-up payment from Roche, such amount will be recorded to Collaboration revenue. If Regeneron is to make a true-up payment to Roche, such amount will be recorded to Cost of goods sold.

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

(In millions)	**Statement of Operations Classification**	**Three Months Ended June 30,**		**Six Months Ended June 30,**	
		2022	**2021**	**2022**	**2021**
Global gross profit payment from Roche in connection with sales of Ronapreve	Collaboration revenue	$ 8.2	$ 167.9	$ 224.5	$ 234.7

Reimbursement of research and development expenses from Roche (recorded as a reduction of Research and development expense) was $41.0 million and $127.8 million for the three and six months ended June 30, 2021. Such amounts were not material for the three and six months ended June 30, 2022.

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

(In millions)	**June 30, 2022**	**December 31, 2021**
Accrued expenses and other current liabilities	$ 5.8	$ 268.8

e. Alnylam

In 2018, the Company and Alnylam Pharmaceuticals, Inc. entered into a collaboration to discover RNA interference ("RNAi") therapeutics for NASH and potentially other related diseases, as well as to research, co-develop and commercialize any therapeutic product candidates that emerge from these discovery efforts (including ALN-HSD, which is currently in clinical development). The parties share equally, on an ongoing basis, development expenses for ALN-HSD.

In 2019, the parties entered into a global, strategic collaboration to discover, develop, and commercialize RNAi therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. For each program, we provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation. Following designation of a lead candidate, the parties may further advance such lead candidate under either a co-commercialization collaboration agreement structure (under which the parties are advancing ALN-APP, which is currently in clinical development) or a license agreement.

In addition, during 2019, the parties entered into a Co-Commercialization Collaboration Agreement for a silencing RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic (cemdisiran) and a fully human monoclonal antibody being developed by the Company (pozelimab), with the Company as the licensee. Under the C5 siRNA Co-Commercialization Collaboration Agreement, the parties share costs equally and under the License Agreement, the licensee is responsible for its own costs and expenses.

Amounts recognized in our Statements of Operations in connection with the Alnylam agreements described above were not material for the three and six months ended June 30, 2022 and 2021. In addition, contract balances in our Balance Sheets were not material as of June 30, 2022 and December 31, 2021.

f. Checkmate

In May 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. ("Checkmate") for a total equity value of approximately $250 million. The Company made an assessment as to whether the set of assets acquired constituted a business and should be accounted for as a business combination. Given that substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, vidutolimod, which is in clinical development for oncology, the transaction was accounted for as an asset acquisition. As a result of the acquisition, the Company recorded (i) a charge of $195.0 million to Acquired in-process research and development and (ii) net assets of $35.3 million, net of cash, related to the assets acquired (including deferred tax assets and investments) and liabilities assumed.

4. Net Income Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2022**	**2021**	**2022**	**2021**
Net income - basic and diluted	$ 852.1	$ 3,098.9	$ 1,825.6	$ 4,214.1
Weighted average shares - basic	107.9	105.0	107.3	105.2
Effect of dilutive securities:				
Stock options	4.7	4.8	4.9	4.7
Restricted stock awards and restricted stock units	1.4	1.0	1.4	0.8
Weighted average shares - diluted	114.0	110.8	113.6	110.7
Net income per share - basic	$ 7.90	$ 29.51	$ 17.01	$ 40.06
Net income per share - diluted	$ 7.47	$ 27.97	$ 16.07	$ 38.07

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(Shares in millions)	**2022**	**2021**	**2022**	**2021**
Stock options	2.2	5.0	2.3	5.0

5. Marketable Securities

Marketable securities as of June 30, 2022 and December 31, 2021 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:

(In millions)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
As of June 30, 2022				
Corporate bonds	$ 7,849.1	$ 0.1	$ (271.0)	$ 7,578.2
U.S. government and government agency obligations	1,051.8	—	(5.8)	1,046.0
Sovereign bonds	45.9	—	(1.8)	44.1
Commercial paper	669.2	—	(1.4)	667.8
Certificates of deposit	337.5	—	(0.9)	336.6
Asset-backed securities	40.9	—	(1.5)	39.4
	$ 9,994.4	$ 0.1	$ (282.4)	$ 9,712.1
As of December 31, 2021				
Corporate bonds	$ 7,518.4	$ 10.2	$ (40.9)	$ 7,487.7
U.S. government and government agency obligations	109.0	0.3	(0.8)	108.5
Sovereign bonds	64.4	0.3	(0.3)	64.4
Commercial paper	439.7	—	(0.1)	439.6
Certificates of deposit	255.2	—	(0.1)	255.1
Asset-backed securities	42.0	—	(0.1)	41.9
	$ 8,428.7	$ 10.8	$ (42.3)	$ 8,397.2

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of June 30, 2022 mature at various dates through April 2027. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

(In millions)	June 30, 2022	December 31, 2021
Maturities within one year	$ 4,171.2	$ 2,809.1
Maturities after one year through five years	5,540.9	5,588.1
	$ 9,712.1	$ 8,397.2

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.

(In millions)	Less than 12 Months		12 Months or Greater		Total	
As of June 30, 2022	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 7,139.8	$ (251.8)	$ 279.9	$ (19.2)	$ 7,419.7	$ (271.0)
U.S. government and government agency obligations	1,005.1	(5.7)	1.2	(0.1)	1,006.3	(5.8)
Sovereign bonds	44.2	(1.8)	—	—	44.2	(1.8)
Commercial paper	620.0	(1.4)	—	—	620.0	(1.4)
Certificates of deposit	285.4	(0.9)	—	—	285.4	(0.9)
Asset-backed securities	39.5	(1.5)	—	—	39.5	(1.5)
	$ 9,134.0	$ (263.1)	$ 281.1	$ (19.3)	$ 9,415.1	$ (282.4)
As of December 31, 2021						
Corporate bonds	$ 5,889.3	$ (40.9)	$ —	$ —	$ 5,889.3	$ (40.9)
U.S. government and government agency obligations	90.0	(0.8)	—	—	90.0	(0.8)
Sovereign bonds	37.0	(0.3)	—	—	37.0	(0.3)
Commercial paper	295.7	(0.1)	—	—	295.7	(0.1)
Certificates of deposit	169.4	(0.1)	—	—	169.4	(0.1)
Asset-backed securities	34.9	(0.1)	—	—	34.9	(0.1)
	$ 6,516.3	$ (42.3)	$ —	$ —	$ 6,516.3	$ (42.3)

With respect to marketable securities, for the three and six months ended June 30, 2022 and 2021, amounts reclassified from Accumulated other comprehensive loss into Other (expense) income, net were related to realized gains and losses on sales of available-for-sale debt securities.

For the three and six months ended June 30, 2022 and 2021, realized gains and losses on sales of marketable securities were not material.

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

(In millions)		Fair Value Measurements at Reporting Date	
As of June 30, 2022	**Fair Value**	**Level 1**	**Level 2**
Available-for-sale debt securities:			
Corporate bonds	$ 7,578.2	$ —	$ 7,578.2
U.S. government and government agency obligations	1,046.0	—	1,046.0
Sovereign bonds	44.1	—	44.1
Commercial paper	667.8	—	667.8
Certificates of deposit	336.6	—	336.6
Asset-backed securities	39.4	—	39.4
Equity securities (unrestricted)	35.2	35.2	—
Equity securities (restricted)	839.9	839.9	—
	$ 10,587.2	$ 875.1	$ 9,712.1
As of December 31, 2021			
Available-for-sale debt securities:			
Corporate bonds	$ 7,487.7	$ —	$ 7,487.7
U.S. government and government agency obligations	108.5	—	108.5
Sovereign bonds	64.4	—	64.4
Commercial paper	439.6	—	439.6
Certificates of deposit	255.1	—	255.1
Asset-backed securities	41.9	—	41.9
Equity securities (unrestricted)	58.4	58.4	—
Equity securities (restricted)	1,191.5	1,191.5	—
	$ 9,647.1	$ 1,249.9	$ 8,397.2

The Company held certain restricted equity securities as of June 30, 2022 which are subject to transfer restrictions that expire at various dates through 2024.

During the three and six months ended June 30, 2022, we recorded $163.7 million and $374.9 million of net unrealized losses, respectively, on equity securities in Other (expense) income, net. During the three and six months ended June 30, 2021, we recorded $409.0 million and $552.9 million of net unrealized gains, respectively, on equity securities in Other (expense) income, net.

In addition to the investments summarized in the table above, as of June 30, 2022 and December 31, 2021, the Company had $47.3 million and $40.0 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), which was determined based on Level 2 inputs, was estimated to be $1.513 billion and $1.887 billion as of June 30, 2022 and December 31, 2021, respectively.

7. Inventories

Inventories consist of the following:

(In millions)	June 30, 2022	December 31, 2021
Raw materials	$ 831.7	$ 721.9
Work-in-process	717.3	707.2
Finished goods	45.6	73.7
Deferred costs	623.9	448.5
	$ 2,218.5	$ 1,951.3

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the three and six months ended June 30, 2022, Cost of goods sold included inventory write-offs and reserves totaling $19.2 million and $66.6 million, respectively. For the three and six months ended June 30, 2021, Cost of goods sold included inventory write-offs and reserves totaling $139.9 million and $149.3 million, respectively.

8. Debt

In 2020, we issued and sold $1.250 billion aggregate principal amount of senior unsecured notes due 2030 and $750 million aggregate principal amount of senior unsecured notes due 2050. Long-term debt in connection with our senior unsecured notes (collectively, the "Notes"), net of underwriting discounts and offering expenses, consists of the following:

(In millions)	June 30, 2022	December 31, 2021
1.750% Senior Notes due September 2030	$ 1,240.4	$ 1,239.9
2.800% Senior Notes due September 2050	740.3	740.1
	$ 1,980.7	$ 1,980.0

Interest expense related to the Notes was $11.1 million and $22.2 million, respectively, for each of the three and six months ended June 30, 2022, and 2021.

9. Leases

In March 2022, we entered into a Second Amended and Restated Lease and Remedies Agreement (the "Restated Lease") with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor (the "Lessor"), which amends, restates, and extends our lease of laboratory and office facilities in Tarrytown, New York (the "Facility"). In March 2022, we also entered into a Second Amended and Restated Participation Agreement (the "Restated Participation Agreement") with Bank of America, N.A., as administrative agent, the Lessor, and a syndicate of financial institutions as rent assignees (collectively with the Lessor, the "Participants"), which amends and restates the original Participation Agreement entered into in March 2017.

The original Participation Agreement and certain related agreements were amended and restated in order to, among other things, (i) effect a five-year extension of the original March 2022 maturity date of the $720.0 million lease financing (which was previously advanced in March 2017 to finance the purchase price for the Facility) and the end of the term of our lease of the Facility from the Lessor to March 2027, at which time all amounts outstanding thereunder will become due and payable in full, and (ii) modify the rate of the interest or yield that is payable to the Participants. In accordance with the terms of the Restated Lease, we continue to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Restated Lease in an amount equal to a variable rate per annum, which was modified in connection with the Restated Lease, to be an adjusted one-month forward-looking term rate based on the Secured Overnight Financing Rate ("SOFR"), plus an applicable margin that varies with our debt rating and total leverage ratio.

The Restated Participation Agreement and Restated Lease include an option for us to elect to further extend the maturity date of the Restated Participation Agreement and the term of the Restated Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. We also have the option prior to the end of the term of the Restated Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Restated Participation Agreement, all accrued and unpaid yield thereon, and all other outstanding amounts under the

Restated Participation Agreement, Restated Lease, and certain related documents or (b) sell the Facility to a third party on behalf of the Lessor.

Consistent with the original lease, the Restated Lease continues to be classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised. The agreements governing the Restated Lease financing contain financial and operating covenants. Such financial covenants and certain of the operating covenants are substantially similar to the covenants set forth in our $750.0 million revolving credit facility. The Company was in compliance with all such covenants as of June 30, 2022.

10. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 11.5% and 17.4% for the three months ended June 30, 2022 and 2021, respectively and 9.8% and 15.8% for the six months ended June 30, 2022 and 2021, respectively. The Company's effective tax rate for the three and six months ended June 30, 2022 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and, to a lesser extent, stock-based compensation. The Company's effective tax rate for the three and six months ended June 30, 2021 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and federal tax credits for research activities. In addition, the effective tax rate for the six months ended June 30, 2021 was positively impacted by the reversal of liabilities related to uncertain tax positions. During the six months ended June 30, 2021, we reduced the amount of liabilities for uncertain tax positions related to the Company’s federal income tax returns for 2015 and 2016, as these audits were effectively settled.

11. Stockholders' Equity

Share Repurchase Programs

In January 2021, our board of directors authorized a share repurchase program to repurchase up to $1.5 billion of our Common Stock. The share repurchase program permitted the Company to make 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. As of December 31, 2021, the Company had repurchased the entire $1.5 billion of its Common Stock that it was authorized to repurchase under the program.

In November 2021, our board of directors authorized an additional share repurchase program to repurchase up to $3.0 billion of our Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase program above. 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. As of June 30, 2022, $2.099 billion remained available for share repurchases under the November 2021 program.

The table below summarizes the shares of our Common Stock we repurchased under the programs and the cost of the shares received, which were recorded as Treasury Stock.

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Number of shares repurchased	0.7	0.6	1.2	1.3
Total cost of shares received	$ 393.6	$ 288.6	$ 745.5	$ 612.1

12. Statement of Cash Flows

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

	June 30,	
(In millions)	**2022**	**2021**
Cash and cash equivalents	$ 3,395.1	$ 2,072.2
Restricted cash included in Other noncurrent assets	13.5	12.5
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$ 3,408.6	$ 2,084.7

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

Supplemental disclosure of non-cash investing and financing activities

(In millions)	**June 30, 2022**	**December 31, 2021**	**June 30, 2021**	**December 31, 2020**
Accrued capital expenditures	$ 81.9	$ 74.8	$ 93.4	$ 83.6

13. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of June 30, 2022 and December 31, 2021, the Company's accruals for loss contingencies were not material. 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 Praluent (alirocumab) Injection

As described in greater detail in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 and 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 of the Company's Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 for a description of the Company's and Sanofi's arrangement regarding the costs resulting from or associated with such actions. In addition, as described below, the Company filed a lawsuit against Amgen alleging that Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws.

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 sought 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. As previously reported, on February 11, 2021, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") affirmed the lower court's decision that certain of Amgen's asserted patent claims are invalid based on lack of enablement. On April 14, 2021, Amgen filed a petition for a rehearing en banc with the Federal Circuit, which was denied on June 21, 2021. On November 18, 2021, Amgen filed a petition for writ of certiorari with the United States Supreme Court.

On May 27, 2022, the Company filed a lawsuit against Amgen in the United States District Court for the District of Delaware, alleging that, beginning in 2020, Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws. The lawsuit seeks damages for harm caused by the alleged scheme, as well as injunctive relief restraining Amgen from continuing its alleged anticompetitive conduct. On August 1, 2022, Amgen filed a motion to dismiss the complaint.

Europe

Amgen has asserted European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, in certain countries in Europe. In October 2020, the '124 Patent claims directed to compositions of matter and medical use relevant to Praluent were ruled invalid based on a lack of inventive step by the Technical Board of Appeal (the "TBA") of the European Patent Office (the "EPO"). Following the EPO's decision, each of the '124 Patent infringement proceedings initiated by Amgen against the Company and certain of Sanofi's affiliated entities in these countries was dismissed, including in Germany. The dismissal in Germany followed an earlier finding of infringement and granting of an injunction, both of which were subsequently overturned. As a result of the overturned injunction in Germany discussed in the preceding sentence, the Company and/or certain of Sanofi's affiliated entities are seeking damages caused by Amgen's enforcement of the injunction. As part of its opposition to these damages claims, on March 23, 2022, Amgen filed a counterclaim that asserted the German designation of European Patent No. 2,641,917 (the "'917 Patent") and seeks, among other things, a judgment of patent infringement, injunctive relief, and monetary damages. The '917 Patent is a divisional patent of the '124 Patent discussed above (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '124 Patent but contains claims to a different invention). The '917 Patent is also subject to opposition proceedings in the EPO, which were initiated by Sanofi on May 5, 2021. An oral hearing before the EPO has been scheduled for February 21, 2023.

Proceedings Relating to Dupixent (dupilumab) Injection

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"), a patent owned by Immunex Corporation 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 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, which appeal was withdrawn at an oral hearing before the TBA on March 10, 2022 following the TBA's ruling discussed below. On May 18, 2022, the revocation action in the U.K. Patents Court was dismissed following the EPO's revocation of the '665 Patent. 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. At an oral hearing before the TBA on March 10, 2022, the TBA maintained the invalidity and revocation of the '420 Patent. The original patent term of the Immunex patents expired in May 2021.

Proceedings Relating to EYLEA (aflibercept) Injection

United States

On February 11, 2020, anonymous parties filed two requests for *ex parte* reexamination of the Company's U.S. Patent Nos. 10,406,226 and 10,464,992, and the United States Patent and Trademark Office ("USPTO") has granted both requests to initiate reexamination proceedings.

On May 5, 2021, Mylan Pharmaceuticals Inc. filed *inter partes* review ("IPR") petitions in the USPTO against the Company's U.S. Patent Nos. 9,254,338 (the "'338 Patent") and 9,669,069 (the "'069 Patent") seeking declarations of invalidity of the '338 Patent and the '069 Patent. On November 10, 2021, the USPTO issued a decision instituting both IPR proceedings. On December 9, 2021, Apotex Inc. and Celltrion, Inc. each filed two separate IPR petitions against the Company's '338 and '069 Patents requesting that their IPRs be instituted and joined with the IPR proceedings initiated by Mylan concerning the '338 and '069 Patents, which petitions were granted on February 9, 2022. An oral hearing has been scheduled for August 10, 2022.

On September 7, 2021, Celltrion, Inc. filed a post-grant review ("PGR") petition in the USPTO against the Company's U.S. Patent No. 10,857,231 (the "'231 Patent") seeking a declaration of invalidity of the '231 Patent. On March 14, 2022, the Company filed a Notice of Disclaimer with the USPTO, disclaiming all claims of the '231 Patent. As a result, on March 15, 2022, the USPTO denied institution of Celltrion's PGR petition.

Europe

On October 26 and October 27, 2021, anonymous parties initiated opposition proceedings in the EPO against the Company's European Patent No. 2,944,306 (the "'306 Patent") seeking revocation of the '306 Patent in its entirety.

Canada

On June 15 and July 15, 2022, the Company and Bayer Inc. filed patent infringement lawsuits against BGP Pharma ULC d.b.a Viatris Canada and two additional defendants in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept biosimilar would directly or indirectly infringe one or more claims of the Company's Canadian Patent Nos. 2,654,510 and 3,007,276 (in the lawsuit filed on June 15, 2022) and the Company's Canadian Patent No. 2,965,495 (in the lawsuit filed on July 15, 2022).

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"). The ITC instituted the investigation on July 22, 2020 and a trial was scheduled for April 19–23, 2021. On March 26, 2021, the staff attorney appointed by the ITC's Office of Unfair Import Investigations ("OUII")—an independent government party to the case representing the public interest—determined that the '631 Patent is invalid on several grounds. On April 8, 2021, Novartis moved to terminate the ITC investigation in its entirety based on its withdrawal of the complaint; and, on May 3, 2021, the ITC terminated the investigation.

On June 19, 2020, Novartis also filed a patent infringement lawsuit (as amended on August 2, 2021) 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), an order of willful infringement of the '631 Patent (which would allow the court in its discretion to award damages up to three times the amount assessed), 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 June 11, 2021, the court, at the request of Novartis, lifted the stay. On November 5, 2021, the Company filed a motion to stay these proceedings in light of the pending IPR proceeding discussed below. On January 31, 2022, the court denied the Company's motion to stay these proceedings.

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 January 15, 2021, the USPTO declined to institute an IPR proceeding on procedural grounds in light of the pending ITC investigation discussed above; the other IPR petition has been withdrawn. Following Novartis's motion to terminate the ITC investigation discussed above, on April 16, 2021 the Company filed a new IPR petition seeking a declaration of invalidity of the '631 Patent based on the same grounds that were the basis for the OUII staff attorney's determination discussed above. On October 26, 2021, the USPTO issued a decision instituting the IPR proceeding. An oral hearing was held on July 21, 2022.

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 "Sherman Antitrust Act"). 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. On January 25, 2021, the Company filed an amended complaint seeking a judgment that Novartis's conduct violates Section 2 of the Sherman Antitrust Act based on additional grounds, as well as a judgment of tortious interference with contract. On February 22, 2021, Novartis filed, and Vetter moved to join, a motion to dismiss the amended complaint. On September 21, 2021, the court granted Novartis and Vetter's motion to transfer this lawsuit to the Northern District of New York. As a result, this lawsuit was transferred to the same judge that had been assigned to the patent infringement lawsuit discussed above. On November 5, 2021, the Company filed a motion to stay these proceedings in light of the pending IPR proceeding discussed above. On January 31, 2022, the court denied the Company's motion to stay these proceedings and granted Novartis and Vetter's motion to dismiss the amended complaint. On June 10, 2022, the Company filed an appeal of the District Court's decision to dismiss the amended complaint with the U.S. Court of Appeals for the Second Circuit.

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. On December 15, 2020, Rinat filed an amended defense and counterclaim seeking a declaration of infringement of the '711 Patent by fasinumab. On May 5, 2021, the court stayed this litigation on terms mutually agreed by the parties. As previously reported, on July 29, 2021, the '711 Patent was revoked in its entirety by the TBA of the EPO.

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. An oral hearing before the TBA was held on April 5, 2022, at which the TBA ruled that the '048 Patent claims directed to compositions of matter and medical use relevant to fasinumab were invalid based on a lack of novelty.

Proceedings Relating to REGEN-COV (casirivimab and imdevimab)

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit (as amended on April 8, 2021) 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, an award of monetary damages (together with interest), an order of willful infringement of the '221 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. On July 16, 2021, the Company filed a motion to dismiss the complaint, which motion was denied on March 2, 2022.

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. On December 4, 2020, the court denied the motion to dismiss.

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. On June 3, 2021, the United States District Court for the Central District of California unsealed a *qui tam* complaint filed against the Company, Regeneron Healthcare Solutions, Inc., and Sanofi-Aventis U.S. LLC by two *qui tam* plaintiffs (known as relators) purportedly on behalf of the United States and various states (the "State Plaintiffs"), asserting causes of action under the federal False Claims Act and state law. Also on June 3, 2021, the United States and the State Plaintiffs notified the court of their decision to decline to intervene in the case. On October 29, 2021, the *qui tam* plaintiffs filed an amended complaint in this matter. On January 14, 2022, the Company filed a motion to dismiss the amended complaint in its entirety.

In June 2021, the Company received a CID from the U.S. Department of Justice pursuant to the federal False Claims Act. The CID states that the investigation concerns allegations that the Company (i) violated the False Claims Act by paying kickbacks to distributors and ophthalmology practices to induce purchase of EYLEA, including through discounts, rebates, credit card fees, free units of EYLEA, and inventory management systems; and (ii) inflated reimbursement rates for EYLEA by excluding applicable discounts, rebates, and benefits from the average sales price reported to CMS. The CID covers the period from January 2011 through June 2021. The Company is cooperating with this investigation.

Proceedings Initiated by Medicare Advantage Plans Relating to Patient Assistance Organization Support

The Company is party to several lawsuits relating to 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. These lawsuits were filed by UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "UHC") and Humana Inc. ("Humana") in the United States District Court for the Southern District of New York on December 17, 2020 and July 22, 2021, respectively; and by Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively, "BCBS"), Medical Mutual of Ohio ("MMO"), Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey ("Horizon"), and Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund ("Local 464A") in the U.S. District Court for the District of Massachusetts on December 20, 2021, February 23, 2022, April 4, 2022, and June 17, 2022, respectively. These lawsuits allege causes of action under state law and the federal Racketeer Influenced and Corrupt Organizations Act and seek monetary damages and equitable relief. The MMO and Local 464A lawsuits are putative class action lawsuits. On December 29, 2021, the lawsuits filed by UHC and Humana were stayed by the United States District Court for the Southern District of New York pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. In the BCBS, MMO, and Horizon matters, on May 31, 2022, June 6, 2022, and June 13, 2022, respectively, the Company filed motions to transfer the actions to the United States District Court of the Southern District of New York or, in the alternative, to stay the actions in favor of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above; or to dismiss the complaints with prejudice.

Shareholder Demands

On or about September 30, 2020, March 30, 2022, and March 31, 2022, the Company's board of directors received three demand letters from purported shareholders of the Company. The demands allege 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 letters request 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, investigated and evaluated the allegations in the demand letters and has concluded that pursuing the claims alleged in the demands would not be in the Company's best interests at this time.

Proceedings Relating to Shareholder Derivative Complaint

On June 29, 2021, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former members of the Company's board of directors and certain current and former executive officers of the Company as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties in relation to the allegations 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 complaint seeks an award of damages allegedly sustained by the Company; an order requiring Regeneron to take all necessary actions to reform and improve its corporate governance and internal procedures; disgorgement from the individual defendants of all profits and benefits obtained by them resulting from their sales of Regeneron stock; and costs and disbursements of the action, including attorneys' fees. On July 28, 2021, the defendants filed a notice of removal, removing the case from the New York Supreme Court to the U.S. District Court for the Southern District of New York. On September 23, 2021, the individual defendants moved to dismiss the complaint in its entirety. Also on September 23, 2021, the plaintiff moved to remand the case to the New York Supreme Court.

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 or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's 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, Evkeeza® (evinacumab), REGEN-COV® (casirivimab and imdevimab), aflibercept 8 mg, fasinumab, pozelimab, odronextamab, itepekimab, fianlimab, REGN5458, REGN5713-5714-5715, REGN1908-1909, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' 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 Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's 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 those listed above; 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, 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 Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's 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 Regeneron's 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), 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, Praluent, and REGEN-COV described further in Note 13 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 13 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 or otherwise) 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 invents, develops, manufactures, and commercializes medicines for people with serious diseases. Our products and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, 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 medicines for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	2022	2021	2022	2021
Revenues	$ 2,857.2	$ 5,138.5	$ 5,822.3	$ 7,667.2
Net income	$ 852.1	$ 3,098.9	$ 1,825.6	$ 4,214.1
Net income per share - diluted	$ 7.47	$ 27.97	$ 16.07	$ 38.07

For purposes of this report, references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), unless otherwise stated or required by the context.

Products

Products that have received marketing approval are summarized in the table below.

		Territory			
Product	Disease	U.S.	EU	Japan	ROW[e]
EYLEA (aflibercept) Injection[a]	- 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 ("DR")	✔			
	- Neovascular glaucoma ("NVG")			✔	
Dupixent (dupilumab) Injection[b]	- Atopic dermatitis (in adults and adolescents)	✔	✔	✔	✔
	- Atopic dermatitis (in pediatrics 6–11 years of age)	✔	✔		✔
	- Atopic dermatitis (in pediatrics 6 months–5 years of age)	✔			
	- Asthma (in adults and adolescents)	✔	✔	✔	✔
	- Asthma (in pediatrics 6–11 years of age)	✔	✔		

Product *(continued)*	Disease	Territory			
		U.S.	EU	Japan	ROW[e]
Dupixent (dupilumab) Injection[b] *(continued)*	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔	✔
	- Eosinophilic esophagitis ("EoE") (in adults and adolescents)	✔			
Libtayo (cemiplimab) Injection[c]	- Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	✔	✔		✔
	- Metastatic or locally advanced basal cell carcinoma ("BCC")	✔	✔		✔
	- Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔		✔
	- Metastatic or recurrent second-line cervical cancer				✔
Praluent (alirocumab) Injection[d]	- LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✔	✔		✔
	- Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔		✔
	- Homozygous familial hypercholesterolemia ("HoFH")	✔			
REGEN-COV[f]	- COVID-19		✔	✔	✔
Kevzara (sarilumab) Solution for Subcutaneous Injection[b]	- Rheumatoid arthritis ("RA")	✔	✔	✔	✔
Evkeeza (evinacumab) Injection[g]	- HoFH (in adults and adolescents)	✔	✔		
Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn) Injection	- Infection caused by *Zaire ebolavirus*	✔			
ARCALYST® (rilonacept) Injection for Subcutaneous Use[h]	- Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	✔			
	- Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults and pediatrics)	✔			
	- Recurrent pericarditis (in adults and adolescents)	✔			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[i]	- 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 or others. In addition, unless otherwise noted, products in the table above are approved for use in adults in the above-referenced diseases.

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

[c] In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the development, commercialization, and manufacturing of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

[d] 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.

[e] Rest of world ("ROW"). A 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.

[f] Known as REGEN-COV in the United States and Ronapreve in other countries. Refer to "Additional Information - Clinical Development Programs" section below for further details regarding the status of the Emergency Use Authorization ("EUA") for REGEN-COV in the United States.

[g] In January 2022, the Company entered into a license and collaboration agreement for Ultragenyx to develop and commercialize Evkeeza outside of the United States.

[h] Kiniksa is solely responsible for the development and commercialization of ARCALYST.

[i] Sanofi is solely responsible for the development and commercialization of ZALTRAP.

Net Product Sales of Regeneron-Discovered Products

	Three Months Ended June 30,						
	2022			2021			% Change
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,621.2	$ 869.8	$ 2,491.0	$ 1,424.7	$ 857.6 *	$ 2,282.3	9 %
Dupixent[b]	$ 1,582.1	$ 509.7	$ 2,091.8	$ 1,146.6	$ 352.4	$ 1,499.0	40 %
Libtayo[c]	$ 90.9	$ 50.4	$ 141.3	$ 78.0	$ 38.9	$ 116.9	21 %
Praluent[d]	$ 31.2	$ 77.7	$ 108.9	$ 41.9	$ 57.5	$ 99.4	10 %
REGEN-COV[e]	$ —	$ 22.8	$ 22.8	$ 2,591.2	$ 470.2	$ 3,061.4	(99 %)
Kevzara[b]	$ 43.0	$ 39.3	$ 82.3	$ 30.7	$ 36.0	$ 66.7	23 %
Other products[f]	$ 12.1	$ 19.0	$ 31.1	$ 3.3	$ 22.2	$ 25.5	22 %

	Six Months Ended June 30,						
	2022			2021			% Change
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 3,138.8	$ 1,738.3	$ 4,877.1	$ 2,771.7	$ 1,668.8 *	$ 4,440.5	10 %
Dupixent[b]	$ 2,907.7	$ 994.5	$ 3,902.2	$ 2,108.1	$ 653.8	$ 2,761.9	41 %
Libtayo[c]	$ 169.8	$ 96.2	$ 266.0	$ 147.1	$ 70.6	$ 217.7	22 %
Praluent[d]	$ 64.8	$ 155.5	$ 220.3	$ 85.2	$ 118.8	$ 204.0	8 %
REGEN-COV[e]	$ —	$ 658.4	$ 658.4	$ 2,853.4	$ 654.4	$ 3,507.8	(81 %)
Kevzara[b]	$ 100.0	$ 88.7	$ 188.7	$ 61.4	$ 74.4	$ 135.8	39 %
Other products[f]	$ 22.0	$ 39.4	$ 61.4	$ 7.4	$ 45.2	$ 52.6	17 %

* Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits and losses based on sales from Bayer to its distributor in Japan. Previously, the Company received from Bayer a tiered percentage of sales based on sales by Bayer's distributor in Japan. Consequently, the prior year net product sales amount has been revised for comparability purposes.

[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] Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits/losses in connection with global sales of Dupixent and Kevzara.

[c] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company will record global net product sales of Libtayo and pay Sanofi a royalty on such sales. Refer to "Products" section above and "Collaboration, License, and Other Agreements" section below for further details.

[d] Regeneron records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales.

[e] Regeneron records net product sales of REGEN-COV in the United States. Roche records net product sales of the antibody cocktail outside the United States and the parties share gross profits from global sales based on a pre-specified formula.

[f] Included in this line item are products which are sold by the Company and others. Refer to "Results of Operations - *Revenues*" below for a complete listing of net product sales recorded by the Company. In addition, not included in this line item are net product sales of ARCALYST subsequent to the first quarter of 2021, which are recorded by Kiniksa; net product sales of ARCALYST were $22.2 million for the first quarter of 2022.

Programs in Clinical Development

Product candidates in clinical development, which are being developed by us and/or our collaborators, are summarized in the table below.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, 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.

Refer to Part II, Item 1A. "Risk Factors" for a description of risks and uncertainties that may affect our clinical programs. Any of such risks and uncertainties may, among other matters, negatively impact the development timelines set forth in the table below.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
Ophthalmology						
EYLEA (aflibercept)[a]			–Retinopathy of prematurity ("ROP")[c]	–ROP (EU and Japan) –Every-16-weeks dosing regimen in patients with DR (U.S.)		–Submit supplemental Biologics License Application ("sBLA") for ROP (third quarter 2022) –U.S. Food and Drug Administration ("FDA") decision on sBLA for every-16-weeks dosing regimen in patients with DR (target action date of February 28, 2023)
Aflibercept 8 mg[a]			–Wet AMD –DME		–Reported detailed results from Phase 2 trial in wet AMD	–Report results from Phase 3 studies in wet AMD and DME (second half 2022)
Immunology & Inflammation						
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*		–Grass allergy	–EoE in pediatrics[c] –Chronic obstructive pulmonary disease ("COPD") –Bullous pemphigoid (Phase 2/3)[c] –Chronic spontaneous urticaria ("CSU") –Prurigo nodularis –Allergic bronchopulmonary aspergillosis ("ABPA") –Chronic inducible urticaria - cold –Chronic rhinosinusitis without nasal polyposis	–Atopic dermatitis in pediatrics (6 months–5 years of age) (EU) –EoE in adults and adolescents (EU) –Prurigo nodularis (U.S., EU, and Japan)	–Approved by FDA for atopic dermatitis in pediatrics (6 months–5 years of age) –Approved by European Commission ("EC") for severe asthma in pediatrics (6–11 years of age) –Approved by FDA for EoE in adults and adolescents –Reported that Phase 3 trial in EoE in pediatrics (1–11 years of age) met its primary endpoint –Reported that second Phase 3 trial in prurigo nodularis met its primary and key secondary endpoints	–EC decision on regulatory submission for atopic dermatitis in pediatrics (6 months–5 years of age) (first half 2023) –Submit regulatory application in Japan for atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) (second half 2022) –EC decision on regulatory submission for EoE in adults and adolescents (first half 2023) –Submit sBLA for EoE in pediatrics (first half 2023) –Report initial results from Phase 3 study in COPD (first half 2023)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*			–Allergic fungal rhinosinusitis –Chronic pruritis of unknown origin		–Stopped one of the Phase 3 trials in CSU (in patients refractory to omalizumab) due to futility, based on pre-specified interim analysis –Discontinued further clinical development in peanut allergy	–FDA decision on sBLA (target action date of September 30, 2022) and EC decision on regulatory submission (first half 2023) for prurigo nodularis –Report results from Phase 3 study in chronic inducible urticaria - cold (first half 2023)
Kevzara (sarilumab)[b] *Antibody to IL-6R*		–Polyarticular-course juvenile idiopathic arthritis ("pcJIA") –Systemic juvenile idiopathic arthritis ("sJIA")				
Itepekimab[b] **(REGN3500)** *Antibody to IL-33*			–COPD			
REGN1908-1909[f] *Multi-antibody therapy to Fel d 1*			–Cat allergy			
REGN5713-5714-5715 *Multi-antibody therapy to Bet v 1*			–Birch allergy			
Solid Organ Oncology						
Libtayo (cemiplimab)[b][g] *Antibody to PD-1*		–Metastatic or locally advanced CSCC[d] –Neoadjuvant CSCC –Second-line cervical cancer, ISA101b combination	–First-line NSCLC, chemotherapy combination –Second-line cervical cancer[e] –Adjuvant CSCC	–Second-line cervical cancer (EU and Japan) –First-line NSCLC, chemotherapy combination (U.S. and EU)	–Voluntarily withdrew sBLA for cervical cancer due to inability to align with FDA on certain post-marketing studies	–FDA decision on sBLA (target action date of September 19, 2022)[p] and EC decision on regulatory submission for NSCLC, chemotherapy combination (first half 2023) –EC decision on regulatory submission for cervical cancer (first quarter 2023)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–Solid tumors and advanced hematologic malignancies		–First-line metastatic melanoma			–Initiate Phase 3 study in first-line adjuvant melanoma (second half 2022)
Vidutolimod *Immune activator targeting TLR9*		–CSCC and Merkel cell carcinoma				
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*	–Platinum-resistant ovarian cancer					–Report results from Phase 1 study in platinum-resistant ovarian cancer (second half 2022)
REGN5668 *Bispecific antibody targeting MUC16 and CD28*	–Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				–Reported preliminary data from dose escalation portion of Phase 1/2 study in prostate cancer	
REGN4336 *Bispecific antibody targeting PSMA and CD3*	–Prostate cancer					
REGN5093 *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC					–Report results from Phase 1 study in MET-altered advanced NSCLC (second half 2022)
REGN5093-M114 *Bispecific antibody-drug conjugate targeting two distinct MET epitopes*	–MET overexpressing advanced cancer					
REGN6569 *Antibody to GITR*	–Solid tumors					
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors					
Hematology						
Odronextamab (REGN1979) *Bispecific antibody targeting CD20 and CD3*	–Certain B-cell malignancies[c][n]	–B-cell non-Hodgkin lymphoma ("B-NHL")[n] (potentially pivotal study)				–Report additional results from potentially pivotal Phase 2 study in B-NHL and submit BLA (second half 2022)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
Odronextamab (REGN1979) *(continued)*						–Initiate Phase 3 program (first half 2023)
REGN5458[f] *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma[c]	–Multiple myeloma (potentially pivotal study)[c]				–Complete enrollment in potentially pivotal Phase 2 study in multiple myeloma (second half 2022) –Report results from potentially pivotal Phase 2 study in multiple myeloma (second half 2022)
REGN5459[f] *Bispecific antibody targeting BCMA and CD3*	–Transplant desensitization in patients with chronic kidney disease					
Pozelimab[f] (REGN3918) *Antibody to C5; studied as monotherapy and in combination with cemdisiran*		–CD55-deficient protein-losing enteropathy, monotherapy[c] (potentially pivotal study)	–Myasthenia gravis, cemdisiran combination[l] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][l]			–Submit BLA for CD55-deficient protein-losing enteropathy, monotherapy (second half 2022)
Cemdisiran[l] *siRNA therapeutic targeting C5*		–Immunoglobulin A nephropathy			–Reported positive topline results from Phase 2 trial in immunoglobulin A nephropathy	
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia					
NTLA-2001[k] *TTR gene knockout using CRISPR/Cas9*	–Transthyretin ("ATTR") amyloidosis[c]				–Reported updated positive interim data from Phase 1 trial in ATTR	
REGN9933 *Antibody to Factor XI*	–Thrombosis					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
General Medicine						
REGEN-COV (casirivimab and imdevimab)[e][j] *Multi-antibody therapy to SARS-CoV-2 virus*				–COVID-19 treatment of non-hospitalized patients and pre-and post-exposure prophylaxis (U.S.) –COVID-19 treatment of hospitalized patients (EU)	–Submitted additional data to the FDA from prophylaxis trial in connection with BLA –FDA revised EUA to exclude use in geographic regions where infection or exposure is likely due to a variant that is not susceptible to the treatment	–FDA decision on BLA for COVID-19 treatment of non-hospitalized patients and prevention –EC decision on regulatory submission for COVID-19 treatment of hospitalized patients (first half 2023)
"Next Generation" Covid Antibodies *Antibodies to SARS-CoV-2 variants*	–Healthy volunteers					
Praluent (alirocumab) *Antibody to PCSK9*			–HeFH in pediatrics			
Fasinumab[i][f] **(REGN475)** *Antibody to NGF*			–Osteoarthritis pain of the knee or hip[e]			–Continue discussions with regulatory authorities and determine next steps for the program (second half 2022)
Evkeeza (evinacumab)[f][m] *Antibody to ANGPTL3*					–Reported that Phase 3 trial for HoFH in pediatrics (5–11 years of age) met its primary endpoint	–Submit sBLA for HoFH in pediatrics (5–11 years of age) (second half 2022)
Garetosmab[f] **(REGN2477)** *Antibody to Activin A*		–Fibrodysplasia ossificans progressiva ("FOP")[c][d][e]				–Initiate Phase 3 study in FOP (second half 2022)
Mibavademab[f] **(REGN4461)** *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[e] –Partial lipodystrophy				
REGN5381/REGN9035 *Agonist antibody to NPR1/reversal agent to REGN5381*	–Reversal agent in healthy volunteers	–Heart failure				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[(h)]	2022 Events to Date	Select Upcoming Milestones
ALN-HSD[(l)] *RNAi therapeutic targeting HSD17B13*	–Nonalcoholic steatohepatitis ("NASH")					
ALN-APP[(l)] *RNAi therapeutic targeting APP*	–Early-onset Alzheimer's disease					

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 REGN6490, an antibody to IL-36R, which was previously being studied in palmo-plantar pustulosis.

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

[(b)] In collaboration with Sanofi

[(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 sales of the product, if any.

[(g)] Studied as monotherapy and in combination with other antibodies and treatments

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

[(i)] In collaboration with Teva and Mitsubishi Tanabe Pharma

[(j)] In collaboration with Roche outside the United States

[(k)] In collaboration with Intellia

[(l)] In collaboration with Alnylam

[(m)] In collaboration with Ultragenyx outside the United States

[(n)] FDA granted Fast Track designation for follicular lymphoma and diffuse large B-cell lymphoma

[(o)] In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the research, development, and commercialization of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

[(p)] We were recently informed that an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe will likely delay its decision on the NSCLC chemotherapy combination sBLA until after the September 19, 2022 target action date.

Additional Information - Clinical Development Programs

REGEN-COV (casirivimab and imdevimab)

REGEN-COV has not been approved by the FDA, but is currently authorized under an EUA for use in certain post-exposure prophylaxis settings and as a treatment for people with mild to moderate COVID-19 who are at high risk of serious consequences from COVID-19. The EUA is temporary and does not replace a formal BLA submission review and approval process. This use is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use, unless terminated or revoked sooner.

Based on laboratory data that showed markedly decreased binding to the Omicron spike protein, REGEN-COV is highly unlikely to be active against the Omicron-lineage variants. In January 2022, the FDA revised the EUA for REGEN-COV to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. With this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions, since Omicron-lineage variants are currently dominant across the United States. If, in the future, patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to REGEN-COV, then the limitation on use may be revised in these areas.

In April 2022, the Company announced that the FDA extended by three months (to July 2022) its review of the BLA for REGEN-COV to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals. The extension was due to ongoing discussions with the FDA relating to pre-exposure prophylactic use, for which the Company has submitted additional data from its completed prophylaxis trial that the FDA has accepted for review. In July 2022, the FDA notified the Company that its review of the BLA for REGEN-COV to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals is ongoing.

Agreements Related to COVID-19

U.S. Government

In the first quarter of 2020, the Company announced an expansion of its Other Transaction Agreement with the Biomedical Advanced Research Development Authority ("BARDA"), pursuant to which the U.S. Department of Health and Human Services ("HHS") was obligated to fund certain of our costs incurred for research and development activities related to COVID-19 treatments.

In July 2020, the Company 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 drug product of REGEN-COV to the U.S. government. The agreement, as subsequently amended, provided for payments to the Company of up to $465.9 million in the aggregate for bulk manufacturing of the drug substance, as well as fill/finish, storage, and other activities.

In January 2021, the Company announced an agreement with an entity acting on behalf of the U.S. Department of Defense and HHS to manufacture and deliver additional filled and finished drug product of REGEN-COV to the U.S. government. Pursuant to the agreement, the U.S. government was obligated to purchase 1.25 million doses of drug product, resulting in payments to the Company of $2.625 billion.

In September 2021, the Company announced an amendment to its January 2021 agreement to supply the U.S. government with an additional 1.4 million doses of REGEN-COV. Pursuant to the agreement, the U.S. government was obligated to purchase all filled and finished doses of such additional drug product delivered by January 31, 2022, resulting in payments to the Company of $2.940 billion in the aggregate. Additionally, Roche supplied a portion of the doses to Regeneron to fulfill our agreement with the U.S. government (see "Roche" section below for further details regarding our collaboration agreement with Roche).

As of December 31, 2021, the Company had completed its final deliveries of drug product under the agreements described above. See "Results of Operations - Revenues" below for REGEN-COV net product sales recognized during the three and six months ended June 30, 2021.

Roche

In 2020, we entered into a collaboration agreement with Roche to develop, manufacture, and distribute the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve in other countries).

Under the terms of the agreement, the parties jointly fund certain studies and each party is obligated to dedicate a certain amount of manufacturing capacity to casirivimab and imdevimab each year. We distribute the product in the United States and Roche distributes the product outside of the United States. The parties share gross profits from worldwide sales based on a pre-specified formula, depending on the amount of manufactured product supplied by each party to the market.

Collaboration, License, and Other Agreements

Sanofi

Antibody

We are collaborating with Sanofi on the global development and commercialization of Dupixent, Kevzara, and itepekimab (the "Antibody Collaboration"). Under the terms of the Antibody License and Collaboration Agreement, Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on our share of collaboration profits from commercialization of collaboration products. As of June 30, 2022, the total amount of our contingent reimbursement obligation to Sanofi in connection with such development expenses was approximately $3.1 billion. Under the terms of the Antibody License and Collaboration Agreement, we were 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. On July 1, 2022, an amendment to the Antibody License and Collaboration Agreement became effective, pursuant to which the percentage of Regeneron’s share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%.

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 co-commercialize Dupixent in the United States and in certain countries outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi equally share profits and losses from sales within the United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit and loss sharing, we are entitled to receive sales milestone payments from Sanofi. In each of the years ended 2020 and 2021, the Company earned a $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.0 billion and $1.5 billion, respectively, on a rolling twelve-month basis, and, in first quarter of 2022, the Company earned a $50.0 million sales-based milestone upon aggregate sales of antibodies outside the United States exceeding $2.0 billion. We are entitled to receive up to an aggregate of $100.0 million in additional sales milestone payments from Sanofi, which includes the next sales milestone payment of $50.0 million that would be earned when such sales outside the United States exceed $2.5 billion on a rolling twelve-month basis.

Immuno-oncology

The Company has been collaborating with Sanofi for antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). Under the terms of the Immuno-oncology License and Collaboration Agreement, the parties were co-developing and co-commercializing Libtayo. The parties shared equally, on an ongoing basis, development and commercialization expenses for Libtayo. We had principal control over the development of Libtayo and led commercialization activities in the United States, while Sanofi led commercialization activities outside of the United States. The parties shared equally in profits and losses in connection with the commercialization of Libtayo.

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA"). Consequently, in July 2022, we made a $900.0 million up-front payment to Sanofi, and Sanofi is eligible to receive a $100.0 million regulatory milestone and up to an aggregate of $100.0 million in sales-based milestones upon achieving certain amounts of worldwide net product sales of Libtayo through 2023. We will also pay Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. The parties have also entered into a transition services agreement, a transitional distribution agreement, and a manufacturing services agreement, pursuant to which, during certain transitional periods, Sanofi will perform for Regeneron certain transition, distribution, and manufacturing services, respectively.

We were obligated to reimburse Sanofi for half of the development costs it funded that were attributable to clinical development of antibody product candidates under the Amended and Restated Immuno-oncology Discovery and Development Agreement from our share of profits from commercialized IO Collaboration products. Under the A&R IO LCA, the amount of development costs incurred under the IO Collaboration for which we are obligated to reimburse Sanofi is $35.0 million, and we will reimburse Sanofi for such development costs by paying Sanofi a 0.5% royalty on net product sales of Libtayo until all such development costs have been reimbursed by us.

Bayer

We and Bayer are parties to a license and collaboration agreement for the global development and commercialization of EYLEA and aflibercept 8 mg outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. Bayer markets EYLEA outside the United States, and the companies share equally in profits and losses from such sales. In Japan, we were entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales through 2021, and, effective January 1, 2022, the companies share equally in profits and losses from sales.

We are obligated to reimburse Bayer for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. 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 and are entitled to all profits from such sales.

Teva

We and Teva are parties to a collaboration agreement to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with Mitsubishi Tanabe Pharma Corporation ("MTPC"). In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment. We lead global development activities, and the parties share equally, on an ongoing basis, development costs under a global development plan. As of June 30, 2022, we had received an aggregate $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).

Alnylam

In 2018, we and Alnylam Pharmaceuticals, Inc. entered into a collaboration to discover RNA interference ("RNAi") therapeutics for NASH and potentially other related diseases, as well as to research, co-develop and commercialize any therapeutic product candidates that emerge from these discovery efforts (including ALN-HSD, which is currently in clinical development). ALN-HSD is being co-developed with Alnylam with terms generally consistent with the form of a Co-Commercialization Collaboration Agreement in connection with the 2019 collaboration agreement as described below. Alnylam is conducting the Phase 1 clinical trial for ALN-HSD and Regeneron will be the lead party for all future development.

In 2019, we and Alnylam entered into a global, strategic collaboration to discover, develop, and commercialize RNAi therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. Under the terms of the agreement, we made an up-front payment of $400.0 million to Alnylam. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to an aggregate of $200.0 million in clinical proof-of-principle milestones for eye and CNS programs. Following designation of a lead candidate, the parties may further advance such lead candidate under either a co-commercialization collaboration agreement structure (under which the parties are advancing ALN-APP, which is currently in clinical development) or a license agreement.

In addition, during 2019, the parties entered into a Co-Commercialization Collaboration Agreement for a silencing RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of cemdisiran and pozelimab, with us as the licensee. Under the C5 siRNA Co-Commercialization Collaboration agreement, the parties share costs equally and will split profits (if commercialized); and under the License Agreement, the licensee is responsible for its own costs and expenses. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on our potential future net sales of the combination product only subject to customary reductions, as well as up to $325.0 million in sales milestones.

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. NTLA-2001, which is in clinical development, is subject to a co-development and co-commercialization arrangement pursuant to which Intellia will lead development and commercialization activities and the parties share an agreed-upon percentage of development expenses and profits (if commercialized).

In 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 companies to jointly develop potential products for the treatment of hemophilia A and B, with Regeneron leading development and commercialization activities. In addition, we also received non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products. In connection with the 2020 agreement, we made a $70.0 million up-front payment and purchased shares of Intellia common stock for an aggregate purchase price of $30.0 million.

BARDA

We and BARDA are parties to agreements pursuant to which HHS provided certain funding to develop, test, and manufacture a treatment for Ebola virus infection. In July 2020, HHS exercised its option under an 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 - U.S. Government" section above for information related to our COVID-19 agreements.

Kiniksa

Pursuant to a 2017 license agreement, we granted Kiniksa Pharmaceuticals, Ltd. the right to develop and commercialize certain new indications for ARCALYST. During the first quarter of 2021, Kiniksa received marketing approval in the United States for a new indication of ARCALYST, recurrent pericarditis. The quarterly period ended March 31, 2021 was the last quarter for which the Company recorded net product sales of ARCALYST.

Following this approval, Kiniksa is solely responsible for the U.S. development and commercialization of ARCALYST in all approved indications, and Regeneron will continue to supply clinical and commercial product to Kiniksa. Kiniksa will pay Regeneron 50% of its profits from sales of ARCALYST and the parties will not share in any losses incurred by Kiniksa in connection with commercialization of ARCALYST.

Ultragenyx

In January 2022, we entered into a license and collaboration agreement for Ultragenyx Pharmaceutical Inc. to develop and commercialize Evkeeza in countries outside of the United States. In connection with the agreement, Ultragenyx made a $30.0 million non-refundable up-front payment to the Company. Ultragenyx will share in certain costs for global trials led by the Company and also have the right to continue to clinically develop Evkeeza in countries outside of the U.S. We will supply commercial product to Ultragenyx 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 additional regulatory and sales milestone payments.

Checkmate

In May 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. for a total equity value of approximately $250 million. In connection with the acquisition, the Company obtained the rights to vidutolimod, which is in clinical development for oncology.

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 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.

Corporate Information

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

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

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

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

Results of Operations

Three and Six Months Ended June 30, 2022 and 2021

Net Income

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	2022	2021	2022	2021
Revenues	$ 2,857.2	$ 5,138.5	$ 5,822.3	$ 7,667.2
Operating expenses	1,747.3	1,791.3	3,453.9	3,207.3
Income from operations	1,109.9	3,347.2	2,368.4	4,459.9
Other income (expense)	(146.7)	405.6	(344.1)	545.9
Income before income taxes	963.2	3,752.8	2,024.3	5,005.8
Income tax expense	111.1	653.9	198.7	791.7
Net income	$ 852.1	$ 3,098.9	$ 1,825.6	$ 4,214.1
Net income per share - diluted	$ 7.47	$ 27.97	$ 16.07	$ 38.07

Revenues

	Three Months Ended June 30,			Six Months Ended June 30,		
(In millions)	2022	2021	$ Change	2022	2021	$ Change
Net product sales in the United States:						
EYLEA	$ 1,621.2	$ 1,424.7	$ 196.5	$ 3,138.8	$ 2,771.7	$ 367.1
Libtayo	90.9	78.0	12.9	169.8	147.1	22.7
Praluent	31.2	41.9	(10.7)	64.8	85.2	(20.4)
REGEN-COV	—	2,591.2	(2,591.2)	—	2,853.4	(2,853.4)
Evkeeza	11.1	2.0	9.1	19.6	2.5	17.1
ARCALYST	— *	— *	*	— *	2.2	*
Collaboration revenue:						
Sanofi	677.5	437.7	239.8	1,308.4	802.5	505.9
Bayer	357.5	349.1	8.4	742.8	671.9	70.9
Roche	8.2	167.9	(159.7)	224.5	234.7	(10.2)
Other collaboration revenue	0.4	—	0.4	0.4	—	0.4
Other revenue	59.2	46.0	13.2	153.2	96.0	57.2
Total revenues	$ 2,857.2	$ 5,138.5	$ (2,281.3)	$ 5,822.3	$ 7,667.2	$ (1,844.9)

* Effective April 1, 2021, Kiniksa records net product sales of ARCALYST in the United States. Previously, the Company recorded net product sales of ARCALYST in the United States.

Net Product Sales

Net product sales of EYLEA in the United States increased for the three and six months ended June 30, 2022, compared to the same periods in 2021, due to higher sales volume.

During the three and six months ended June 30, 2021, we recorded net product sales of REGEN-COV in connection with our agreements with the U.S. government. As of December 31, 2021, the Company had completed its final deliveries of drug product under its agreements with the U.S. government; as a result, there were no net product sales of REGEN-COV in the United States recorded during the three and six months ended June 30, 2022. Refer to "Agreements Related to COVID-19 - *U.S. Government*" section above for further details.

As described under "Collaboration, License, and Other Agreements - Sanofi - *Immuno-oncology*" above, effective July 1, 2022, the Company became solely responsible for the research, development, and commercialization of Libtayo and will record worldwide net product sales of Libtayo.

Collaboration Revenue

Sanofi Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 496.6	$ 327.6	$ 911.9	$ 588.2
Sales-based milestone earned	—	—	50.0	—
Reimbursement for manufacturing of commercial supplies[(a)]	145.5	110.9	306.3	216.5
Other	28.9	—	28.9	—
Total Antibody	671.0	438.5	1,297.1	804.7
Immuno-oncology:				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	3.9	(3.5)	6.7	(9.6)
Reimbursement for manufacturing of ex-U.S. commercial supplies[(a)]	2.6	2.7	4.6	7.4
Total Immuno-oncology	6.5	(0.8)	11.3	(2.2)
Total Sanofi collaboration revenue	$ 677.5	$ 437.7	$ 1,308.4	$ 802.5

[(a)] Corresponding costs incurred by us in connection with such production is recorded within Cost of collaboration and contract manufacturing

Antibody

Global net product sales of Dupixent and Kevzara are recorded by Sanofi. 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. The increase in our share of profits in connection with commercialization of antibodies during the three and six months ended June 30, 2022, compared to the same periods in 2021, was driven by higher Dupixent profits.

Regeneron's share of profits in connection with the commercialization of Dupixent and Kevzara is summarized below:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Dupixent and Kevzara net product sales	$ 2,174.1	$ 1,565.7	$ 4,090.9	$ 2,897.7
Regeneron's share of collaboration profits	$ 551.7	$ 364.5	$ 1,013.9	$ 654.4
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(55.1)	(36.9)	(102.0)	(66.2)
Regeneron's share of profits in connection with commercialization of antibodies	$ 496.6	$ 327.6	$ 911.9	$ 588.2
Regeneron's share of collaboration profits as a percentage of Dupixent and Kevzara net product sales	23%	21%	22%	20%

As described above under "Collaboration, License, and Other Agreements - Sanofi - *Antibody*", on July 1, 2022, an amendment to the Antibody License and Collaboration Agreement became effective, pursuant to which the percentage of Regeneron's share of profits in any calendar quarter used to reimburse Sanofi for development costs which were funded by Sanofi increased from 10% to 20%.

During the six months ended June 30, 2022, the Company earned a $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $2.0 billion on a rolling twelve-month basis.

Bayer Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	2022	2021	2022	2021
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 339.7	$ 335.4	$ 678.1	$ 644.3
Reimbursement for manufacturing of ex-U.S. commercial supplies[(a)]	17.8	13.7	42.8	27.6
One-time payment in connection with change in Japan arrangement	—	—	21.9	—
Total Bayer collaboration revenue	$ 357.5	$ 349.1	$ 742.8	$ 671.9

[(a)] Corresponding costs incurred by us in connection with such production is recorded within Cost of collaboration and contract manufacturing

Bayer records net product sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profits 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 is adjusted accordingly, as necessary.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	2022	2021	2022	2021
EYLEA net product sales outside the United States	$ 869.8	$ 857.6*	$ 1,738.3	$ 1,668.8*
Regeneron's share of collaboration profit from sales outside the United States	$ 354.5	$ 350.4	$ 707.9	$ 674.1
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(14.8)	(15.0)	(29.8)	(29.8)
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 339.7	$ 335.4	$ 678.1	$ 644.3
Regeneron's share of profits as a percentage of EYLEA net product sales outside the United States	39%	39%	39%	39%

[*] Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits and losses based on sales from Bayer to its distributor in Japan. Previously, the Company received from Bayer a tiered percentage of sales based on sales by Bayer's distributor in Japan. Consequently, the prior year net product sales amount has been revised for comparability purposes.

Roche Collaboration Revenue

As described above under "Agreements Related to COVID-19 - *Roche*", Roche distributes and records net product sales of Ronapreve outside the United States, and the parties share gross profits from worldwide sales, depending on the amount of manufactured product supplied by each party to the market. Each quarter, a single payment is due from one party to the other to true-up the global gross profits between the parties. If Regeneron is to receive a true-up payment from Roche, such amount will be recorded to Collaboration revenue. If Regeneron is to make a true-up payment to Roche, such amount will be recorded to Cost of goods sold.

Amounts recognized in Collaboration revenue in connection with the Roche collaboration agreement are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Global gross profit payment from Roche in connection with sales of Ronapreve	$ 8.2	$ 167.9	$ 224.5	$ 234.7

Roche provides us with an estimate of its gross profits for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and the true-up of global gross profits is adjusted accordingly, as necessary.

Other Revenue

Other revenue during the six months ended June 30, 2022 included a $30.0 million up-front payment received from Ultragenyx in connection with our January 2022 license and collaboration agreement for Evkeeza outside the United States.

Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
(In millions, except headcount data)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Research and development[(a)]	$ 794.3	$ 714.2	$ 80.1	$ 1,638.1	$ 1,457.1	$ 181.0
Acquired in-process research and development	197.0	—	197.0	225.1	—	225.1
Selling, general, and administrative[(a)]	476.3	414.7	61.6	926.3	820.3	106.0
Cost of goods sold[(b)]	149.2	539.4	(390.2)	356.5	722.6	(366.1)
Cost of collaboration and contract manufacturing[(c)]	147.9	154.3	(6.4)	345.5	279.1	66.4
Other operating (income) expense, net	(17.4)	(31.3)	13.9	(37.6)	(71.8)	34.2
Total operating expenses	$ 1,747.3	$ 1,791.3	$ (44.0)	$ 3,453.9	$ 3,207.3	$ 246.6
Average headcount	10,939	9,822	1,117	10,715	9,635	1,080

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

[(b)] Cost of goods sold primarily includes costs in connection with producing commercial supplies for products that are sold by Regeneron (i.e., for which we record net product sales), any royalties we are obligated to pay on such sales, and amounts we are obligated to pay to collaborators for their share of gross profits.

[(c)] 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 $159.8 million and $145.5 million for the three months ended June 30, 2022 and 2021, respectively, and $326.7 million and $276.4 million for the six months ended June 30, 2022 and 2021, respectively, of stock-based 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. The table below also includes reimbursements of research and development expenses by collaborators, as when we are entitled to reimbursement of all or a portion of such expenses that we incur under a collaboration, we record those reimbursable amounts in the period in which such costs are incurred.

(In millions)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021*	$ Change	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021*	$ Change
Direct research and development expenses:						
Dupixent (dupilumab)	$ 40.1	$ 37.0	$ 3.1	$ 72.2	$ 64.4	$ 7.8
Libtayo (cemiplimab)	37.2	38.2	(1.0)	75.8	78.0	(2.2)
EYLEA	16.3	26.7	(10.4)	40.7	54.8	(14.1)
REGEN-COV	10.9	97.2	(86.3)	13.6	305.9	(292.3)
Other product candidates in clinical development and other research programs	121.6	128.7	(7.1)	219.5	244.9	(25.4)
Total direct research and development expenses	226.1	327.8	(101.7)	421.8	748.0	(326.2)
Indirect research and development expenses:						
Payroll and benefits	285.5	236.9	48.6	569.3	469.9	99.4
Lab supplies and other research and development costs	47.3	33.4	13.9	85.3	66.8	18.5
Occupancy and other operating costs	122.1	98.5	23.6	242.4	193.6	48.8
Total indirect research and development expenses	454.9	368.8	86.1	897.0	730.3	166.7
Clinical manufacturing costs	196.2	153.8	42.4	467.9	287.4	180.5
Reimbursement of research and development expenses by collaborators	(82.9)	(136.2)	53.3	(148.6)	(308.6)	160.0
Total research and development expenses	$ 794.3	$ 714.2	$ 80.1	$ 1,638.1	$ 1,457.1	$ 181.0

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

Reimbursement of research and development expenses by collaborators included $41.0 million and $127.8 million of reimbursements from Roche related to REGEN-COV for the three and six months ended June 30, 2021, respectively. For the three and six months ended June 30, 2022, reimbursements from Roche related to REGEN-COV were not material.

Research and development expenses included stock-based compensation expense of $89.7 million and $70.9 million for the three months ended June 30, 2022 and 2021, respectively, and $182.1 million and $140.6 million for the six months ended June 30, 2022 and 2021, respectively.

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

Acquired In-process Research and Development ("IPR&D")

Acquired IPR&D for the three and six months ended June 30, 2022 included a $195.0 million charge related to the Company's acquisition of Checkmate. Additionally, Acquired IPR&D for the six months ended June 30, 2022 included a $20.0 million opt-in payment in connection with a product candidate under our collaboration agreement with Adicet Bio, Inc.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased for the three and six months ended June 30, 2022, compared to the same periods in 2021, primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses for EYLEA, partly offset by costs in 2021 for educational campaigns related to COVID-19 that did not recur during 2022. Selling, general, and administrative expenses also included stock-based compensation expense of $57.5 million and $49.6 million for the three months ended June 30, 2022 and 2021, respectively, and $118.2 million and $100.4 million for the six months ended June 30, 2022 and 2021, respectively.

Cost of Goods Sold

Cost of goods sold decreased for the three and six months ended June 30, 2022, compared to the same periods in 2021, primarily due to the Company not recognizing any REGEN-COV net product sales in the United States during 2022. In addition, Cost of goods sold included inventory write-offs and reserves totaling $139.9 million and $149.3 million for the three and six months ended June 30, 2021, respectively, primarily related to REGEN-COV. The six months ended June 30, 2022 included $58.0 million of costs related to REGEN-COV, including inventory write-offs and reserves.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased for the six months ended June 30, 2022, compared to the same period in 2021, primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent and an increase in shipments of commercial supplies of Praluent for Sanofi outside the United States.

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 our Sanofi immuno-oncology, Teva, and MTPC collaborative arrangements. As the A&R IO LCA became effective July 1, 2022 (as further described under "Collaboration, License, and Other Agreements - Sanofi - *Immuno-oncology*" above), the three months ended June 30, 2022 will be the last period in which such amounts will be recognized in connection with our Sanofi immuno-oncology collaborative arrangement.

Other Income (Expense)

Other income (expense) for the three and six months ended June 30, 2022, compared to the same periods in 2021, was primarily impacted by the recognition of net unrealized losses on equity securities of $163.7 million and $374.9 million for the three and six months ended June 30, 2022, respectively, compared to $409.0 million and $552.9 million of net unrealized gains for the three and six months ended June 30, 2021, respectively.

Income Taxes

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except effective tax rate)	**2022**	**2021**	**2022**	**2021**
Income tax expense	$ 111.1	$ 653.9	$ 198.7	$ 791.7
Effective tax rate	11.5 %	17.4 %	9.8 %	15.8 %

The decrease in the effective tax rate for the three and six months ended June 30, 2022, compared to the same periods in 2021, was primarily driven by the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, the impact of income earned in the United States during 2021 related to REGEN-COV, and, to a lesser extent, stock-based compensation.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	June 30, 2022	December 31, 2021	$ Change
Financial assets:			
Cash and cash equivalents	$ 3,395.1	$ 2,885.6	$ 509.5
Marketable securities - current	4,171.3	2,809.1	1,362.2
Marketable securities - noncurrent	6,415.9	6,838.0	(422.1)
	$ 13,982.3	$ 12,532.7	$ 1,449.6
Borrowings and finance lease liabilities:			
Long-term debt	$ 1,980.7	$ 1,980.0	$ 0.7
Finance lease liabilities	$ 720.0	$ 719.7 *	$ 0.3
Working capital:			
Current assets	$ 15,529.9	$ 14,014.9	$ 1,515.0
Current liabilities	3,033.9	3,932.5 *	(898.6)
	$ 12,496.0	$ 10,082.4	$ 2,413.6

* The $719.7 million related to finance lease liabilities was classified within current liabilities as of December 31, 2021. See "*Tarrytown, New York Leases*" section below for details.

As of June 30, 2022, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Six Months Ended June 30, 2022 and 2021

(In millions)	Six Months Ended June 30, 2022	2021	$ Change
Cash flows provided by operating activities	$ 2,666.1	$ 1,295.2	$ 1,370.9
Cash flows used in investing activities	$ (2,119.2)	$ (933.2)	$ (1,186.0)
Cash flows used in financing activities	$ (36.4)	$ (484.6)	$ 448.2

Cash Flows from Operating Activities

As of June 30, 2022, Accounts receivable had decreased by $875.1 million, compared to December 31, 2021, primarily due to the Company's collection of amounts due from the U.S. government in connection with REGEN-COV sales in the fourth quarter of 2021. As of June 30, 2022, deferred tax assets increased by $381.0 million, compared to December 31, 2021, primarily related to the impact of the Tax Cuts and Jobs Act of 2017, which requires, for tax purposes, the capitalization and amortization of research and development expenses effective for years beginning after December 31, 2021.

Cash Flows from Investing Activities

Capital expenditures during the six months ended June 30, 2022 included costs associated with the expansion of our manufacturing facilities in Rensselaer, New York (including the ongoing construction of a fill/finish facility and related equipment) and Limerick, Ireland, as well costs incurred in connection with our expansion of the Tarrytown, New York campus. We expect to incur capital expenditures of $620 million to $670 million for the full year of 2022 primarily in connection with the continued expansion of our manufacturing facilities (including the fill/finish facility) and the expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown, New York campus.

Asset acquisition, net of cash acquired, of $230.3 million during the six months ended June 30, 2022 was related to our acquisition of Checkmate.

Cash Flows from Financing Activities

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $828.4 million during the six months ended June 30, 2022, compared to $308.2 million during the six months ended June 30, 2021. For additional information related to cash flows from financing activities, see the "*Share Repurchase Program*" section below.

Share Repurchase Program

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock. The share repurchase program permits the Company to make 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.

During the six months ended June 30, 2022, we repurchased 1,227,288 shares of our Common Stock under the program and recorded the cost of the shares received, or $745.5 million, as Treasury Stock. As of June 30, 2022, $2.099 billion remained available for share repurchases under the program.

Tarrytown, New York Leases

In March 2022, we entered into a Second Amended and Restated Lease and Remedies Agreement (the "Restated Lease") with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor (the "Lessor"), which amends, restates, and extends our lease of laboratory and office facilities in Tarrytown, New York (the "Facility"). In March 2022, we also entered into a Second Amended and Restated Participation Agreement (the "Restated Participation Agreement") with Bank of America, N.A., as administrative agent, the Lessor, and a syndicate of financial institutions as rent assignees (collectively with the Lessor, the "Participants"), which amends and restates the original Participation Agreement entered into in March 2017.

The original Participation Agreement and certain related agreements were amended and restated in order to, among other things, (i) effect a five-year extension of the original March 2022 maturity date of the $720.0 million lease financing (which was previously advanced in March 2017 to finance the purchase price for the Facility) and the end of the term of our lease of the Facility from the Lessor to March 2027, at which time all amounts outstanding thereunder will become due and payable in full, and (ii) modify the rate of the interest or yield that is payable to the Participants. In accordance with the terms of the Restated Lease, we continue to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Restated Lease in an amount equal to a variable rate per annum, which was modified in connection with the Restated Lease, to be an adjusted one-month forward-looking term rate based on the Secured Overnight Financing Rate ("SOFR"), plus an applicable margin that varies with our debt rating and total leverage ratio.

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

The Restated Lease is classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised. The agreements governing the Restated Lease financing contain financial and operating covenants. Such financial covenants and certain of the operating covenants are substantially similar to the covenants set forth in our credit facility. The Company was in compliance with all such covenants as of June 30, 2022.

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, 2021 (filed February 7, 2022). There have been no material changes to our critical accounting policies and use of estimates during the six months ended June 30, 2022.

Future Impact of Recently Issued Accounting Standards

As of June 30, 2022, 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, 2021 (filed February 7, 2022). There have been no material changes to our market risks or to our management of such risks as of June 30, 2022.

ITEM 4. CONTROLS AND PROCEDURES

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

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2022 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 13 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 (as well as this report in general), references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees; and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), 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 SEC 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 commercialization of REGEN-COV and "next generation" monoclonal antibodies targeting SARS-CoV-2.

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 drug price control measures that have been or may be introduced in the United States by various federal and state authorities.
- 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 response to higher product demand or in anticipation of a potential regulatory approval, 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.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines.
- 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 and the U.K. Bribery 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 risks related to the personal data we collect, process, and share.

Risks Related to Our Reliance on or Transactions with Third Parties

- If our collaborations with Sanofi or Bayer or other third parties 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.
- We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions could adversely affect our business, operating results, and financial condition.

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, evolved into multiple new variants, and caused a global pandemic. This pandemic has adversely affected and/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 the imposition of various restrictions and mandates around the world to reduce the spread of the disease, including governmental orders that 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, order cessation of non-essential travel, and require proof of vaccination and/or negative COVID-19 test results. The COVID-19 pandemic has continued to ebb and flow, with different jurisdictions having higher levels of infections than others and new variants of the SARS-CoV-2 virus (such as the Omicron-lineage variants) emerging and spreading more easily and quickly than other variants. The trajectory and the ultimate impact of the pandemic are highly uncertain and subject to change and 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.

By way of example, continuation or re-imposition of various government-imposed or private-sector measures relating to the COVID-19 pandemic (including those we previously implemented, such as work-from-home policies for some employees) 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. 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. We and our employees may also be subject to government vaccine mandates, which may have a negative impact on our ability to retain employees or hire new employees and could adversely impact our business. In addition, our sales and marketing efforts were previously 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 be further reduced if shelter-in-place, social distancing, or similar orders remain in effect or are re-implemented 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, prospects, operating results, and financial condition.

Various government-imposed or private-sector measures relating to the COVID-19 pandemic (or the perception that such restrictions or limitations on the conduct of business operations could occur) previously impacted, and may impact in the future, personnel at our research and manufacturing facilities, our suppliers, and other third parties on which we rely, as well as 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 and services may be obtained from more than one supplier or provider, port closures and other restrictions, whether resulting from the COVID-19 pandemic or otherwise (including any government restrictions or limitations, such as those that may be imposed under the Defense Production Act), could materially disrupt our supply chain or limit our ability to obtain sufficient materials or services (including fill/finish services) required for the development and manufacturing of our products and 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 providers 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, hospitalizations, and deaths related to COVID-19 previously disrupted and may in the future disrupt the United States' healthcare and healthcare regulatory systems. These and other possible disruptions relating to the COVID-19 pandemic 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. In addition, some of our clinical trials were previously and may in the future be affected by the COVID-19 pandemic. This impact could result in further delays in site initiation and patient enrollment due to prioritization of hospital resources toward the COVID-19 pandemic, patients' inability to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, and restrictions on trial initiations imposed by hospitals and other trial sites as a result of the COVID-19 pandemic. 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, was previously and may in the future be delayed or disrupted. We continue to evaluate the adverse impact of the COVID-19 pandemic on an individual trial basis. Any such disruptions 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.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it previously caused significant disruption of global financial markets and could cause more economic disruption in the future, making 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.

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 commercialization of REGEN-COV and "next generation" monoclonal antibodies targeting SARS-CoV-2.

In response to the COVID-19 pandemic, we developed REGEN-COV (known as Ronapreve in other countries outside the United States), a novel investigational antibody cocktail treatment designed to prevent and treat infection from the SARS-CoV-2 virus. REGEN-COV received an EUA from the FDA in November 2020 for the treatment of mild to moderate COVID-19 in certain patients. However, based on laboratory data that showed markedly decreased binding to the Omicron spike protein, REGEN-COV is highly unlikely to be active against the Omicron-lineage variants. In January 2022, the FDA revised the EUA to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. With this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions, since Omicron-lineage variants are currently dominant across the United States.

In light of these developments, we cannot predict whether (if at all) or to what extent REGEN-COV may be reauthorized for use by the FDA in any such jurisdictions in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA based on its determination that the underlying health emergency no longer exists or warrants such authorization or other reasons. Similar limitations on the use of REGEN-COV may also be imposed by foreign regulatory authorities in jurisdictions where REGEN-COV is currently authorized for use. It is also possible that the FDA and certain other regulatory authorities may not grant REGEN-COV full marketing approval for the treatment or prevention of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use. In July 2022, the FDA notified us that its review of the BLA for REGEN-COV to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals is ongoing; it is possible that approval of this BLA may be further delayed or not granted at all. Further, besides currently available therapeutic and prevention options for COVID-19, additional products for treatment or prevention of COVID-19 that are more efficacious, more easily administered, more cost-effective, or otherwise superior may be successfully developed; and utilization of REGEN-COV previously was, and any future utilization may be, adversely impacted by other factors, such as the widespread availability of vaccines providing acquired immunity against COVID-19, other products for treatment or prevention of COVID-19, or the distribution model for REGEN-COV. Any of these factors may further negatively impact any potential future uptake or commercialization of REGEN-COV, and such impact may be material. The intense public interest, including speculation by the media, in the development and commercialization of monoclonal antibodies and other products for treatment or prevention of COVID-19 has caused or contributed to significant volatility in our stock price, which may continue as data and other information from any studies evaluating REGEN-COV (whether conducted by us or others), our "next generation" monoclonal antibodies targeting SARS-CoV-2 discussed below, and third-party product candidates for the treatment or prevention of COVID-19 as well as any other regulatory actions become public. We are also subject to similar risks in connection with the development and potential commercialization of any such "next generation" monoclonal antibodies.

In addition to our REGEN-COV program, we are progressing "next generation" monoclonal antibodies targeting SARS-CoV-2 that are active against Omicron, Delta, and other variants, and have initiated a first-in-human trial of one of these "next

generation" antibodies. There can be no assurance as to the timing or success of this study or any future studies evaluating "next generation" antibodies and whether any of such antibodies will retain activity against present or future variants of concern.

We also face risks related to our significant investment in the development, supply, allocation, distribution, pricing, and commercialization of REGEN-COV and our "next generation" monoclonal antibodies (together with REGEN-COV referred to below as "our COVID-19 monoclonal antibodies"). Given the severity and urgency of the COVID-19 pandemic, we have committed and may continue to commit significant capital and resources to fund and supply clinical trials and to accelerate and scale up the production of our COVID-19 monoclonal antibodies, which involves a complex manufacturing process that is both resource- and time-sensitive. For example, the impact of prioritizing certain manufacturing-related resources for our COVID-19 monoclonal antibodies includes, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products (including any future demand for our COVID-19 monoclonal antibodies), our ability to re-establish successfully our customary manufacturing cadence, and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient quantities to satisfy our commercial and development needs. We expect our investment in the development and manufacture of our COVID-19 monoclonal antibodies to continue through 2022 and potentially 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 a new EUA for any of our "next generation" monoclonal antibodies, or obtain regulatory approvals for any of the foregoing, or if we make a strategic decision to discontinue development of, or not commercialize, our COVID-19 monoclonal antibodies or are otherwise not successful in their commercialization, we may be unable to recoup our significant expenses incurred to date and/or in the future related to the development and production of our COVID-19 monoclonal antibodies. While we previously recognized significant revenues in connection with sales of REGEN-COV, the degree to which future sales of our COVID-19 monoclonal antibodies will continue to impact our results of operations is highly uncertain.

We and our collaborator Roche have faced and may in the future face additional challenges related to the allocation of supply of REGEN-COV and other COVID-19 monoclonal antibodies (as applicable), particularly with respect to geographic distribution. For example, if supplies of REGEN-COV are constrained in response to future demand, it is possible that the U.S. government may limit or restrict our and/or Roche's ability to distribute and commercialize REGEN-COV outside the United States. In addition, as a result of the emergency situations in many countries, there is a heightened risk that products for treatment or prevention of COVID-19 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, our July 2020 agreement with the U.S. government relating to REGEN-COV gives the U.S. government, among other rights, 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 our COVID-19 monoclonal antibodies), 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 development program for our COVID-19 monoclonal antibodies, including any allocation, distribution, or pricing decisions. If we are unable to successfully manage these risks, we could face significant reputational harm, which could, among other adverse consequences, 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 six months ended June 30, 2022 and 2021, EYLEA net sales in the United States represented 54% and 36% 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 are 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 have been or 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 branded and biosimilar 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;
- 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;
- 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, Praluent, and REGEN-COV (described further in Note 13 to our Condensed Consolidated Financial Statements included in this report), as well as other risks relating to our marketed products and product candidates 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 13 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); and
- 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.

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 or satisfy other obligations for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies (such as those required under an accelerated approval by the FDA or other similar type of approval), 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 ("PBMs"), 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. 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 most of our 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 may continue to 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 PBMs, 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 PBMs) 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 (in addition to those already in effect) 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. President Biden and various members of his administration and the current U.S. Congress have indicated that lowering drug prices continues to be a legislative and political priority, as evidenced, for example, by the "Executive Order on Promoting Competition in the American Economy" issued by President Biden in July 2021. The main proposal aimed at drug pricing introduced at the federal level as part of the "Build Back Better Act" (portions of which may be enacted into law even if the entire bill is not) includes measures that would allow the government to negotiate prices of certain prescription drugs under Medicare (including those covered under Medicare Part B, such as EYLEA) ("Drug Price Negotiation Program") and would redesign the Medicare Part D benefit to limit patient out-of-pocket drug costs and shift liabilities among stakeholders, including manufacturers. It was recently reported that Democrats in the U.S. Senate reached an agreement on a legislative proposal that would include a Drug Price Negotiation Program; it is unclear whether this proposal will be enacted into law in the current form, how this proposal would be implemented if approved, and the extent to which this proposal (if approved) would ultimately impact reimbursement levels of our marketed products covered under Medicare Part B (such as EYLEA). 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, PBMs and other managed-care organizations often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one PBM 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 competitors, regardless of their size, may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with other 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), Novartis' Beovu® (brolucizumab), and Genentech/Roche's Susvimo® (ranibizumab ocular implant) and Vabysmo® (faricimab-svoa), as well as Samsung Bioepis Co., Ltd. and Biogen Inc.'s biosimilar referencing Lucentis. 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. 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 increasingly competitive. In atopic dermatitis, there are topical and systemic JAK inhibitors and an antibody against IL-13 approved for atopic dermatitis and others are in development. In addition, a number of companies are developing antibodies against IL-4Ra, IL-13Ra1, OX40(L), and/or IL-31R. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or thymic stromal lymphopoietin ("TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP and EoE. 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 the IL-33 ligand or receptor. Dupixent also faces competition from 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 (some of which were approved in the relevant indications and commercialized before Libtayo), 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, ANGPTL3 and IL-6 and/or IL-6R, which currently (or, for product candidates in development, may in the future if approved) compete with Praluent, Evkeeza, and Kevzara, respectively.

Product Candidates

Our *VelocImmune* technology, other antibody generation technologies, and 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 RNAi, chimeric antigen receptor T cell (CAR-T cell), and gene therapy 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 or other treatments 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) for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, under the terms of our Antibody Collaboration, we and Sanofi co-commercialize Dupixent in the United States and, as further discussed below, certain jurisdictions outside the United States. As a result, we rely in part on Sanofi's sales and marketing organization for Dupixent. If we and Sanofi fail to coordinate our sales and marketing efforts effectively, sales of Dupixent may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent. 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 in countries outside the United States. While we exercised our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States and have commenced this co-commercialization, we will continue to rely in part on Sanofi's sales and marketing organization in such jurisdictions and there can be no assurance that we will be able to successfully conduct such co-commercialization in the expected time frame or at all.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see "Risks Related to Our Reliance on or Transactions with 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 commercialize EYLEA outside the United States would be materially harmed*" below and "Risks Related to Our Reliance on or Transactions with Third Parties - *If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, 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 or co-commercialize with us 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 with Sanofi, pricing and reimbursement for the products commercialized or co-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 our marketed products for which we record net product sales in the United States to several distributors and specialty pharmacies, as applicable, which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the six months ended June 30, 2022 and 2021, our gross product sales of such products to two customers accounted on a combined basis for 85% and 49% of our total gross product revenue, respectively. We expect 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 a fully established organization for the sales, marketing, and distribution of marketed products outside the United States. We will need to establish some or all of these capabilities outside the United States for any product we decide to independently commercialize or co-commercialize outside the United States. For example, following the exercise of our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, we have begun establishing certain commercial capabilities for Dupixent in such jurisdictions. In addition, we and Sanofi recently amended the IO Collaboration to transfer the rights to develop, commercialize, and manufacture Libtayo exclusively to our Company, on a worldwide basis, over the course of a defined transition period, and we will need to establish commercial, development, and manufacturing capabilities for Libtayo in certain jurisdictions outside the United States. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Collaboration, License, and Other Agreements - Sanofi." 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 an existing collaborator 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 capabilities in the relevant markets or make arrangements with third parties to perform these services, any of which will 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 (including as it relates to Dupixent and Libtayo) within an acceptable time frame, without incurring substantial expenses, 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 or other authorization. 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. Additionally, the FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. 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 or product labeling updates for 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 post-marketing 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. Obligations equivalent in scope, but which can vary widely in application, apply in foreign countries.

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. The FDA's goal for a standard review is to review the application within 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, and may be delayed for reasons beyond our control. For example, we were recently informed that an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe will likely delay the FDA's decision on the sBLA for the combination treatment of Libtayo with chemotherapy in NSCLC until after the September 19, 2022 target action date. 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. Procedures that are equivalent in scope, but which can vary widely in application, apply in foreign countries.

The FDA and comparable foreign regulatory authorities enforce Good Clinical Practice requirements ("GCPs") and other regulations and legal requirements 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 and similar instances of non-compliance with GCPs could result in non-approval of our product candidates by the FDA or foreign regulatory authorities such as the EC, or we or the FDA or such other regulatory authorities 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 and such comparable foreign regulatory authorities require 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. Additionally, manufacturers of biological products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to any commitments made in the applicable BLA. 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 with cGMP, the FDA and comparable foreign regulatory authorities can impose monetary penalties or other civil or criminal 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.

We are also subject to ongoing requirements imposed by the FDA and comparable foreign regulatory authorities governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping, and reporting of safety and other post-marketing information. The holder of an approved BLA or foreign equivalent is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA or foreign equivalent must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA regulations and those of foreign regulatory authorities and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition to the standard drug approval process, the Secretary of HHS may authorize the issuance of, and the FDA Commissioner may issue, an EUA to allow an unapproved medical product to be used in an emergency based on criteria established by the Food, Drug, and Cosmetic Act, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. For example, REGEN-COV has been authorized for use in certain individuals in the United States based on an EUA from the FDA. An EUA terminates when the emergency determination underlying the EUA terminates. The FDA may also revoke, revise, or restrict an

EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorization or the medical product is no longer effective in diagnosing, treating, or preventing the underlying health emergency. For example, in January 2022, the FDA revised the EUA for REGEN-COV to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. With this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions, since Omicron-lineage variants are currently dominant across the United States. Any such termination, revocation, or revision of an EUA 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. For example, during the fourth quarter of 2021, we recorded a charge of $231.7 million to write down REGEN-COV inventory.

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 may ask for additional data in order to begin a clinical study, including phase 3 clinical trials required to submit a Marketing Authorization Application ("MAA") in the EU. In addition such authorities often have the authority to require post-approval studies, such as a post-authorization safety study ("PASS") and/or post-authorization efficacy study ("PAES"), which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can market that product or any other product in those countries.

Furthermore, in the European Economic Area ("EEA"), if we do not manage to retain a Qualified Person Responsible for Pharmacovigilance ("QPPV"), to maintain a Pharmacovigilance System Master File ("PSMF"), or to comply with other pharmacovigilance obligations, we may be at risk of our clinical trials being closed prematurely, our marketing authorization being suspended, and we may be subject to other enforcement actions by the national competent authorities of the EEA or the EC.

The exact requirements concerning pharmacovigilance reporting may differ in the numerous countries in which we conduct clinical trials. Failure to comply with the related pharmacovigilance requirements may result in the premature closure of the clinical trials and other enforcement actions by the relevant regulatory authorities.

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 or retain a sufficient number of patients to achieve a statistically significant result or the desired level of statistical significance for the endpoint in question, 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 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.

Additionally, conducting clinical trials in foreign countries presents additional risks, including political and economic risks that are not present in the United States, such as armed conflict and economic embargoes or boycotts. For example, we and our collaborators are currently conducting and may in the future conduct or initiate clinical trials with sites in Russia and/or Ukraine. While we currently do not expect the conflict between Russia and Ukraine and related developments to have a

significant impact on our ability to obtain results from clinical trials conducted by us or our collaborators, actions taken by Russia or potentially other countries in Ukraine and surrounding areas may adversely affect our ability to adequately conduct certain clinical trials and maintain compliance with relevant protocols due to, among other reasons, the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government-imposed curfews, warfare, violence, or other governmental action or events that restrict movement. These developments may also result in our inability to access sites for monitoring or to obtain data from affected sites or patients going forward. We could also experience disruptions in our supply chain or limits to our ability to provide sufficient investigational materials in Ukraine and surrounding regions. Clinical trial sites may suspend or terminate the trials being conducted and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in such trials. Alternative sites in these areas may not be available and we may need to find other countries to conduct the relevant trials. Furthermore, military action may prevent the FDA or other regulatory agencies from inspecting clinical sites in these countries. Such interruptions may delay our plans for clinical development and approvals for our product candidates.

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) 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.

In some jurisdictions such as the EU, initiating phase 3 clinical trials and clinical trials in the pediatric population is subject to a requirement to obtain approval or a waiver from the competent authorities of the EU Member States and/or the European Medicines Agency ("EMA"). If we do not obtain such approval, our ability to conduct clinical trials and obtain marketing authorizations or approvals may be severely impaired and our business may be adversely impacted.

Certain of our research and development activities are conducted at our existing facilities primarily located in Tarrytown, New York. As we continue to expand, we may lease, operate, purchase, or construct additional facilities to expand our research and development capabilities in the future. Expanding our research and laboratory facilities may require significant time and resources. Further, we may be unable to pursue our research and development efforts if the relevant facility were to cease operations due to fire, climate change, natural disasters, acts of war or terrorism, or other disruptions. Any related delays may interfere with our research and development efforts and our business may be adversely impacted.

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 had 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 have failed to meet the relevant endpoints. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees ("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 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 and aflibercept 8 mg, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully commercialize EYLEA and to obtain regulatory approval for aflibercept 8 mg. 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 aflibercept include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. There is no guarantee that we will be able to successfully obtain regulatory approval for aflibercept 8 mg. In addition, commercialization of EYLEA or our other products and potential future commercialization of aflibercept 8 mg or our other product candidates 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. These and other complications or issues or side effects could harm further development and/or commercialization of EYLEA as well as further development and potential future commercialization of aflibercept 8 mg.

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 regulatory 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, eye problems (including conjunctivitis and keratitis), injection-site reactions, eye and eyelid inflammation, cold sores, oropharyngeal pain, eosinophilia, insomnia, toothache, gastritis, joint pain (arthralgia), parasitic (helminth) infections, and facial rash or redness; and the side effects previously reported for Libtayo include certain immune-mediated adverse reactions that may occur in any organ system or tissue, including 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. In addition, there are risks inherent in intravenous administration (which are used for some of our antibody-based products and product candidates), such as infusion-related reactions (including nausea, pyrexia, rash, and dyspnea). 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.

Many of 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, sometimes 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 13 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

For purposes of this subsection, references to our intellectual property (including patents, trademarks, copyrights, and trade secrets) include that of our collaborators and licensees, unless otherwise stated or required by the context.

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. For example, certain of our U.S. patents (including those pertaining to our key products, such as EYLEA) have been and may in the future 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, as described in Note 13 to our Condensed Consolidated Financial Statements included in this report. Post-grant proceedings are increasingly common in the United States and are costly to defend. In addition, patent applications filed outside the United States may be challenged by other parties, for example, by filing pre-grant third-party observations that argue against patentability or a post-grant opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 2,264,163 (which concerns genetically engineered mice capable of producing chimeric antibodies that are part human and part mouse) is the subject of opposition proceedings in the European Patent Office (the "EPO") (currently pending before its Boards of Appeal). In addition, on October 26 and October 27, 2021, anonymous parties initiated opposition proceedings in the EPO against our European Patent No. 2,944,306 (which concerns pre-filled syringes comprising ophthalmic formulations containing VEGF antagonists such as aflibercept for intravitreal administration), as described in Note 13 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. 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.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions or our ability to obtain, maintain, and enforce our intellectual property rights. Any such changes could also affect the value of our intellectual property or narrow the scope of our patents. For example, the World Trade Organization ("WTO") is currently considering an extension of a recently adopted waiver of certain intellectual property rights under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights for COVID-19 vaccines to include therapeutics. The timing of a decision on whether or not to extend the waiver is unknown. We cannot be certain that our intellectual property rights related to REGEN-COV or any other current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such extension or other rulemaking.

Additionally, the United States and other government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. Further, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patent holders from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.

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 other intellectual property proceedings relating to Dupixent, as described in Note 13 to our Condensed Consolidated Financial Statements. In addition, we are currently party to patent infringement and other proceedings relating to EYLEA and REGEN-COV, as described in Note 13 to our Condensed Consolidated Financial Statements.

We are aware of patents and pending patent applications owned by others that claim compositions and methods of treatment relating to targets and conditions that we are also pursuing with our products and/or product candidates. 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.

In addition, other parties may have regulatory exclusivity in the United States or foreign jurisdictions for products relating to targets or conditions we are also pursuing, which could prevent or delay our ability to apply for or obtain regulatory approval for our product candidates in such jurisdictions. For example, in the EU, a designated orphan drug is provided up to 10 years of market exclusivity in the orphan indication, during which time the EMA is generally precluded from accepting a MAA for a similar medicinal product unless it can be demonstrated that it is safer, more effective, or otherwise clinically superior to the original orphan medicinal product.

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 ("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, as discussed further under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to significant competition* - Marketed Products" above. 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 ROP 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. Refer to the table under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Programs in Clinical Development" for more information. 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. In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. As we increase our production in anticipation of potential regulatory approval for our product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. The COVID-19 pandemic has exacerbated and may in the future further exacerbate certain of these risks. For example, the impact of prioritizing certain manufacturing-related resources for our COVID-19 monoclonal antibodies includes, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products (including any future demand for our COVID-19 monoclonal antibodies), our ability to re-establish successfully our customary manufacturing cadence, and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient quantities to satisfy our commercial and development needs. We also rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties 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 are in the process of constructing fill/finish facilities (refer to Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for information about expected capital expenditures relating to this and other projects). 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 it 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 13 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 or otherwise authorized for use. 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. For example, during the fourth quarter of 2021, we recorded a charge of $231.7 million to write down REGEN-COV inventory.

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, supply chain interruptions or constraints (including with respect to natural gas and other raw materials), contaminations, fire, climate change, 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 most of our product candidates are biologics, they require processing steps that are more difficult than those required for many other 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 and Russia's invasion of Ukraine, which have exacerbated many of these issues). 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. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

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, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and sales representatives' communications. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. Any such failures could also cause significant reputational harm. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal civil False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. The U.S. federal healthcare program anti-kickback statute (the "AKS") prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving payments or other remuneration, directly or indirectly, to induce or reward someone to purchase, prescribe, endorse, arrange for, or recommend a product or service that is reimbursed under federal healthcare programs such as Medicare or Medicaid. 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. The Bipartisan Budget Act of 2018 has increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal anti-kickback statute.

The federal civil False Claims Act prohibits any person from, among other things, 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. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Pharmaceutical companies have been investigated and/or 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. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal fraud and false statement statutes that extend to non-government health benefit programs.

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, damages, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment for individuals and the curtailment or restructuring of operations. 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 13 to our Condensed Consolidated Financial Statements included in this report, we are party to civil litigation initiated in June 2020 by the U.S. Attorney's Office for the District of Massachusetts concerning our support of a 501(c)(3) organization that provides financial assistance to patients; and we are cooperating with pending government investigations 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. licensed physicians and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. 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. Beginning in 2022, applicable manufacturers also are required to report information (starting with information collected during 2021) regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. We also have similar reporting obligations in other countries based on laws, regulations, and/or industry trade association requirements.

We continue to dedicate significant resources to comply with these requirements and need to be prepared to comply with additional reporting obligations outside the United States that may apply in the future. 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; restrict when pharmaceutical companies may provide meals or gifts to prescribers or engage in other marketing-related activities; require identification or licensing of sales representatives; and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

We participate in the Medicaid Drug Rebate program, the Public Health Service's 340B drug pricing program (the "340B program") (which is administered by the Health Resources and Services Administration ("HRSA")), the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program, and the Tricare Retail Pharmacy Program.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. Such interpretation can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also decide to terminate our Medicaid drug rebate agreement, or HRSA could decide to terminate our 340B program participation agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our financial results. The final regulation governing the Medicaid Drug Rebate program issued by CMS has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we have taken in our implementation of the final regulation. Other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program may have a similar impact.

In addition, the final regulation issued by HRSA regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities has affected our obligations and potential liability under the 340B program. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an ADR process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. Further, any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the PPACA or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations.

We have obligations to report the average sales price for certain of our drugs to the Medicare program as a part of our agreement to participate in the Medicaid Drug Rebate program. For calendar quarters beginning January 1, 2022, we need to report the average sales price for certain drugs under the Medicare program regardless of whether we participate in the Medicaid Drug Rebate program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Starting in 2023, manufacturers must pay refunds to Medicare for single-source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract-based requirements under the VA/FSS and/or Tricare programs can subject a manufacturer to civil monetary penalties. These program and contract-based obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the

government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and/or response to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

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 the United States (which have recently increased, and are expected to continue to increase, due to, in part, our efforts to establish our commercialization and co-commercialization capabilities in certain jurisdictions outside 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 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. For example, in March 2022, the SEC proposed new rules for extensive and prescriptive climate-related disclosure in annual reports and registration statements, which would also require inclusion of certain climate-related financial metrics in a note to companies' audited financial statements. Also in March 2022, the SEC proposed rules that are intended to enhance and standardize disclosures regarding cybersecurity risk management, strategy, and governance, as well as cybersecurity incident reporting, by public companies. Our efforts to comply with these requirements and regulations (as well as corporate governance and disclosure expectations of investors and other

stakeholders) 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 cGMP requirements 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 other significant changes in legislation, regulation, and government policy, including with respect to government reimbursement changes and drug price control measures (such as 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 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. For example, we recently commenced co-commercialization activities under the Antibody Collaboration related to Dupixent in certain jurisdictions outside the United States and we will need to establish commercial capabilities related to Libtayo outside the United States following the recently announced amendment to the IO Collaboration. 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, including those with which we and/or our collaborators must comply in order to maintain our marketing authorizations outside the United States;
- other laws and regulatory and industry trade association 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, including as a result of Russia's invasion of Ukraine;
- 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." The transition period for Brexit expired on December 31, 2020 following the entry into a trade agreement that now governs the United Kingdom's relationship with the EU. 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. For example, the impact of Brexit on the ongoing validity in the United Kingdom of current EU authorizations for medicinal products and on the future process for obtaining and maintaining marketing authorization for pharmaceutical products manufactured or sold in the United Kingdom remains uncertain. 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 for uncertain tax positions that involve significant management judgment as to the application of law. The Internal Revenue Service or other domestic or foreign taxing authorities have previously disagreed, and may in the future 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 (see also Note 14 of the Company's Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021). Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country, changes in tax laws and regulations, and tax effects of the accounting for stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control). Changes to U.S. tax laws and/or recommendations from the Organization for Economic Co-operation and Development (the "OECD") regarding a global minimum tax and other changes being considered and/or implemented in countries where we operate could materially impact our tax provision, cash tax liability, and effective tax rate. In addition, recommendations by the OECD and the EU could 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 risks related to the personal data we collect, process, and share.

Our ability to conduct our business is significantly dependent on the data that we collect, process, and share in discovering, developing, and commercializing drug products. These data are often considered personal data and are therefore regulated by data privacy laws in applicable jurisdictions.

Our activities outside the U.S., including clinical trial programs and research collaborations (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 non-U.S. data protection laws, including the EU's General Data Protection Regulations ("GDPR"). The GDPR has a wide range of compliance obligations, including increased transparency requirements and 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. In June 2021, the European Commission introduced new standard contractual clauses required to be incorporated into new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside the EU. Compliance with these requirements has been and is expected to continue to be costly and time consuming.

We conduct clinical trials in many countries around the world, which have new or evolving data privacy laws that have resulted in increased liability in the management of clinical trial data, and additional contractual and due-diligence obligations that could lead to a delay in clinical trial site start-up. There is an increase of enforcement activities in various EU countries that require evidence of compliance with local data privacy requirements. 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 the EU into the U.S. may

result in the imposition of criminal and administrative sanctions on such collaborators or impact the flow of personal data outside the EU, which could adversely affect our business and could create liability for us.

Most U.S. health care providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations promulgated under HIPAA. 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 HIPAA. Regeneron is not a covered entity or business associate under HIPAA and thus is not subject to its requirements. However, we could be subject to criminal penalties if we, our affiliates, or our agents knowingly receive, use, or disclose protected health information ("PHI") in a manner that is not permitted under HIPAA. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive PHI from a health care provider or research institution that has not satisfied HIPAA's requirements for its disclosure. There are instances where we collect and maintain personal data, which may include health information that is outside the scope of HIPAA but within the scope of state health privacy laws or similar state level privacy legislation. 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).

Consumer protection laws impact the manner in which we develop and maintain processes to support our patient assistance programs, product marketing activities, and the sharing of employee and clinical data for internal and third-party commercial activities. Several U.S. states have proposed and passed consumer privacy laws, which were modeled after the California Consumer Privacy Act of 2018 (the "CCPA"). The CCPA, which became effective on January 1, 2020, is a consumer protection law that establishes requirements for data use and sharing transparency and provides California residents with personal data privacy rights regarding the use, disclosure, and retention of their personal data. Amendments to the CCPA have, among other things, imposed new obligations to provide notice where personal data will be de-identified. These laws and regulations are constantly evolving and may impose limitations on our business activities. Several other U.S. states have introduced similar consumer protection laws that may go into effect in the near future. At the federal level, Section 5 of the Federal Trade Commission Act is a consumer protection law that bars unfair and deceptive acts and practices and requires, among other things, companies to notify individuals that they will safeguard their personal data and that they will fulfil the commitments made in their privacy notices. The Federal Trade Commission has brought legal actions against organizations that have violated consumers' privacy rights or have misled them by failing to maintain appropriate security.

Furthermore, health privacy laws, data breach notification laws, consumer protection laws, data localization laws, and genetic privacy 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 data. New state level genetic privacy and consumer protection laws in the United States may require additional transparency and permissions in our informed consent forms. Moreover, individuals about whom we or our collaborators obtain health or other personal data, 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. Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. Compliance with these laws requires a flexible privacy framework as they are constantly evolving. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation, and/or adverse publicity. Federal regulators, state attorneys general, and plaintiffs' attorneys have been active in this space. 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 data 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 or Transactions with Third Parties

If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, 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 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.

If Sanofi terminates the Antibody 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 it is co-developing with us, 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 (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 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 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 or other 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, such as due to Russia's invasion of Ukraine) 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.

We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions could adversely affect our business, operating results, and financial condition.

We may acquire companies, businesses, products, or product candidates that complement or augment our existing business. For example, in May 2022, we completed our acquisition of Checkmate Pharmaceuticals, Inc. The process of proposing, negotiating, completing, and integrating any such acquisition is lengthy and complex. Other companies may compete with us for such acquisitions. In addition, we may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational, and financial resources, result in a loss of key personnel of the acquired business, and could prove to be more difficult or expensive than we predict. The diversion of our management’s attention and any delay or difficulties encountered in connection with any acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, products, or product candidates, which may result in dilution for shareholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, businesses, products, or product candidates or to enter into other significant transactions, we will conduct business, legal, and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits

from acquisitions we have consummated or may consummate in the future, whether as a result of unidentified risks or liabilities, integration difficulties, regulatory setbacks, litigation with current or former employees and other events, our business, operating results, and financial condition could be adversely affected. For any acquired product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, and the market for any such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we may experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants, and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our operating results for particular periods.

Risks 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 the Chair of our board of directors. 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 Chair 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 related developments. 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. There is the potential that our systems may be directly or indirectly affected as nation-states conduct global cyberwarfare, including in connection with the current Russia-Ukraine hostilities.

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, and to oversee and monitor the security measures of our suppliers and/or service providers, there can be no assurance that our efforts will prevent service interruptions or security breaches. In addition, we depend in part on third-party security measures over which we do not have full control to protect against data security breaches.

If we or our suppliers and/or service providers fail to maintain or protect our information technology systems and data security effectively, or fail to anticipate, plan for, or manage significant disruptions to these systems, we or our suppliers and/or service providers could have difficulty preventing, detecting, or controlling such disruptions or security breaches, which could result in

legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, government investigations, breach of contract claims, 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

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 and other similar 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 our senior unsecured notes at maturity or redeem, repurchase, or refinance the notes prior to maturity on acceptable terms or at all. In addition, in March 2022, we completed an extension of the $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 is set to expire in March 2027. Refer to Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - *Tarrytown, New York Leases*" for further details. Our ability to refinance or to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of our marketed products, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

Our indebtedness could adversely impact our business.

We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of June 30, 2022, we had an aggregate of $2.701 billion of outstanding indebtedness under our senior unsecured 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 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 June 30, 2022, we had $3.395 billion in cash and cash equivalents and $10.587 billion in marketable securities (including $875.1 million in equity securities). Our investments consist primarily of debt securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect our business, operating results, and financial condition.

We are subject to risks related to uncertainty regarding the London Interbank Offered Rate ("LIBOR"), which is in the process of being phased out. The publication of U.S. dollar LIBOR for certain tenors and all non-U.S. dollar LIBOR tenors ceased after December 31, 2021 (other than certain sterling and Japanese yen settings being published on a synthetic temporary basis). Banks reporting information used to set U.S. dollar LIBOR for all other tenors are currently expected to stop doing so after June 30, 2023, although the LIBOR administrator may discontinue or modify LIBOR prior to that date. In 2021, the U.S. Federal Reserve Board and certain other regulatory bodies issued guidance encouraging banks and other financial market participants to cease entering into new contracts that use U.S. dollar LIBOR as a reference rate as soon as practicable and in any event no later than December 31, 2021. Although regulators in various jurisdictions have been working to replace LIBOR and have encouraged the development and adoption of alternative reference rates, such as the Secured Overnight Financing Rate ("SOFR"), there continues to be uncertainty regarding the nature of potential changes to and future utilization of specific LIBOR tenors, the development and acceptance of alternative reference rates, and other reforms. We cannot predict the consequences and timing of these developments or other market or regulatory changes related to the phase-out of LIBOR. A transition away from LIBOR as a benchmark for establishing the applicable interest rate may adversely affect our outstanding variable-rate indebtedness (if any), as well as floating-rate debt securities in our investment portfolio. For example, if a published U.S. dollar LIBOR is unavailable or no longer representative, interest for borrowings (if any) with an interest rate based on LIBOR under our revolving credit facility 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 prior to any LIBOR phase-out.

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 on our business, including future sales of REGEN-COV;
- 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 PBMs) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding (i.e., a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient);
- large sales of our Common Stock by our executive officers or other employees, directors, or significant shareholders (or the expectation of any such sales);
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) may be lower than the public float of other large public companies with broader public ownership. Therefore, the trading price of our Common Stock may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and

resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of June 30, 2022, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 38.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2022. 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 repurchase shares of our Common Stock or that we will repurchase shares at favorable prices.

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock (of which $2.099 billion remained available as of June 30, 2022). There can be no assurance of any future share repurchases or share repurchase program authorizations. 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 repurchase shares of our Common Stock at favorable prices, if at all.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of June 30, 2022, holders of Class A Stock held 14.4% 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 substantially influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of June 30, 2022:

- our current executive officers and directors beneficially owned 7.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2022, and 18.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2022; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 38.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2022. In addition, these five shareholders plus our Chief Executive Officer held approximately 45.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of June 30, 2022.

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.*"

Further, Sanofi, Bayer, and Teva are currently bound by certain "standstill" provisions under the January 2014 amended and restated investor agreement between us and Sanofi, as amended; our 2016 ANG2 license and collaboration agreement with Bayer; and our 2016 collaboration agreement with Teva, respectively. These provisions contractually prohibit Sanofi, Bayer, and Teva from seeking to directly or indirectly exert control of our Company or acquiring more than a specified percentage of our Class A Stock and Common Stock, taken together (30% in the case of Sanofi, 20% in the case of Bayer, and 5% in the case of Teva).

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 stock granted under one of our long-term incentive plans, during the three months ended June 30, 2022. Refer to Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for further details of the share repurchase program.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs *(in millions)*
4/1/2022–4/30/2022	43,252	$ 693.35	40,486	$ 2,464.9
5/1/2022–5/31/2022	7,141	$ 647.88	7,000	$ 2,460.4
6/1/2022–6/30/2022	615,026	$ 588.98	612,829	$ 2,099.4
Total	665,419 [(a)]		660,315 [(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 relates to Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock granted under one of our long-term incentive plans.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1*	Modification No. 05 to Project Agreement, dated as of March 22, 2022, by and between Regeneron Pharmaceuticals, Inc. (the "Registrant") and Advanced Technology International.
10.2*	Amended and Restated Immuno-Oncology License and Collaboration Agreement, dated as of June 1, 2022, by and between the Registrant and Sanofi Biotechnology SAS.
10.3*	Fifth Amendment to Amended and Restated License and Collaboration Agreement, dated as of June 1, 2022, by and between the Registrant, Sanofi Biotechnology SAS, and Sanofi.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Condensed Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2022 and 2021; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2022 and 2021; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021; 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: August 3, 2022

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

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

March 22, 2022

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

Attention:

Subject: Modification No. 05 to Project Agreement No. 01; MCDC2008-005

Reference: MCDC Base Agreement No. 2020-504

Dear :

In accordance with the terms and conditions of the referenced MCDC Base Agreement, Modification No. 05 hereby amends Project Agreement No. 01 as follows:

DESCRIPTION OF MODIFICATION

1) **The Term of the Project Agreement clause of the Project Agreement is hereby amended as indicated in bold below:**

2. TERM OF THE PROJECT AGREEMENT

The period of performance for this Project Agreement is from July 6, 2020 through **June 30, 2022** (*this is an eight (8) month no-cost extension*).

2) **Attachment A, Statement of Work, of the Project Agreement is hereby amended as attached herein.**

Except as provided herein, all Terms and Conditions of the referenced MCDC Base Agreement, Project Agreement, and preceding modifications remain unchanged and in full force and effect.

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 & CFO

Date: March 22, 2022

Advanced Technology International

By: /s/

Name:

Title:

Date: 3/23/2022

Attachment A

Statement of Work

(Incorporated as of Modification No. 05; changes to Sections 4.0, 5.0 and 6.0 are indicated in bold italics.)

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
Date Updated: March 22, 2022

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. Greater than 65 processes have been transferred since 2008 with a success rate of 100%. 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 deliver 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.

In addition, Regeneron, as a service to the Government, will engage one or more third party service providers (each a "Distributor") to perform storage and distribution activities for such drug product for the Government in the United States, at the direction of the Government. The Government will be solely responsible to determine the allocation of product to end users and to communicate such allocation determinations to the Distributor. The Government agrees that Regeneron will not be involved in or responsible for any such determinations.

Regeneron may conduct such activities itself or through one or more of its affiliates, including Regeneron Healthcare Solutions, Inc. References to "Regeneron" will be deemed to include such affiliates. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing Practices (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. In addition, Regeneron will engage the Distributor to perform storage and distribution of the product for the Government in the United States, at the Government's direction and control.

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, to the extent applicable, 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 approval 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. It is also important to note that the distribution and storage services performed for the Government by the Distributor engaged by Regeneron, are not part of the 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. Other deliverables will include product storage and support for the Government's distribution activities in the United States to be provided at the Government's direction.
- 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). In the event the FDA grants an EUA, the product will be distributed by the Distributor pursuant to direction from the Government (i.e., the Government will direct the Distributor where the product is to be distributed and in what quantities, and Regeneron will not be responsible for, or involved in, such direction).

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 up to 800,000 treatment courses, 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

3.0 REQUIREMENTS

3.1 Technical

- The Offeror's technical approach is expected to be similar, but not duplicative, to its manufacturing activities under its current agreements with the Biomedical Advanced Research and Development Authority (BARDA), including contract # HHSO100201700016C, and will include the following:
    - Drug Substance, Formulated Drug Substance, Drug Product (DS/FDS/DP) quality and control.
        - Regeneron will apply statistical process analysis to continuously qualify in-process controls and release parameters.
        - The manufacturing process will be evaluated against parameters that are correlated to process performance and product quality. Ranges for the performance of each unit operation will be established through process development recommended ranges, the generation of statistical limits based on small-scale studies, and/or continuous commercial-scale manufacturing experience. These ranges will be monitored during the execution of quality and control, and are designed to ensure that the process is in a state of control and to ensure that the manufacturing process operates in a consistent and reproducible manner. The quality and control runs will also confirm that the process and product impurity profiles are within limits, demonstrate the consistent removal of impurities, and demonstrate that the process is capable of operating within acceptable microbiological control limits. Additional sampling and testing beyond that needed to assess process performance, may be completed to further process understanding.
        - *Intermediate Hold Time Validation*: Intermediate hold time validation to be performed via combination of at scale and small scale executions:
            - Microbial Control: Where appropriate, microbial control data from at scale hold time studies, will be leveraged from historical validation runs with molecules which have similar equipment and sanitization procedures.
            - Chemical Stability: Chemical stability will be demonstrated using data from laboratory scale hold time studies performed for each of the prototypes, using material obtained from in-process pools from the 10,000 L manufacturing executions.

- *Media, Feed and Buffer Mixing Validation*: Preparation of buffers and media will be validated at commercial-scale. These validation studies will demonstrate that the preparation process consistently produces solutions meeting predefined limits for parameters indicative of homogeneity, such as pH, conductivity, osmolality, and turbidity. Where vessels of equivalent design and construction exist within the manufacturing facility, validation of media and buffer preparation will be performed on one representative vessel on at least three consecutive and successful executions.
- *Medium Storage Validation*: Medium storage validation will be separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Pre-filtration microbial control is specific to the raw materials and the environment, and post-filtration microbial control is specific to each storage container and the ability of the storage container to maintain a microbial free condition. Maximum storage times for medium solutions with respect to microbial control will be validated as necessary at commercial scale, through preparation and storage of medium for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established in the relevant validation protocol. Solutions will be prepared, stored for defined periods and tested for bioburden and endotoxin. Chemical stability of medium may be performed at small-scale to demonstrate storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the different feeds and medium used, provided the individual protocol justifies the bracket.
- *Buffer Storage Validation:* Buffer storage validation is separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Preparation holds are dependent on the solution composition. The worst- case solution for growth is determined using a risk-based approach, and post-filtration microbial control is specific to each vessel and the ability of a vessel to maintain a microbial free condition. Maximum storage times for buffer solutions will be validated as necessary at commercial-scale for microbial control, through preparation and storage of a non-growth inhibiting buffer for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established by the protocol. Buffer hold validation in stainless steel vessels will require ongoing evaluation and monitoring; however, buffer hold validation in disposable bioprocess containers may be shortened, if appropriate, by a bracketing approach. Solutions will be prepared, held and monitored over time for bioburden, endotoxin. Chemical stability of buffers may be performed at small-scale to demonstrate that storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the large number of buffers used, provided the individual protocol justifies the bracket.
- *Chromatography Column Sanitization and Storage Validation*: Any newly required studies will be performed to validate the cleaning and storage procedures for [* * *] chromatography columns used in the manufacture of the prototypes. In addition, the maximum allowable storage period following cleaning will be established for each of the chromatography resins.

- *Chromatography Column Cleaning Validation*: The efficacy of the solutions used to clean the chromatography columns will be examined as necessary over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning procedures will be assessed by sampling the post cleaning (post-use) Water for Injection (WFI) flush effluent; at approximately [* * *] into the flush for bioburden and endotoxin levels (the purpose of which is to demonstrate microbial control). In addition, Total Organic Carbon (TOC) will be measured to verify the absence of lot to lot protein carry over.
- *Chromatography Column Storage Validation*: The efficacy of the solutions used to store the chromatography columns will be examined, as necessary, over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning and storage procedures will be assessed by sampling the post storage (pre-use) WFI flush effluent for bioburden, endotoxin levels and TOC. The maximum allowable storage period for each column will be established based on the shortest of the three consecutive executions for which the column remained in the storage solution.
- *Establishment of In-Process Control (IPC) Program*: The IPC program will utilize Statistical Process Control (SPC) to monitor critical and general process parameters, and critical and general quality attributes for each lot manufactured. On completion of quality and control activities, the IPC development report will establish the set of parameters and attributes to be monitored, and justify appropriate action limits for each. Upon approval of the development report, a Process Performance Monitoring (PPM) Plan will be generated containing the list of IPCs, historical data, selection of monitoring tools and response to signal strategy, statistical summary, and visualization of the IPCs. The IPC development report and PPM Plan will be further updated as laboratory and production scale characterization and validation data is gained, once defined production milestones are achieved, and then annually afterward. The annual updates will assess the overall state of process control and include process capability analysis and assessment of evidence of special cause variation for all applicable IPCs. Process data for individual lots will be monitored through [* * *] PPM meetings, where any trend signals are identified and responded to. These meetings will be attended by subject matter experts from departments including, but not limited to, [* * *].

- **Master Cell Bank (MCB) Genetic Characterization**: [* * *].
- **Working Cell Bank (WCB) Genetic Characterization**: [* * *].
- **DS/FDS/DP Registration Stability**: Stability studies for DS/FDS/DP will be initiated and executed according to stability protocols, International Council for Harmonisation (ICH) guidelines and internal procedures. Quality and control lots will be stored and monitored at the routine long term storage condition per the Specification for [* * *]. Samples will also be stored and monitored at Accelerated [* * *] condition for [* * *], and Stress [* * *] condition for [* * *] for the evaluation and identification of degradation pathways of the molecule. Stability studies performed on the quality and control lots will support the shelf life of each prototype, and confirm that the manufacturing process is suitable for commercial-scale manufacture. All testing will be conducted in a GMP Quality Control (QC) Laboratory. Any Out of Specification (OOS) or Out of Trend (OOT) results will be investigated.

- **DS/FDS/DP Shipping Validation**: Shipping Validation by actual transport will be performed on the DS/FDS/DP of each prototype to cover a distance and duration that will exceed routine shipment to the intended fill site. Successful shipping validation of intended shipping lanes is based on the ability of the container to maintain the product at a specified temperature, to preserve product quality, and meet specifications.
- **DS/FDS/DP Photostability Studies**: To determine overall photosensitivity of DS/FDS/DP per ICH requirements, a study will be performed at [* * *] under [* * *] and [* * *] light. Samples will be oriented for maximum light exposure using container closures designed for direct exposure, immediate pack/marketing pack, and a foil covered control. Testing will then be performed on [* * *] sample sets for stability indicating attributes.
- **QC Reference Standard Production and Stability**: Reference standards for the individual DS/FDS/DP GMP lots will be generated according to internal standard operating procedures. The DS/FDS/DP for each prototype will be filled as a product reference standard. The first manufactured lot (lead lot) will be sub-aliquoted into single use vials, stored and routinely monitored at [* * *] by Offeror's Quality Control personnel. The reference standard will be qualified prior to use, according to specifications. A Certificate of Qualification (CofQ) will be issued for each individual reference standard at the time of initial qualification and following recertification testing. A stability study to monitor the critical quality attributes of each reference standard will also be conducted.
- **Assay Validation**: Will be performed as necessary to support any applicable EUA or other regulatory requirements.
- **Manufacturing**: Following the completion of the activities described above, Offeror will manufacture prototypes at scale in order to achieve the intended scope of the contract.
- **Label/Pack**: Labeling and packaging of investigational product for clinical studies or for use under an EUA or approval, will be completed at a GMP contract manufacturing organization managed by Offeror's External Manufacturing group.
- **Storage** and Distribution: Packaged and labeled material storage will be managed by Offeror's External Manufacturing group and, if an EUA is granted, the Distributor will store and distribute the product in the U.S. at the direction of the Government (i.e., the Government will direct the Distributor as to where the product is to be distributed and in what quantities, and Regeneron will not be responsible for, or involved in, such direction). The process and obligations are illustrated in Figure 1 below.

Figure 1 – Distribution Process:

[* * *]

3.2 Management and Reporting

3.2.1 Program Management

Below are the individuals currently assigned to key roles on the project team. Regeneron reserves the right to make personnel changes which will be communicated accordingly.

a. Regeneron will manage, integrate and coordinate all activities, including utilizing Regeneron's state-of-the-art technical and administrative infrastructure to ensure efficient planning, initiation, implementation and direction of contracted activities.

b. The [* * *], is responsible for guiding the project approach and scope of this Program.

c. [* * *], will serve as Lead PI for this Program. The PI will be responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including any projects undertaken by subcontractors.

d. A [* * *], will be responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities, costs incurred, and program management for this Program. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract.

e. [* * *], will provide development of compliant subcontracts, consulting, and other legal agreements.

f. [* * *], will be responsible for financial management and reporting on all activities conducted by Regeneron and any subcontractors.

g. A [* * *], will be responsible for facilitating the development of integrated CMC plans and for monitoring and tracking the progress of the CMC milestones.

h. A [* * *], will be responsible for management of batch disposition, oversight of discrepancy investigations, and to ensure all released product conforms to GMP standards.

i. A [* * *], will be responsible for analytical method development, method transfer and specification development.

j. A [* * *], will be responsible for ensuring Regeneron quality, preclinical, and clinical drug development programs are conducted in compliance with regulations governing pharmaceutical drug development, and with project specific regulatory commitments/requirements, and will serve as the liaison for communications with the US Food and Drug Administration.

k. Regeneron shall provide Quarterly Progress Reports, which shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period.

l. Regeneron shall provide Annual Progress Reports, which shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period.

m. Regeneron shall provide Draft and Final Reports, which shall include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall describe the results achieved.

n. Regeneron shall participate in regular meetings to coordinate and oversee the contract effort, as directed by a single point of contact established by the Government. Such meetings may include, but are not limited to, meetings of Regeneron and subcontractors to discuss clinical manufacturing progress, product development, scale-up manufacturing development, preclinical/clinical study designs and regulatory issues, meetings with individual contractors and other Health and Human Services (HHS) officials to discuss the technical, regulatory, and ethical aspects of the program, and meetings with technical consultants to discuss technical data provided by Regeneron. Regeneron shall also consult with the Government as required in

connection with meetings and submissions to regulatory agencies, including the FDA. The Government will establish a single point of contact for regular meetings and coordinate all requests for information through such point of contact, such that Regeneron shall not be required to attend multiple meetings with different Government agencies for the same (or similar) subject matter, or respond to multiple requests for information or materials concerning the same (or similar) subject matter.

o. Regeneron shall participate in teleconferences at an agreed upon frequency between Regeneron and the Government to review technical progress.

3.2.2 Integrated Master Schedule (IMS)

Regeneron will provide an Integrated Master Schedule within [* * *] of the award, and shall update such schedule to reflect any material changes. Within an agreed upon timeframe of the effective date of the contract, Regeneron will make any agreed upon changes between Regeneron and Agreements Officer and/or Project Officer at the Government. The IMS shall be incorporated into the contract and will be used to monitor performance of the contract. Regeneron shall include the key milestones and Go/No-Go decision gates. The IMS for the period of performance will be accepted by the Government [* * *] of the Government's receipt of such IMS.

3.2.3 Reporting

On completion of a stage of the product development, as defined in the agreed upon IMS and Integrated Master Plan, Regeneron shall prepare and submit to the Project Officer and the Agreements Officer, reports from time to time that contain (i) reasonable detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria, and (ii) a description of the next stage of product development to be initiated, and a request for approval to proceed to the next stage of product development.

3.2.4 Data Management

Regeneron will utilize existing systems to implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of contract data. Provide analysis of data generated with contract funding to the Project Officer or Agreements Officer, upon request.

3.2.5 Technical and Financial Reporting

Technical Reports are described in Section 3.3.1 k., l. and m. They are also listed in the milestone schedule and deliverables table in Section 5 of this Statement of Work.

For Financial Reporting, firm fixed price or cost-reimbursement invoices will be submitted on a quarterly or monthly basis, as described in Section 5 below. Invoices will include data and technical reports sufficient to support the accomplishment of each milestone, as appropriate, during the invoicing period. Regeneron will provide quarterly Financial Status Reports outlining billed vs. budgeted activity for each period, and in aggregate for the contract.

3.2.6 Product Development Manufacturing Reports and Projections

Regeneron will provide manufacturing reports and manufacturing dose tracking projections/actuals, in the format and having the content mutually agreed upon by the Government and Regeneron. Regeneron will update the reports [* * *] during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared),

with the first deliverable submission within [* * *] of award/modification. For clarity, the reports described in this Section 3.2.6 apply to Formulated Drug Substance and Drug Product prior to delivery and acceptance by the Government. Tracking reports for product following delivery and acceptance, shall be set forth in the Memorandum of Understanding between Regeneron, the Distributor, and the Government.

4.0 DELIVERABLES

Offeror assumed [* * *]; Filled/Finished Drug Product Deliveries [* * *]. 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 2022)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Package/Label Product	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated

Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Support Distribution of Drug Product [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Quarterly Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
Annual Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
Quarterly Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
[* * *]	[* * *]	[* * *]	Limited Rights
		$465,861,635 **(FFP** and Cost Reimbursement)	

*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).
***Total Program Funds for distribution and [* * *] is a not-to-exceed amount, and shall be invoiced as described in Section 5.0 below.
****If an EUA is granted, then the product shall be transferred from VMI to the Distributor for distribution in the United States, as directed by the Government, and the VMI storage milestones shall be equitably adjusted.

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone No.	**Milestone Description (Deliverable Reference)**	**Due Date**	**Total Program Funds**
5.1	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.2	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.3	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.4	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.5	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.6	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.7	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.8	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.9	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.10	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.11	Quarterly Technical and Business Status Report, Reference ***3.2.1.k***	[* * *]	[* * *]
5.12	Annual Technical and Business Status Report, Reference ***3.2.1.l***	[* * *]	[* * *]
5.13	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.14	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.15	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.16	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.17	***Storage of Drug Product in VMI*** [* * *]	[* * *]	[* * *]
5.18	***Storage of Drug Product in VMI*** [* * *]	[* * *]	[* * *]
5.19	***Storage of Drug Product in VMI*** [* * *]	[* * *]	[* * *]
5.20	***Support of Distribution of Drug Product and*** [* * *]	[* * *]	[* * *]
		Total (Include Payment Type; FFP/CR):	**$465,861,635**
		Period of Performance:	**June 2020 – *June 2022***

The overall price is a not-to-exceed price of $465,861,635, structured as a firm fixed price of [* * *] and a cost reimbursement budget (for support of distribution and [* * *] costs only) of [* * *]. Milestone payments will be made monthly or quarterly. The Parties acknowledge that deliverables for a given month or quarter may not correspond to the table above. In the event the deliverables in a given month or quarter are less than or exceed the projected quantity for such

month or quarter, or in the event of a monthly invoice against an amount designated for a quarter in the table above, the milestone payment will be equitably adjusted based on the shortfall, excess or monthly amount, as applicable. With respect to the Distribution and Insurance Costs milestone (***5.20***), Regeneron shall invoice against such milestone based on actual, external costs incurred by Regeneron during the applicable period, plus an allowance for Regeneron's general and administrative expense. Milestone payment terms will be net 30 days.

Total pricing for Drug Substance and Drug Product 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, unless waived or otherwise not applicable. Drug product will not be co-formulated, except as otherwise mutually agreed upon by the parties. Unless and until otherwise mutually agreed upon, approximately [* * *] of the drug product produced under this Statement of Work will be filled in [* * *]. In order to change this allocation, Regeneron will require at least [* * *] prior written notice, in order to meet Regeneron's notification requirements to its fill/finish subcontractor. ~~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 of up to [* * *], as well as any additional drug product for such uses, as 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; [* * *]; raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products; and [* * *].

6.0 SALE, STORAGE, AND SHIPPING PROVISIONS

Upon acceptance by the Agreements Officer Representative of any lot of antibodies under this contract, title to such antibodies will transfer as follows: upon delivery of drug product to vendor-managed inventory and the Government's corresponding written acceptance of the delivery of each such lot of drug product. The Government shall accept product that conforms to contract requirements based on a Certificate of Analysis (COA) provided by Regeneron, and the parties shall perform their obligations relating to product delivery set forth in the applicable Quality Agreement for the product. The Government's acceptance of product will be [* * *] provide written notice of acceptance or rejection [* * *]. In the event of an EUA, Regeneron will transfer product from VMI to the Distributor for distribution directed by the Government; provided that, product shall not be provided to the Distributor until it is accepted by the Government. Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government or distributed, as applicable, within the continental United States. Regeneron will [* * *] for all product stored as vendor-managed inventory, and while such product is in the possession of the Distributor and being distributed for the Government in the United States. With respect to product being distributed in the United States, [* * *] Government upon delivery from the Distributor to the end-user (e.g., the hospital, infusion center or other end-user). To the extent that Regeneron is responsible for the correction, repair or replacement of

Government property held in vendor-managed inventory or in distribution and in the possession of the Distributor, [* * *], the Government will [* * *] of such property. Vendor-managed storage of product manufactured under this agreement is supported through **June 30*, 2022 ~~2021 or, if an EUA is granted, for the 12-month period following an EUA.~~2022.*** As such, ***~~if an EUA is not granted,~~*** the Government must either (a) take possession on or before June 30, ***2022*** and provide Regeneron with disposition instructions in sufficient time to transfer physical material from Regeneron by this date, or (b) bilaterally modify this agreement to extend the period of vendor management of storage prior to this date. ***~~If an EUA is granted prior to June 30, 2021, then storage and distribution activities under the EUA shall be supported under this agreement for up to 12 months following the grant of an EUA, except that additional.~~ Additional*** costs may apply (and the storage milestones shall be equitably adjusted) if storage of product as VMI is required following the end of June 30, ***2022***.

The Government understands that prices identified in this contract include [* * *] applicable to material that will become Government property, including product stored as vendor-managed inventory or in the possession of the Distributor, and being distributed for the Government.

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: Includes, but is not limited to, [* * *]:

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”

63/030,260, filed May 26, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

63/033,198, filed June 1, 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”

63/034,348, filed June 3, 2020, “Methods for Treating or Preventing SARS-CoV-2 Infections and COVID-19 with Anti-SARS-CoV-2-Spike Glycoprotein Antibodies”

63/036,956, filed June 9, 2020, “Methods for Treating or Preventing SARS-CoV-2 Infections and COVID-19 with Anti-SARS-CoV-2-Spike Glycoprotein Antibodies”

63/038,274, filed June 12, 2020, “Methods for Treating or Preventing SARS-CoV-2 Infections and COVID-19 with Anti-SARS-CoV-2-Spike Glycoprotein Antibodies”

[* * *]

[* * *]

63/012,074, filed April 17, 2020, “Detection Assays for Coronavirus Neutralizing Antibodies”

63/020,445, filed May 5, 2020, “Detection Assays for Coronavirus Neutralizing Antibodies”

63/029,267, filed May 22, 2020, “Detection Assays for Coronavirus Neutralizing Antibodies”

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, except as set forth in Section 7.6, 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 Donation of Excess Product

A. In the event the Government determines that doses of REGN10987 and REGN10933 (casirivimab and imdevimab) funded under the agreement are no longer needed by the Government, the Government may donate remaining doses to any foreign government to the extent mutually agreed to by the Government and Contractor; provided that:

(x) the Contractor secures any necessary approvals that are contractually required under existing licensing agreements for REGN10987 and REGN10933 (casirivimab and imdevimab);

(y) the foreign nation has an active commercial marketing approval or active regulatory authorization in place for use of REGN10987 and REGN10933 (casirivimab and imdevimab) combined (and not individually) at the time of donation; and

(z) the Contractor has the option to establish an indemnification agreement with the applicable recipient foreign government.

B. The Government shall notify the Contractor in writing prior to any planned donation to a foreign nation. The Contractor (itself or through its collaborators) agrees to work with the Government in good faith with respect to applicable regulatory submissions, import/export permits, and other reasonable requirements for donation to the extent that donation is authorized under paragraph A above. For clarity, the Contractor's obligations under this paragraph shall not include any requirement to grant licenses to intellectual property or to provide sensitive manufacturing information to any such foreign government nor any obligation to ship product outside the United States.

C. The Government will be responsible for shipment of REGN10987 and REGN10933 (casirivimab and imdevimab) to the receiving foreign nation in accordance with applicable shipping specifications, and the Contractor's obligations regarding distribution and risk of loss in Section 6.0 shall not apply.

D. The parties acknowledge that PREP Act coverage may not apply to the provision of any doses under this Section 7.6 to a foreign nation. The USG makes no representations as to PREP Act coverage thereto. Any immunity or indemnity arrangements in a foreign jurisdiction are the responsibility of the Contractor.

E. The Government agrees that the Contractor's collaborators may perform the Contractor's activities described in this Section 7.6 and that the Government shall cooperate with any such collaborators.

7.7 **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 AND SUPPLY CHAIN RESILIENCY

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

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.

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.

AMENDED AND RESTATED IMMUNO-ONCOLOGY LICENSE AND COLLABORATION AGREEMENT

By and Between

SANOFI BIOTECHNOLOGY SAS
(on behalf of itself and its Affiliates)

and

REGENERON PHARMACEUTICALS, INC.

Dated as of June 1, 2022

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Schedule 2.2	True-Up as of the A&R Effective Date
Schedule 2.6	Preliminary List of Licenses
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AMENDED AND RESTATED IMMUNO-ONCOLOGY LICENSE AND COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED IMMUNO-ONCOLOGY LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), executed as of June 1, 2022 (the "A&R Execution Date") and effective as of the A&R Effective Date (as defined below), is by and between Sanofi Biotechnology SAS (on behalf of itself and its Affiliates, "Sanofi"), a société par actions simplifée, organized under the laws of France, having a principal place of business at 54, rue La Boétie, 75008 Paris, France, an indirect wholly owned subsidiary of Sanofi, a company organized under the laws of France with its principal headquarters at 54, rue La Boétie, 75008 Paris, France, and Regeneron Pharmaceuticals, Inc., a company organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Sanofi, Regeneron and their respective Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory (each as defined below);

WHEREAS, Regeneron and Sanofi entered into the original Immuno-Oncology License and Collaboration Agreement dated as of July 1st, 2015 (the "Effective Date") and executed as of July 27, 2015 (the "Execution Date"), pursuant to which the Parties collaborated on the Development, Manufacture and Commercialization of the IO Licensed Product in the Field in the Territory (each as defined below) upon the terms and conditions set forth in this Agreement prior to the A&R Effective Date (the "Collaboration," and such terms and conditions as set forth in this Agreement prior to the A&R Effective Date, the "Pre-A&R Terms");

WHEREAS, as of the A&R Execution Date, Regeneron and Sanofi desire to restructure such Collaboration so as to transition the rights for the Development, Manufacture and Commercialization of the IO Licensed Product from Sanofi to Regeneron, effective as of the A&R Effective Date (except as otherwise set forth herein), including by Sanofi granting to Regeneron certain exclusive rights under Sanofi's interest in the Sanofi Intellectual Property (as defined below) and after such restructuring, Sanofi will not be obligated to perform (nor liable in respect of) any Development, Manufacturing or Commercialization of the IO Licensed Product from and after the A&R Effective Date, except as set forth in this Agreement or any Ancillary Agreement, in each case, upon the terms and conditions set forth herein.

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

ARTICLE I
DEFINITIONS

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

1.1 "Accounting Standards" shall mean, with respect to either Party, GAAP or IFRS, in each case, as generally and consistently applied throughout the Party's organization. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained.

1.2 "Adjustable Study" shall mean a study set forth in the table below and "Study Percentage" shall mean the percentage set forth for an Adjustable Study in the table below:

Adjustable Study	**Study Percentage**
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

1.3 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such first Person. For purposes of this definition, a Person shall be deemed to "control" another Person if such first Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to "control" another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of Sanofi's Affiliates be deemed Affiliates of Regeneron or any of Regeneron's Affiliates, nor shall Regeneron or any of Regeneron's Affiliates be deemed Affiliates of Sanofi or any of Sanofi's Affiliates.

1.4 "Ancillary Agreements" shall mean the MSA, the TSA, the TDA, the PVA, the Bill of Sale, the Domain Name Assignment, the Trademark Assignment and any Quality Agreement.

1.5 "Antitrust Clearance" shall mean, with respect to any country in the Territory, that all necessary authorizations, consents, orders or approvals of, or declarations of filing with, or expirations of waiting periods, as applicable to the consummation of the transactions contemplated by this Agreement have been received, authorized, permitted or expired in such country.

1.6 "Approval" shall mean, with respect to the IO Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the development, manufacture or commercialization of the IO Licensed Product in the Field in a regulatory jurisdiction in the

Territory, and shall include any approval, registration, license or authorization granted in connection with any Registration Filing.

1.7 "Bill of Sale" shall mean that certain Bill of Sale and Assignment and Assumption Agreement, by and between the Parties (or their Affiliates), entered into as of the A&R Execution Date and effective as of the A&R Effective Date, in the form set forth on Schedule 1.7 hereto.

1.8 "BLA" shall mean, with respect to the IO Licensed Product, a biologics license application filed with respect to such IO Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

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

1.10 "Calendar Year" shall mean each successive period beginning on January 1 and ending on December 31 during the Term.

1.11 "[* * *]" shall mean the period [* * *].

1.12 "[* * *]" shall mean [* * *].

1.13 "[* * *]" shall mean the IO Licensed Product in the labelling (if applicable), dosage form, combinations, formulations and route of administration and for the Indications: (a) [* * *], or (b) [* * *], in each case (a) and (b), [* * *].

1.14 "Combination Product" shall mean any combination product containing cemiplimab and one or more additional active ingredients or products, whether combined in a single co-formulation or package, as applicable, or formulated or packaged separately but sold together for a single price.

1.15 "Combination Therapy" shall mean any use or method of using at least two (2) active pharmaceutical ingredients [* * *], where [* * *] of those active pharmaceutical ingredients is [* * *].

1.16 "Commercialize," "Commercialization" or "Commercializing" shall mean, with respect to the IO Licensed Product, any and all activities directed to marketing, promoting, detailing, distributing, importing, offering for sale, having sold or selling such IO Licensed Product in the Field in the Territory, including market research, obtaining Pricing Approvals, pre-launch marketing, marketing and educational activities, post-Approval pharmacovigilance excluding pharmacovigilance for clinical trials, sampling and Non-Approval Trials in the Territory. For clarity, the terms "Commercialize," "Commercialization" and "Commercializing" are used herein with respect to the IO Licensed Product while the terms "commercialize," "commercialization" and "commercializing" are used herein with corresponding meanings with respect to other products.

1.17 "Control" or "Controlled" means, with respect to any item of New Information or Party Information, material, regulatory documentation, Know-How, Patents or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise, to assign, or grant a license, sublicense, right of reference or other right to or under such New Information or Party Information, material,

regulatory documentation, Know-How, Patents or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.18 "Develop," "Development" or "Developing" shall mean with respect to the IO Licensed Product, the following activities: (a) activities relating to research, pre-clinical and clinical drug development of the IO Licensed Product in the Field, including test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation and submission of Registration Filings but excluding activities necessary to obtain a Pricing Approval, reimbursement or listing on health care providers' and payers' formularies, (b) [* * *], (c) the development of companion diagnostics for use with the IO Licensed Product, and (d) any other research and development activities with respect to the IO Licensed Product in the Field, including activities to support the discovery of biomarkers and activities to support new product formulations, delivery technologies or new indications in the Field. For clarity, the terms "Develop," "Development" and "Developing" are used herein with respect to the IO Licensed Product while the terms "develop," "development" and "developing" are used herein with corresponding meanings with respect to other products.

1.19 "Distribution" shall have the meaning ascribed to such term in the TDA.

1.20 "Dollars" or "$" shall mean United States Dollars.

1.21 "Domain Name Assignment" shall mean that certain Domain Name Assignment Agreement, by and between the Parties (or their Affiliates), entered into as of the A&R Execution Date and effective as of the A&R Effective Date, in the form set forth on Schedule 1.21 hereto.

1.22 "EMA" shall mean the European Medicines Agency or any successor agency thereto.

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

1.24 "Existing IO Licensed Product" shall mean the IO Licensed Product [* * *], that in each case: (a) [* * *], or (b) [* * *].

1.25 "Existing License and Collaboration Agreement" shall mean the Amended and Restated License and Collaboration Agreement, between Sanofi, as successor-in-interest to Aventis Pharmaceuticals Inc. and sanofi-aventis Amerique du Nord and Regeneron, dated as of November 10, 2009, as the same may be amended from time-to-time.

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

1.27 "Field" shall mean the treatment, prevention, palliation or diagnosis of any disease.

1.28 "Finished Product" shall mean the IO Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.

1.29 "Formulated Bulk Product" shall mean IO Licensed Product formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.30 "[* * *]" shall mean, [* * *].

1.31 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

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

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

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

1.35 "IFRS" shall mean International Financial Reporting Standards of the International Accounting Standards Board.

1.36 "IND" shall mean an Investigational New Drug Application filed with the FDA with respect to the IO Licensed Product pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving the IO Licensed Product, including all amendments and supplements to such application or any equivalent filing with any Regulatory Authority outside the United States.

1.37 "Indication" shall mean any disease, state or condition.

1.38 "Interim Period" shall mean the period from the Transition Date through the date immediately prior to the A&R Effective Date.

1.39 "IO Licensed Product" shall mean any product that is comprised of or contains cemiplimab as an active ingredient, [* * *].

1.40 "Joint Intellectual Property" shall mean Joint Patent Rights and Joint Inventions.

1.41 "Joint Invention" shall mean all intellectual property (including Know-How, Patents and copyrights) discovered, invented, authored or otherwise created [* * *], jointly by or on behalf of Sanofi, its Affiliates or its or their Sublicensees, on the one hand, and Regeneron, its Affiliates or its or their Sublicensees.

1.42 "Joint Patent Rights" shall mean Patents that cover or claim a Joint Invention.

1.43 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and

other information, including marketing and supply information (whether or not patentable or otherwise protected by trade secret Law) and that are neither disclosed nor claimed in such Party's or such Party's Affiliates' Patents or Patent applications.

1.44 "Knowledge" shall mean [* * *].

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

1.46 "Legal Dispute" shall mean any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement.

1.47 "Legal Proceeding" shall mean any lawsuit or any other civil or administrative proceeding, or any claim asserted in or to any court, arbitration, tribunal, agency (including any government patent office), trade commission or other adjudicative body.

1.48 "License" shall mean any license or other agreement to acquire rights from a Third Party, which license or other agreement has been entered into prior to the A&R Effective Date and pursuant to the Pre-A&R Terms, in each case, for the Development, Manufacture or Commercialization of the IO Licensed Product in the Field as a "License" under the Pre-A&R Terms.

1.49 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of Formulated Bulk Product or Finished Product and any constituent components thereof (including the active ingredient cemiplimab), placebo or a comparator agent, as the case may be. For clarity, the terms "Manufacture" and "Manufacturing" are used herein with respect to IO Licensed Product while the terms "manufacture" and "manufacturing" are used herein with corresponding meanings with respect to other products.

1.50 "Marketing Approval" shall mean an Approval required for the marketing and sale of any product in the Field in a country in the Territory, but excluding, for clarity, any IND or separate Pricing Approval.

1.51 "Milestone Payment" shall mean individually, and "Milestone Payments" shall mean collectively, each of the Development Milestone Payment, the 2022 Sales Milestone Payment, and the 2023 Sales Milestone Payment.

1.52 "Net Sales" shall mean the gross amount invoiced (subject to Section 6.7) for bona fide arms' length sales of the IO Licensed Product in the Field in the Territory by or on behalf of: (1) [* * *], and (2) [* * *], in each case of (1) or (2), to Third Parties, less the following deductions, determined in accordance with such Party's Accounting Standards, consistently applied:

(a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of the IO Licensed Product;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;

(c) chargebacks and other amounts paid on sale or dispensing of the IO Licensed Product;

(d) Third Party cash rebates and chargebacks related to sales of the IO Licensed Product, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory refunds, credits, rebates and co-pay assistance directly related to the sale of the IO Licensed Product, accrued, paid or deducted pursuant to agreements (including managed care agreements) or governmental regulations;

(g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering the IO Licensed Product that are separately identified on the invoice or other documentation;

(h) bad debt incurred by a Party or its Affiliates or its or their Sublicensees (including by Sanofi or its Affiliates pursuant to the TDA) attributable to the IO Licensed Product in the Field sold after the Transition Date in the Territory;

(i) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of the IO Licensed Product, which are separately identified on the invoice or other documentation;

(j) commissions allowed or paid to Third Party distributors, brokers or agents other than sales personnel, sales representatives and sales agents employed by a Party or its Affiliates or its or their Sublicensees (including by Sanofi or its Affiliates pursuant to the TDA); and

(k) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of the IO Licensed Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than Dollars shall be translated into Dollars according to the provisions of Section 9.8. Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. 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. Notwithstanding the foregoing, for purposes of the True-Up as of the A&R Effective Date, Net Sales shall be calculated consistent with the Pre-A&R Terms, and the deductions in clauses (h) and (j) above shall not be deducted from the gross amount invoiced. In the case of any sale of the IO Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the basis set forth in Section 6.7. Solely for purposes of calculating Net Sales, if a Party or its Affiliate or Sublicensee sells the IO Licensed Product in the form of a Combination Product, (x) if at the time of the anticipated first commercial sale of such Combination Product in such country, cemiplimab and the other active ingredients in such Combination Product are each sold separately as a stand-alone product in finished form in such country for quantities comparable to those used in such Combination Product and of substantially the same purity and potency or functionality, then Net Sales of such Combination Product in such country shall be a portion of the amount of Net Sales calculated above multiplied by the fraction A/(A+B), where A is the net selling price of cemiplimab as a stand-alone product in finished form in such country and B is the net selling price of each other active ingredient as a stand-alone product in finished form in such country in each case, A and B, for quantities comparable to those used in such Combination Product and of substantially the same purity and potency or functionality and (y) if at the time of

the anticipated first commercial sale of such Combination Product in such country, any of cemiplimab or another active ingredient in such Combination Product is not sold separately as a stand-alone product in finished form in such country for quantities comparable to those used in such Combination Product and of substantially the same purity and potency or functionality, then Net Sales of such Combination Product in such country shall be resolved by mutual agreement of the Parties, each acting reasonably in good faith; provided however, that if the Parties cannot so agree within [* * *] of the first commercial sale of such Combination Product in such country, the Net Sales of such Combination Product in such country shall be resolved by [* * *].

1.53 "New Information" shall mean any and all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public that arise or are conceived or developed during the Term [* * *] by (a) either Party or its Affiliates or (b) the Parties or their Affiliates jointly, in each case ((a) and (b)) to the extent specifically related to the IO Licensed Product in the Field. "New Information" under this Agreement shall include any "New Information" under, and as defined in, the Existing License and Collaboration Agreement to the extent specifically related to the IO Licensed Product in the Field.

1.54 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with applicable Accounting Standards) by or on behalf of a Party or its Affiliates in connection with its activities under this Agreement.

1.55 "Out-of-Pocket Development Costs" shall mean the Out-of-Pocket Costs included in Development Costs.

1.56 "Party Information" shall mean, subject to Section 16.1(a), with respect to a Party, all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information (whether or not patentable or protectable as a trade secret) not generally known to the public (in each case, other than New Information) that are disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates under this Agreement, the Pre-A&R Terms or, except as otherwise provided under any confidentiality or intellectual property provisions of any Service Agreement, any of the Ancillary Agreements. With respect to each Party, Party Information does not include New Information. "Party Information" under this Agreement shall include any "Party Information" under, and as defined in, the Existing License and Collaboration Agreement.

1.57 "Patent Cooperation Treaty" or "PCT" means the Patent Cooperation Treaty, opened for signature June 19, 1970, 28 U.S.T. 7645.

1.58 "Patent Rights" shall mean unexpired Patents.

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

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

1.61 "Pre-Transition Development Costs" shall mean, with respect to an Adjustable Study, the Out-of-Pocket Development Costs incurred by Regeneron or its Affiliates for such Adjustable Study prior to the Transition Date. The Pre-Transition Development Costs for each Adjustable Study are set forth below (each in thousands):

Adjustable Study	**Pre-Transition Development Costs (in thousands)**
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

1.62 "Pricing Approval" shall mean such approval, agreement, determination or governmental or other entity decision establishing prices or reimbursement for the IO Licensed Product that can be charged to consumers or that will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities, Regulatory Authorities or other entities of such country approve or determine pricing for or reimbursement or pharmaceutical products for reimbursement or otherwise.

1.63 "Product-Specific Patent" shall mean [* * *] (considering [* * *] to be issued as then pending).

1.64 "Product Trademark" shall mean, with respect to the IO Licensed Product in the Field in the Territory, the Trademark(s) selected by the Parties pursuant to the Pre-A&R Terms for use on such IO Licensed Product in one or more countries in the Territory and accompanying logos, slogans, trade names, trade dress or other indicia of origin (other than the corporate names of the Parties or their respective Affiliates and Sublicensees), in each case solely to the extent used or held for use by a Party in respect of such IO Licensed Product on or before the A&R Effective Date.

1.65 "Promotional Materials" shall mean promotional, advertising, communication and educational materials relating to the IO Licensed Product for use in connection with the marketing, promotion and sale of the IO Licensed Product in the Field in the Territory, and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.66 "PVA" means the Pharmacovigilance Agreement, dated as of July 7, 2019, between Sanofi-Aventis Recherche et Développement S.A. and Regeneron Pharmaceuticals, Inc., as amended, supplemented or otherwise modified from time to time.

1.67 "Quality Agreement" shall mean any quality agreement entered into by the Parties or their Affiliates with respect to the IO Licensed Product after the A&R Execution Date but prior to the A&R Effective Date.

1.68 "Quarter" or "Quarterly" shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1 during the Term, except that the first (1st) Quarter shall commence on the Effective Date and shall end on [* * *] and the last Quarter shall end on [* * *].

1.69 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include any testing, marketing authorization application, supplementary application or variation thereof, IND, BLA, or any equivalent applications in any country.

1.70 "REGN2810" or "cemiplimab" shall mean Regeneron's hinge stabilized fully human monoclonal antibody of IgG4 isotype that targets PD-1, and which has heavy chain and light chain amino acid sequences of SEQ ID NO 330 and SEQ ID NO 331, respectively, which sequences are set forth in U.S. Patent Appl. No. 14/603,776, filed on January 23, 2015 (referred to therein as antibody clone H4H7798N). The generic name for cemiplimab as of the A&R Effective Date in the United States is "cemiplimab-rwlc," and the generic name for cemiplimab as of the A&R Effective Date outside the United States is "cemiplimab".

1.71 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of the IO Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes the FDA, the EMA and the Japanese Ministry of Health, Labour and Welfare.

1.72 "Restricted Activity" shall mean, with respect to the performance by or on behalf of Sanofi of any obligation hereunder, any requirement that Sanofi: [* * *].

1.73 "Sales Deduction Costs" means, with respect to sales of IO Licensed Product during any period, items deducted from the gross amount invoiced for bona fide arms' length sales of the IO Licensed Product to determine Net Sales for such period, in accordance with Accounting Standards, but excluding [* * *]).

1.74 "Sanofi Ex-LCA Know-How" shall mean [* * *].

1.75 "Sanofi Ex-LCA Patent Rights" shall mean, [* * *].

1.76 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.77 "Sanofi Know-How" shall mean [* * *].

1.78 "Sanofi Patent Rights" shall mean [* * *].

1.79 "Sanofi Product Agreements" shall mean the agreements, including all amendments thereto existing as of the A&R Effective Date, to which Sanofi or its Affiliates are a party that relate to the Commercialization of the IO Licensed Product in the Territory, excluding the Transferred Product Contracts.

1.80 [* * *]

1.81 "Study Completion" shall mean, with respect to any Adjustable Study, the date that is [* * *] after the date on which Regeneron has received all Third Party invoices related to an Adjustable Study.

1.82 "Sublicensee" shall mean a Third Party or an Affiliate to whom: (a) Regeneron, a Regeneron Affiliate or a Regeneron Sublicensee (as applicable) will have granted a license or sublicense under Regeneron's rights pursuant to Section 4.4 to Develop, Manufacture, Commercialize or use the IO Licensed Product in the Field in the Territory (including through multiple tiers), except for [* * *], and (b) Sanofi, a Sanofi Affiliate or a Sanofi Sublicensee granted a license or sublicense pursuant to Section 4.4 of the Pre-A&R Terms prior to the A&R Effective Date or Section 4.4 of this Agreement, to Develop, Manufacture, Commercialize or use the IO Licensed Product in the Field in the Territory (including through multiple tiers).

1.83 "Territory" shall mean all the countries and territories of the world.

1.84 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

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

1.86 "Trademark Assignment" shall mean that certain Transferred Trademark Assignment Agreement, by and between the Parties (or their Affiliates), entered into as of the A&R Execution Date and effective as of the A&R Effective Date, in the form set forth on Schedule 1.86 hereto.

1.87 "Transferred Product Contracts" shall mean all Product Contracts and Master Agreements that are assigned to Regeneron in accordance with Section 3.8(c)(i) and Section 3.11.

1.88 "Transferred Product Trademarks" shall mean any Product Trademarks Controlled by Sanofi or any of its Affiliates or its or their Sublicensees as of the A&R Effective Date and all registrations and applications therefor and renewals thereof, together with all goodwill associated with, or symbolized by, any of the foregoing, other than the corporate names of Sanofi or any of its Affiliates or Sublicensees.

1.89 "Transition Date" shall mean April 1, 2022.

1.90 "Transition Services" shall have the meaning ascribed to such term in the TSA.

1.91 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.92 "Valid Claim" shall mean (a) a claim of an issued and unexpired Patent that has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and that has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) [* * *].

1.93 Additional Definitions. Each of the following definitions is set forth in the Sections (or Schedules or Exhibits) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
2022 Sales Milestone	9.2(b)
2022 Sales Milestone Payment	9.2(b)
2023 Sales Milestone	9.2(c)
2023 Sales Milestone Payment	9.2(c)
A&R Effective Date	ARTICLE XIX
A&R Execution Date	Preamble
Aggregate Profits True-Up	Schedule 2.2
Agreement	Preamble
At-Risk Period	6.9(b)
[* * *]	3.8(c)(i)
Certificate	9.10(b)
CNTS Patents	4.8
Collaboration	Preamble
Contingent Agreement	3.8(c)(i)
CTSA	5.4
Damages	17.2(a)
Default	9.1
Default Interest Rate	9.9
Development Compensation Payment	Exhibit 2
Development Cost Reconciliation	2.3(a)
Development Milestone	9.2(a)
Development Milestone Payment	9.2(a)
[* * *]	4.1(b)

DEFINITION	SECTION/SCHEDULE
Effective Date	Preamble
Execution Date	Preamble
Excluded Trials	5.2(a)
Existing Trials	5.2(a)
Expert	6.9(a)
Expert Committee	6.9(a)
Force Majeure	ARTICLE XVIII
Governance Disputes	10.2
Indemnified Party	17.3
Indemnifying Party	17.3
Interim Period	Schedule 2.2
Interim Period Payments	Schedule 2.2
IO Development Balance	Exhibit 2
IO Development Balance Report	9.4
Master Agreements	3.11(c)
Mid-Price Close	9.8
Modified Clause	20.6
MSA	8.1
[* * *]	2.6
Owed Party	9.6
Owing Party	9.6
Party(ies)	Preamble
[* * *]	4.1(b)
Payment	9.1

DEFINITION	SECTION/SCHEDULE
Post-Approval Procedure	9.10(b)
Pre-A&R Terms	Preamble
[* * *]	4.1(b)
[* * *]	4.1(b)
Product Contract	3.11
Product Information	16.1
Quarterly Royalty Report	9.3(b)
Regeneron	Preamble
Regeneron Indemnitees	17.2(a)
Residuals	16.4
Royalties	9.3(a)
Royalty Term	9.3(a)
Sales Taxes	9.10(d)
Sanofi	Preamble
[* * *]	4.1(b)
Sanofi Indemnitees	17.2(b)
[* * *]	4.1(b)
Selected Recall	7.5(a)
Service Agreements	20.16(d)
[* * *]	1.82
SOPs	3.9
Study Percentage	1.2
TCT	3.2
TDA	3.1(a)

DEFINITION	SECTION/SCHEDULE
Term	ARTICLE XIX
Term SOFR	9.9
Third Party Claim	17.2(a)
[* * *]	2.3(a)
Transferred Approvals	3.8(a)
Transferred Domain Names	3.8(c)(ii)
Transferred Items	3.8
Transferred Product Records	3.8(b)(i)
Transferred Regulatory Documentation	3.8(b)(ii)
Transition Completion Date	20.8
Transition Lead	3.6
True-Up as of the A&R Effective Date	Schedule 2.2
TSA	3.1(a)
Unresolved Matter	3.5
Working Group	3.2

ARTICLE II
AMENDMENT; GENERAL PROVISIONS

2.1 Transition Generally. Upon and subject to terms and conditions of this Agreement and subject to and pursuant to each of the Ancillary Agreements, upon the A&R Effective Date, the Parties will cooperate in good faith to transition all Development, Manufacture and Commercialization of the IO Licensed Product in the Field in the Territory from Sanofi to Regeneron, and following the A&R Effective Date, except as otherwise set forth in this Agreement or any of the Ancillary Agreements, as between the Parties, Regeneron shall have the sole right to Develop, Manufacture, Commercialize and use the IO Licensed Product. From and after the Transition Completion Date, Sanofi will, except as otherwise set forth in this Agreement or in any of the Ancillary Agreements, completely discontinue its and its Affiliates' and Sublicensees' participation in, and no longer have any right or obligation to conduct, the Development, Manufacture, Commercialization or use of the IO Licensed Product. Except as set forth in Section 2.2, Section 2.3, Section 3.11(d), Section 3.14, Section 5.2, ARTICLE XIII, Section 17.1 or Section 17.2 or any Ancillary Agreement, Sanofi shall not be responsible or liable for the Development, Manufacture, Commercialization or use of the IO Licensed Product from and after the A&R Effective Date. Notwithstanding anything to the contrary in this

Agreement, from and after the A&R Effective Date, except where otherwise required under applicable Law, Regeneron shall not have any obligation to Develop, Manufacture, Commercialize or use the IO Licensed Product, and Regeneron shall have the right to cease the Development, Manufacturing, Commercialization or use of the IO Licensed Product at any time; provided that Regeneron shall comply with its obligations (including applicable notice periods) set forth in the TSA.

2.2 Rights, Obligations and Liabilities Before and After the Transition Date. Except as set forth in ARTICLE XIII:

(a) The Parties shall share the Aggregate Profits (as defined in the Pre-A&R Terms) with respect to the first Quarter of Calendar Year 2022 pursuant to the Pre-A&R Terms.

(b) There shall be a True-Up as of the A&R Effective Date between Sanofi and Regeneron as described in (and as such term is defined in) Schedule 2.2.

(c) For clarity, any Other Shared Expenses incurred after the A&R Effective Date shall [* * *].

(d) After the A&R Effective Date, Sanofi shall continue to account for [* * *] in accordance with its Accounting Standards and its historical practices under the Pre-A&R Terms and:

(i) in determining Net Sales for purposes of the amounts payable by Regeneron under the TDA and Regeneron's payment obligations under this Agreement, [* * *], shall be taken into account in determining such amounts, and

(ii) in determining the amounts payable by Regeneron under the TSA, Regeneron shall have the benefit of any [* * *].

2.3 Development Cost Reconciliation as at Study Completion.

(a) With respect to each Adjustable Study for which Study Completion occurs on or prior to [* * *], no later than [* * *] after Study Completion for such Adjustable Study, Regeneron shall deliver electronically to Sanofi a written report setting forth (i) the total Out-of-Pocket Development Costs actually paid, or for which an invoice was actually received, by or on behalf of Regeneron or its Affiliates in the performance of such Adjustable Study (the "Total Development Costs") and (ii) the Pre-Transition Development Costs for such Adjustable Study, *minus* the product of (A) the Total Development Costs for such Adjustable Study, *multiplied by* (B) the Study Percentage for such Adjustable Study (the "Development Cost Reconciliation"). An example Development Cost Reconciliation is set forth below:

Adjustable Study	Ph2 CSCC – 1540
Pre-Transition Development Costs – (A)	[* * *]
Total Development Costs at Study Completion (which occurred prior to [* * *]) – (B)	[* * *]
Study Percentage – (C)	[* * *]
(D) = (B) * (C)	[* * *]
Development Cost Reconciliation (A) – (D)	[* * *]
Amount Owed by Sanofi to Regeneron pursuant to Section 2.3(b)	[* * *]

(b) With respect to each Adjustable Study, (i) if the Development Cost Reconciliation for such Adjustable Study is positive, then promptly after receipt of such report, Sanofi shall submit an invoice to Regeneron for an amount equal to [* * *]of the Development Cost Reconciliation for such Adjustable Study, and Regeneron shall pay such amount to Sanofi within [* * *] of Regeneron's receipt of Sanofi's invoice therefor, and (ii) if the Development Cost Reconciliation for such Adjustable Study is negative, then promptly after receipt of such report, Regeneron shall submit an invoice to Sanofi for an amount equal to [* * *] of the absolute value of the Development Cost Reconciliation for such Adjustable Study, and Sanofi shall pay such amount to Regeneron within [* * *] of Sanofi's receipt of Regeneron's invoice therefor.

(c) For clarity, Regeneron shall be [* * *] responsible for any [* * *] and there shall be [* * *]. Within [* * *] of [* * *], Regeneron shall provide Sanofi with a written notice confirming which (if any) Adjustable Studies did not reach Study Completion on or prior to [* * *].

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

2.5 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use commercially reasonable efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement and the Ancillary Agreements, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the Ancillary Agreements and the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements, (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the Ancillary Agreements and the transactions contemplated by this Agreement and the Ancillary Agreements required to be made under applicable Laws (including, for clarity, any filings or other submissions necessary anywhere in the Territory for the purposes of obtaining Antitrust Clearance) and (d) in the period prior to the Transition Completion Date, cause applicable Third Parties to execute, acknowledge

and deliver such assignments, transfers, consents, assumptions and other documents and instruments and take such other actions as may reasonably be requested by Regeneron to more effectively assign, convey or transfer to or vest in Regeneron or its applicable designee, on a Transferred Item-by-Transferred Item basis, all right, title and interest in and to such Transferred Items as are described in Section 3.8 below. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish all information in its possession and control (or in its control and accessible by it consistent with its regular business practices) required for any applicable filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement and the Ancillary Agreements. Without limiting the foregoing, and subject to the terms of the TSA, each Party shall [* * *] to collect and provide to the other Party [* * *], any and all required documentation or other information, notices, consents or approvals necessary to effectuate the transfer of the Approvals and any other licenses included in the Transferred Items, in each case, in each applicable country in the Territory, without any undue or unreasonable delay. Regeneron will [* * *] within [* * *] after the A&R Execution Date.

2.6 Compliance with Third Party Agreements. From and after the A&R Effective Date, Sanofi shall not, and shall cause its Affiliates not to, (a) [* * *], enter into any agreement to obtain a license or other rights for the Development, Manufacture, Commercialization or use of cemiplimab in the Field in such country ([* * *]), or (b) except to the extent required hereunder or under any Ancillary Agreement, terminate or amend any License or other material agreement, with respect to the cemiplimab in the Field, in each case ((a) and (b)), without Regeneron's prior written consent. Without the prior written consent of Regeneron, such consent not to be unreasonably withheld, conditioned or delayed ([* * *]), Sanofi may not terminate or amend any License or any other material agreement entered into pursuant to a Plan (as defined in the Pre-A&R Terms) if such termination or amendment would impose any [* * *]with respect to the Development, Manufacture, Commercialization or use of the IO Licensed Product in the Field in the Territory. [* * *], Schedule 2.6 sets forth a preliminary list of the Licenses to which Sanofi or its Affiliates are a party as of the A&R Execution Date.

2.7 No Restriction on Competitive Activities. The Parties acknowledge that each of them may, from and after the A&R Effective Date, engage in research, development (including Development), manufacturing (including Manufacturing) or commercialization (including Commercialization) activities that utilize technologies similar to or involve products competitive with those contemplated by this Agreement. Nothing in this Agreement, including any obligation to use commercially reasonable efforts, shall infer or imply any obligation not to research, develop, manufacture, commercialize or otherwise exploit any compound or product. Neither Party shall be prevented from using any publicly available research results or other information (including any publicly available information of the other Party) to the same extent as Third Parties generally are legally permitted to do so.

ARTICLE III
TRANSITION MANAGEMENT AND TRANSFER

3.1 Transition Services Agreement and Transitional Distribution Agreement.

(a) As of the A&R Execution Date, (i) Sanofi (as defined in the TSA) and Regeneron Ireland DAC shall execute the transition services agreement ("TSA") in the form attached as Schedule 3.1(a)(i) hereto and (ii) Sanofi Winthrop Industrie and Regeneron Ireland DAC shall execute the transitional distribution agreement ("TDA") in the form attached as Schedule 3.1(a)(ii) hereto.

(b) Pursuant to the TSA, the TDA and as contemplated in this Agreement and the other Ancillary Agreements, the Parties intend to transition all Development, Manufacture and Commercialization of the IO Licensed Product in the Field in the Territory from Sanofi to Regeneron as rapidly as possible.

3.2 Transition Coordination Team. The Parties agree to establish, as provided for in and for the purposes of coordinating and overseeing each Party's activities under the TSA, the TDA and the MSA and to oversee the program transfer contemplated in Section 3.8, a Transition Coordination Team (the "TCT"). The TCT shall be established within [* * *] after the A&R Effective Date. The purpose of the TCT shall be: (i) to oversee and coordinate delivery of the Transition Services under the TSA and Distribution under the TDA and the Parties' activities under the MSA; (ii) to exchange information between the Parties relating to the delivery and receipt of the Transition Services, Distribution activities and services under the MSA; (iii) to resolve any issues or disputes that arise under (and in accordance with the terms of) the TSA, the TDA or the MSA; (iv) to oversee and facilitate the transfer contemplated in Section 3.8 below; (v) to resolve any issues or disputes in respect of the transfer contemplated in Section 3.8 below; and (vi) to perform such roles and responsibilities of the Committees established under the Pre-A&R Terms as may be necessary to responsibly wind-down those Committees, as determined by the TCT (e.g., 2022 Budget matters relating to the pre-Transition Date period). The TCT shall be composed of an equal number of representatives appointed by each of Regeneron and Sanofi, with each representative having the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of the TCT. Each Party may replace its TCT members upon written notice to the other Party (email being agreed by the Parties as sufficient for this purpose); provided that such replacement has the foregoing requisite experience and seniority; and provided, further, that the TCT composition meets the requirements of this ARTICLE III. The TCT shall have [* * *] co-chairpersons, [* * *]designated by each of Regeneron and Sanofi, and each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of each meeting and prepare and issue final minutes within [* * *] thereafter. The TCT shall operate by consensus. The TCT shall exercise its decision-making authority (in respect of those matters specified in the TSA as being the subject of such authority) in good faith and in a commercially reasonable manner. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. The TCT shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on such committee are given due consideration. Any failure by the TCT to reach consensus shall be resolved pursuant to the steps set forth in Section 3.5 below. The Parties acknowledge and agree that the TCT shall not have the power to amend any of the terms or conditions of this Agreement, the TSA, the TDA, the MSA or any other Ancillary Agreement other than by mutual agreement of the Parties as set forth in Section 20.5. From time to time, the TCT may establish working groups (each, a "Working Group") to oversee particular projects, activities, transition work streams or specific countries or jurisdictions, and each such Working Group shall be constituted and operate as the TCT determines, and may be disbanded at any time thereafter by the TCT.

3.3 TCT Meetings. The TCT shall hold meetings at such times as the Parties shall determine, but in no event less frequently than [* * *] during the term of the TSA, the TDA and MSA (whichever terminates or expires latest), commencing from and after the A&R Effective Date until the Transition Completion Date. All TCT meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons. Further, in addition to the regularly scheduled quarterly meetings, the TCT shall meet upon the reasonable request of the co-chairpersons or either Party's co-chairperson, as applicable, upon at least [* * *] notice. A reasonable number of other representatives of a Party may attend a TCT meeting as non-voting observers (provided that such additional representatives

are under obligations of confidentiality and non-use applicable to the confidential information of the other Party that are at least as stringent as those set forth in ARTICLE XVI). Each Party shall be responsible for [* * *]. Any alternative agreement of the Parties or the applicable co-chairpersons with respect to TCT meetings under this ARTICLE III shall be in writing.

3.4 TCT Disbandment. Upon the Transition Completion Date or as contemplated in this ARTICLE III, either Party shall have the right to request that the other Party consent to the disbandment of the TCT, such consent not to be unreasonably withheld, conditioned or delayed. For clarity, upon the disbandment of the TCT, any Working Group established thereunder shall also disband, effective immediately.

3.5 Resolution of TCT Matters. If the TCT is unable to reach consensus regarding any matter before it, and such inability continues for a period of [* * *] after such matter first being brought before the TCT for resolution (any such matter, an "Unresolved Matter"), then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within [* * *] of receiving such written notification, failing which, such Unresolved Matter shall be resolved pursuant to ARTICLE X in the case of a Legal Dispute, and for all other Unresolved Matters, Regeneron shall have final decision-making authority with respect to such Unresolved Matter; provided that: (a) Regeneron shall not [* * *]to: (i) [* * *], or (ii) [* * *], provided that the foregoing (i) and (ii) shall not be construed as relieving Sanofi of its obligation under Section 3.8 to assign or transfer the Transferred Items consistent with the terms of this ARTICLE III; and (b) in respect of any Unresolved Matter relating to the subject matter of the TSA, the TDA or MSA, the terms of the TSA, the TDA or MSA (as applicable) shall govern, and Regeneron may not [* * *].

3.6 Transition Leads. Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, regulatory, manufacturing and commercialization issues to act as its Transition Lead ("Transition Lead"). Each Transition Lead shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Transition Lead will also be responsible for being the primary point of communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization and for the sharing of information and responding to information requests or other matters relating to this ARTICLE III between TCT meetings.

3.7 Exchange of Information. Each of Regeneron and Sanofi, will provide regular and fulsome updates to the other Party, through the TCT or the Transition Leads, with respect to all activities undertaken by or on behalf of such Party under the TSA, the TDA or the MSA or in respect of the program transfer contemplated in Section 3.8 below. Without limiting the foregoing, during the Term, Sanofi will promptly notify Regeneron of any material information regarding the research, Development, Manufacturing, Commercialization or use of the IO Licensed Product, including any material correspondence with a Governmental Authority.

3.8 Program Transfer. To facilitate the assumption by Regeneron (as contemplated in ARTICLE II above) of the Development, Manufacture and Commercialization of the IO Licensed Product, Sanofi shall transfer, assign or cause to be transferred or assigned, to Regeneron or Regeneron's designee, and Regeneron or its designee shall accept, on a country-by-country basis where applicable, as soon as practicable following the A&R Effective Date and, on a Transferred Item-by-Transferred Item basis, no later than: (1) in respect of Transferred Items that solely relate to the Development, Commercialization or use of the IO Licensed

Product in the United States, [* * *], or (2) in respect of all other Transferred Items that relate to the Development, Manufacture, Commercialization or use of the IO Licensed Product, [* * *], in each case of (1) and (2), the following items in the form and format as exist on the date of such transfer or assignment (collectively, the items listed in (a) through (c) below, the "Transferred Items"):

(a) Regulatory Transfers. All ex U.S. and ex-EMA Approvals ("Transferred Approvals").

(b) [* * *]Licensed Know-How [* * *]. Subject to Section 3.10, [* * *]:

(i) all books and records of the Existing IO Licensed Product business, including all books and records (or parts thereof) specifically related to the Development, Manufacture, Commercialization or use of the Existing IO Licensed Product, but [* * *] ("Transferred Product Records"),

(ii) all pricing and reimbursement documents and correspondence, other regulatory filings (including Registration Filings), related correspondence with regulators and dossiers and all other material regulatory documentation with respect to the Existing IO Licensed Product (the "Transferred Regulatory Documentation"), and

(iii) (A) such information as is contained in Sanofi's regulatory database that specifically relates to the Existing IO Licensed Product; and (B) such information as is contained in Sanofi's safety database that specifically relates to the Existing IO Licensed Product, consistent with the PVA, as amended.

(c) Assignments of Right, Title & Interest.

(i) subject to Section 3.11, any Product Contracts, including that certain [* * *], and any Master Agreements that Sanofi agrees ([* * *]) to transfer and assign in accordance with Section 3.11(c) (which shall be solely subject to Section 3.11(c)), in each case subject to obtaining any necessary third party consents; provided that to the extent the assignment of any such agreement requires any notice to or consent of the relevant Third Party counterparty to such agreement, as applicable (each such agreement, a "Contingent Agreement"), the terms of Section 3.9(b) shall apply with respect to the assignment or transfer of such Contingent Agreement,

(ii) domain names associated with the Existing IO Licensed Product ("Transferred Domain Names"),

(iii) any remaining inventory of Promotional Materials and sales training materials, in each case as specifically relates to the Existing IO Licensed Product, and

(iv) the Transferred Product Trademarks.

Except for those Transferred Items that shall be assigned or otherwise transferred pursuant to the Bill of Sale, Trademark Assignment or Domain Name Assignment, and subject to the terms of Section 3.8(c)(i) above and Section 3.10 below, Sanofi shall and does hereby, and shall cause its Affiliates to: (x) assign to Regeneron all of its right, title and interest in and to the Transferred Items described in Section 3.8(a) and Section 3.8(c) above, and transfer to Regeneron (or its

designee) the Transferred Items described in Section 3.8(b) above, in each case, [* * *]and (y) execute, acknowledge and deliver any required assignments, transfers, consents, assumptions and other documents and instruments [* * *].

3.9 Limitations on Sanofi Obligation to Transfer. For clarity, nothing in the foregoing Section 3.8 shall require Sanofi or any of its Affiliates to (1) violate any Law, regulatory requirement or contractual restrictions on transfer or assignment (including but not limited to pursuant to any License), nor (2) [* * *]; provided that:

(a) to the extent the transfer or assignment of any Transferred Item under Section 3.8 (but excluding any [* * *] described in Section 3.8(c)(i)) is [* * *]; and

(b) subject to the process set forth in Section 3.11, to the extent any Transferred Item described in Section 3.8(c)(i) is identified as a Contingent Agreement, then [* * *]; provided that, subject to and without limiting Section 17.2, Regeneron shall [* * *]provided, further, that [* * *].

For further clarity, nothing in the foregoing Section 3.8 shall require Sanofi to [* * *]. No decision of the TCT, nor any exercise by Regeneron of its decision-making rights under Section 3.5, shall in any case require Sanofi or any Sanofi Affiliate to undertake any Restricted Activity in respect of Sanofi's obligation to transfer the Transferred Items on the terms set forth in this ARTICLE III [* * *].

3.10 [* * *]. [* * *].

3.11 Third Party Agreements.

(a) As soon as practicable after the A&R Execution Date, Sanofi shall [* * *].

(b) Within: (1) for all [* * *] in the U.S., [* * *], and (2) for all other countries in the Territory other than the U.S., [* * *], in each case of (1) and (2), of the date on which a given [* * *]is either provided to Regeneron or [* * *], Regeneron may request, and upon receipt of such request, Sanofi shall, either (i) [* * *], or (ii) [* * *], in each case ((i) and (ii)), [* * *].

(c) With respect to any [* * *], within: (1) for all [* * *] in the U.S., [* * *], and (2) for all other countries in the Territory other than the U.S., [* * *], in each case of (1) and (2), [* * *]. For clarity, once Regeneron has [* * *], Sanofi shall [* * *]. During such period, to the extent not already the subject of a Transition Service under the TSA, the Parties will reasonably cooperate to provide to Regeneron the benefits under such [* * *] that relate to [* * *]; provided that, subject to and without limiting Section 17.2, Regeneron shall be solely responsible for [* * *].

(d) Except to the extent otherwise provided under this Agreement or any Ancillary Agreement, each Party shall [* * *] in connection with the transfer, amendment or termination of any [* * *].

3.12 Maintenance of Transferred Items Prior to Transfer.

(a) Subject to the terms of the TSA (and in the event of any conflict between the terms of the TSA and this Section 3.12, the terms of the TSA shall expressly govern), and except as may be required or prohibited by applicable Law, prior to the assignment

or transfer of the applicable Transferred Item to Regeneron, Sanofi shall, and shall cause its Affiliates [* * *]:

(i) maintain each Transferred Item until such time as either such Transferred Item is transferred to Regeneron pursuant to Section 3.8 or [* * *];

(ii) [* * *];

(iii) [* * *]; and

(iv) [* * *].

(b) Notwithstanding anything to the contrary in Section 3.12(a)(i), Sanofi may, and may cause its Affiliates and applicable Third Parties to, take reasonable actions in compliance with applicable Laws or, to the extent consistent with Sanofi's actions in respect of its business generally, as necessary to respond to operational emergencies (including any measures in response to any Force Majeure event) or immediate and material threats to the health or safety of natural Persons or the overall economic stability of the businesses of Sanofi, its Affiliates or such applicable Third Parties, as the case may be, provided that such actions taken in respect of such emergencies, events or threats shall not relieve Sanofi of its obligations under Section 3.12(a)(i) for any longer time than is necessary in light of such emergencies, events or threats.

3.13 Wrong Pockets. If either Sanofi or Regeneron becomes aware (a) that any of the Transferred Items have not been transferred to Regeneron or (b) of any right, record or other asset owned by Sanofi or any of its Affiliates, including any contract, Approval, domain name, physical inventory or Registration Filing (for clarity, [* * *]) that (i) [* * *]relates to the Existing IO Licensed Product, (ii) is not contained in the Transferred Items and [* * *], (iii) that is [* * *], and (iv) is not otherwise transferred hereunder or under any Ancillary Agreements, in each case ((a) and (b)), it shall promptly notify the other Party in writing and the Parties shall, as soon as reasonably practicable, take all actions reasonably necessary to ensure that such Transferred Item, right, asset or record is assigned and transferred, with any reasonably necessary prior Third Party consent or approval, to Regeneron (subject to Section 3.9). Without limiting the foregoing, if either Sanofi or Regeneron becomes aware that any right, record or other asset included in the Transferred Items was not intended by the Parties to be transferred from Sanofi to Regeneron, it shall notify the other Party in writing and, [* * *], the Parties shall take all actions reasonably necessary to transfer such right, record or other asset back from Regeneron or its Affiliates to Sanofi, or if such transfer is not possible, to otherwise provide Sanofi and its Affiliates with the benefit of such right, record or other asset. Notwithstanding anything to the contrary in this Agreement, [* * *].

3.14 Program Transfer Costs. Except as provided for under this Agreement, the TSA or the TDA, each Party shall bear [* * *]; provided that, except as otherwise provided in Section 3.11, Section 3.12 or Section 3.13, any [* * *] incurred by Sanofi or its Affiliates in respect of the program transfer contemplated in Section 3.8 (or any subsequent transfers pursuant to Section 3.13) shall be [* * *], on a [* * *], with such payment to be made in accordance with [* * *]. Notwithstanding the foregoing, [* * *].

ARTICLE IV
LICENSE GRANTS

4.1 Sanofi License Grants. Subject to the terms and conditions of this Agreement, Sanofi hereby grants to Regeneron and its Affiliates:

(a) an exclusive (including with regard to Sanofi and its Affiliates), royalty-bearing (solely pursuant to Section 9.3), sublicensable (pursuant to Section 4.4), transferable (pursuant to Section 20.8), worldwide, perpetual, irrevocable right and license under the [* * *];

(b) [* * *];

(c) [* * *];

provided that with respect to [* * *], the foregoing licenses in clauses (a) – (c) shall include [* * *], but specifically excludes [* * *].

(d) a non-exclusive, royalty-bearing (solely pursuant to Section 9.3), sublicensable (pursuant to Section 4.4), transferable (pursuant to Section 20.8), worldwide, perpetual, irrevocable right and license under any unregistered copyright subsisting in or embodied by any of the Transferred Items solely to the extent necessary or reasonably useful [* * *]; and

(e) subject to Section 11.5(b), the right [* * *].

4.2 Regeneron License Grants. Subject to the terms and conditions of this Agreement, Regeneron (on behalf of itself and its Affiliates) hereby grants to Sanofi and its Affiliates a non-exclusive, fully paid-up, royalty-free, sublicensable (pursuant to Section 4.4), transferable (pursuant to Section 20.8) right and sublicense under the license rights granted to Regeneron and its Affiliates in Section 4.1 above, solely for the purposes of, and to the extent and duration required for, Sanofi and its Affiliates (and its and their sublicensees) fully and finally performing its and their obligations under each of the Ancillary Agreements.

4.3 [* * *]. In addition to the licenses granted under this ARTICLE IV and subject to the other terms and conditions of this Agreement, [* * *].

4.4 Sublicensing.

(a) Subject to Section 20.8, the licenses granted by Sanofi to Regeneron in Section 4.1 and Section 4.3 above and the rights of reference granted by Sanofi to Regeneron in Section 7.3 below may in each case be freely sublicensed, or further rights of reference may be granted, by Regeneron or its Affiliates to Third Parties through one or multiple tiers, subject to each such sublicense complying with the terms of this Section 4.4. [* * *].

(b) Each Party shall remain responsible and liable for the compliance by its Affiliates, Sublicensees, subcontractors and delegates with the terms and conditions set forth in this Agreement, and any action or failure to act by such Affiliate, Sublicensee, subcontractor or delegate that would constitute a breach of this Agreement if such action or failure to act were committed by such Party shall be deemed a breach by such Party of this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including the confidentiality and non-use obligations set forth in ARTICLE XVI, and in the case of any Sublicensee of Regeneron or its Affiliates, will include an obligation of such Sublicensee to account for and report its sales of the IO Licensed Product to Regeneron on the same basis as if such sales were Net Sales by Regeneron or its Affiliates. For the avoidance of doubt, [* * *], and Regeneron shall [* * *].

(c) For the avoidance of doubt, [* * *], shall be deemed a "Sublicensee" for all purposes hereunder, [* * *] and (ii) any [* * *] shall not be considered a "Sublicensee" hereunder, irrespective of [* * *]; provided that in the event any such Third Party

becomes an Affiliate of Regeneron during the Term, the exclusion described in this Section 4.4(c)(ii) shall cease to apply with respect to such Person.

4.5 No Implied License. Except as expressly provided in this ARTICLE IV or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.6 Retained Rights. For the avoidance of doubt, Sanofi retains all rights in [* * *] not expressly licensed hereunder, including the right to exploit [* * *] for purposes unrelated to the IO Licensed Product in the Field. For avoidance of doubt, the [* * *]. Except as otherwise expressly provided in the [* * *], in no event will this license grant require Sanofi to disclose to Regeneron any Know-How.

4.7 Transitional Right to Use Transferred Product Trademarks. Regeneron (on behalf of itself and its Affiliates) hereby grants to Sanofi, the right, [* * *], to use the Transferred Product Trademarks on product labels, package inserts, packaging, trade packaging, samples and all Promotional Materials for the IO Licensed Product solely for the purposes of, and to the extent and duration required for, Sanofi and its Affiliates (and its and their sublicensees) fully and finally performing its and their obligations under the TSA, the TDA or the MSA; provided that: (a) with respect to each such use of the Transferred Product Trademarks, Sanofi shall, and shall cause its Affiliates (and its and their sublicensees) to, (i) conform to standards for the protection and use of the Transferred Product Trademarks provided by Regeneron to Sanofi in writing (or until any such standards are provided, customary industry standards) and (ii) comply with applicable Law, (b) upon Regeneron's reasonable request (and [* * *]), Sanofi shall provide Regeneron samples of such product labels, package inserts, packaging, trade packaging, samples and Promotional Materials to enable Regeneron to monitor Sanofi's compliance with the foregoing clause (a); and (c) Regeneron shall have the right to terminate the grant to Sanofi under this Section 4.7, if Sanofi breaches its obligations under either of the foregoing clauses (a) or (b).

4.8 [* * *]. Sanofi shall not, and shall cause its Affiliates not to [* * *].

ARTICLE V
DEVELOPMENT ACTIVITIES

5.1 Development of the IO Licensed Product. Subject to the terms of this Agreement, except as expressly provided for under the TSA, as between the Parties, Regeneron shall have the sole right to, and shall have the sole decision-making authority with respect to, the Development of the IO Licensed Product from and after the A&R Effective Date. For clarity, Regeneron shall not have the obligation to Develop the IO Licensed Product in the Territory and may discontinue any or all Development of the IO Licensed Product at its sole discretion. Except as set forth in Section 2.2, Section 2.3, Section 3.11(d), Section 3.14, Section 5.2, ARTICLE XIII, Section 17.1 or Section 17.2 or any Ancillary Agreement, Regeneron shall be solely responsible for one hundred percent (100%) of any Development Costs incurred with respect to Development of the IO Licensed Product conducted from and after the Transition Date. For clarity, during the period from the Transition Date until the A&R Effective Date, any and all Development Costs incurred by Sanofi for Development in such period shall be subject to Section 2.2. Regeneron's obligation to reimburse Sanofi for Development conducted from or after the A&R Effective Date shall be limited to the Transition Services Fees (as such term is defined in the TSA) payable pursuant to the TSA.

5.2 Transfer of Existing Trials; Excluded Trials.

(a) Schedule 5.2(a) lists the Sanofi-sponsored clinical trials and investigator initiated studies relating to the IO Licensed Product that are ongoing as of the A&R Execution Date, but excluding: (i) any combination studies being conducted pursuant to the CTSA, and (ii) the trial to be conducted by [* * *] set forth on Schedule 5.2(a)-2 (such ongoing trials and studies, subject to the exclusions in (i) and (ii), the "Existing Trials" and the studies excluded by clauses (i) and (ii), the "Excluded Trials"). For clarity, the terms of the CTSA and the terms of any agreement(s) that may be entered into by Regeneron and [* * *], in either case, shall solely and exclusively govern in respect of the disclosure, license, access or use by or to Regeneron of any results or intellectual property rights generated in or arising from such Excluded Trials. As between the Parties, any Excluded Trials conducted by or on behalf of Sanofi or any of its Affiliates or Sublicensees will be [* * *].

(b) Existing Trials. Each Party shall use commercially reasonable efforts to transfer the sponsorship of, and responsibility for, all such Existing Trials from Sanofi to Regeneron in a timely manner and conduct all such activities in compliance with applicable Laws, including Good Practices. Regeneron shall be responsible for [* * *] of any costs and expenses incurred in connection with the conduct of any Existing Trials from and after the Transition Date (subject to the exceptions and limitations described in Section 5.1 above). Sanofi shall promptly disclose to Regeneron any Know-How, results, Patents or other intellectual property rights that are solely generated in or arising from the Existing Trials. For clarity, except as otherwise agreed by the Parties in writing or otherwise expressly provided for within the scope of a Transition Service under the TSA, Regeneron shall not be obligated to disclose, license or otherwise permit access to or use of any Know-How, results, Patents or other intellectual property rights generated in or arising from any Existing Trials, or any other studies that are conducted from and after the Transition Date.

5.3 Development Records. Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner in accordance with its internal practices and standard operating procedures, complete and accurate Development records with respect to activities initiated under the Pre-A&R Terms in respect of the IO Licensed Product, including with respect to the Existing Trials, and, with respect to Sanofi, activities initiated or conducted under this Agreement, the Pre-A&R Terms or the TSA until the Transition Completion Date; provided that neither Party shall be deemed to have breached its obligations under this Section 5.3 with respect to periods prior to the A&R Effective Date to the extent that such obligations would not have applied to such Party under the Pre-A&R Terms. Such records shall (a) include sufficient detail to verify compliance with such Party's obligations under this Agreement, the Pre-A&R Terms or the TSA, as applicable, (b) be appropriate for patent and regulatory purposes, (c) be in compliance with applicable Law, (d) properly reflect all work done and results achieved in the performance of such Development activities and (e) in the case of such records as relate to a clinical trial, record only activities relating to such clinical trial and not include or be commingled with records of activities outside the scope of such clinical trial. Prior to the Transition Completion Date, Regeneron shall have the right, during normal business hours and upon reasonable notice (and [* * *]), to inspect and copy all such records maintained by Sanofi pursuant to this Section 5.3; provided, however, that Regeneron shall maintain any such records so disclosed in confidence to the extent provided in ARTICLE XVI. Without limiting the foregoing, upon Regeneron's reasonable request for Sanofi to provide copies of any particular items within such records, Sanofi shall provide such copies to Regeneron ([* * *]); provided, however, that Regeneron shall maintain such copies so disclosed in confidence to the extent provided in ARTICLE XVI. After the Transition Completion Date, if Sanofi desires to no longer maintain any such records in its custody, then Sanofi shall notify Regeneron of such desire, and Regeneron shall have [* * *] after receipt of such notice to take custody of any such records [* *

]. If Regeneron does not take custody of such records within such [* *], then Sanofi shall have the right to destroy such records.

5.4 Clinical Trial Collaboration and Supply Agreement. The Parties each acknowledge and agree that certain Clinical Trial Collaboration and Supply Agreement by and between the Parties, dated as of the A&R Execution Date (the "CTSA") shall remain in full force and effect following the A&R Execution Date, and shall not be amended, modified or otherwise affected by the amendment and restatement of this Agreement on the A&R Effective Date. In the event of an inconsistency between the terms of this Agreement (from and after the A&R Effective Date) and the terms of the CTSA, the terms of the CTSA shall control.

5.5 Combination Studies prior to the A&R Effective Date. The Parties acknowledge that the Parties rights to receive a copy of the results of any clinical studies that are subject to Section 5.6(g)(i) of the Pre-A&R Terms shall continue to apply with respect to any such clinical studies that were initiated prior to the A&R Effective Date, subject to the other terms and conditions of such Section 5.6(g)(i).

ARTICLE VI
COMMERCIALIZATION

6.1 Commercialization of the IO Licensed Product in the Field in the Territory. Subject to the terms of this Agreement, and except as expressly provided for under the TSA or the TDA, as between the Parties, Regeneron shall have the sole and exclusive right to, and shall have the sole decision-making authority with respect to, the Commercialization of the IO Licensed Product from and after the A&R Effective Date, including determining and controlling all marketing and sales activity and pricing and reimbursement decisions in the Territory from and after the A&R Effective Date. For clarity, Regeneron shall not have the obligation to pursue the Commercialization of the IO Licensed Product in the Territory and may discontinue any or all Commercialization of the IO Licensed Product at its sole discretion. Except as set forth in Section 2.2, Section 2.3, Section 3.11(d), Section 3.14, Section 5.2, ARTICLE XIII, Section 17.1 or Section 17.2 or any Ancillary Agreement, Regeneron shall be solely responsible for one hundred percent (100%) of any Shared Commercial Expenses (as defined in the Pre-A&R Terms) incurred with respect to Commercialization of the IO Licensed Product conducted from and after the Transition Date. For clarity, during the period from the Transition Date until the A&R Effective Date, any and all Shared Commercial Expenses incurred by Sanofi for Commercialization during such period shall be subject to Section 2.2. Regeneron's obligation to reimburse Sanofi for Commercialization conducted from or after the A&R Effective Date shall be limited to the Transition Services Fees (as such term is defined in the TSA) payable pursuant to the TSA and the distribution fee payable pursuant to the TDA.

6.2 Cessation of Co-Commercialization Activities. Effective as of the A&R Effective Date, the Parties shall cease any and all co-commercialization planning and implementation activities in the United Kingdom, Germany, Canada and any other country in the Territory where such activities are or were being undertaken, and shall instead focus on the wind-down and transition of such activities, and Regeneron's assumption of the sole rights with respect to all such Commercialization activities in those countries, to be carried out pursuant to the terms and conditions of, and subject to the timetable set forth in, the TSA and TDA.

6.3 Booking of Sales and IO Licensed Product Distribution. As of the A&R Effective Date, subject to the TSA and TDA, (a) Regeneron, its Affiliates and its and their Sublicensees (or its or their designees) shall invoice, book and record all sales of the IO Licensed Product in the Territory and (b) Regeneron (or its Affiliate or its or their Sublicensee (or its or their designee)) shall also be responsible for (i) the distribution of the IO Licensed Product in the Territory and for paying Medicaid (if applicable) and any and all other governmental rebates that

are due and owing with respect to the IO Licensed Product distributed by or on behalf of Regeneron, its Affiliates or its or their Sublicensees in the Territory, (ii) handling all other rebates, returns or chargebacks of the IO Licensed Product sold under this Agreement in the Territory and (iii) handling all aspects of ordering, processing, invoicing, collection, receivables and returns with respect to the IO Licensed Product in the Territory.

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

6.5 Promotional Materials.

(a) As between the Parties, Regeneron shall have the sole right to use any Promotional Materials in its possession from or after the A&R Effective Date (including any such Promotional Materials that are transferred to Regeneron as part of the Transferred Items) for the purpose of Commercializing the IO Licensed Product in the Territory. Except to the extent necessary to perform its obligations under the TSA, TDA or MSA, from and after the A&R Effective Date, Sanofi shall not reproduce, distribute, create derivative works based on (including translations thereof), publicly perform, publicly display or otherwise use any Promotional Materials; provided that the foregoing shall not prohibit Sanofi from utilizing any designs, features or other components thereof to the extent used in common with respect to any other Sanofi product or service.

(b) Except with respect to any Transferred Items, subject to the TSA and TDA, Regeneron shall be responsible, [* * *], for preparing and producing Promotional Materials for use in the Territory and, except to the extent Regeneron has the right to use the name or logo of Sanofi or its Affiliate under Section 4.1(d), such Promotional Materials shall bear the corporate name and logo of Regeneron, its Affiliates or its Sublicensees only. Sanofi shall not have any right to review Promotional Materials of Regeneron from or after the A&R Effective Date, except for any Promotional Materials that bear the name or logo of Sanofi or its Affiliate, in which case, upon Sanofi's reasonable request, Sanofi shall have a reasonable opportunity to review samples of such Promotional Materials to monitor Regeneron's compliance with Section 11.5(b).

6.6 Market Access; Pricing Approvals; Re-Sale Price. As between the Parties, Regeneron shall have the sole right to conduct market access activities and to obtain and maintain Pricing Approvals and determine the price(s) at which the IO Licensed Product shall be sold in the Territory, subject to any Pricing Approvals or other requirements imposed by any applicable Law.

6.7 [* * *].

6.8 Medical and Consumer Inquiries. The Parties acknowledge and agree that, notwithstanding anything in the PVA to the contrary, the amendment and restatement of the Pre-A&R Terms shall not result in the termination of the PVA, and the PVA shall continue to govern the Parties' handling of medical questions or inquiries from consumers relative to the IO Licensed Product in the Territory, including management of the global safety database for the IO Licensed Product, and setting forth specific procedures to be used for the exchange of reports of

adverse events/ adverse drug reactions and IO Licensed Product complaints (provided, that product technical complaints covered under any applicable Quality Agreement will be handled in accordance with such Quality Agreement) to ensure timely communication to Regulatory Authorities and compliance with Laws. For clarity, and subject to the terms of the PVA (which PVA terms shall govern in the event of any conflict with the terms of this Section 6.8), from and after the A&R Effective Date, as between the Parties, Regeneron shall solely manage pharmacovigilance and product complaints and formulate and implement any related strategies, and shall have the sole right to fulfill all regulatory requirements concerning pharmacovigilance and risk management and product complaint reporting in all countries in which the IO Licensed Product is being or will during the Term be Developed, Manufactured, Commercialized or used anywhere in the Territory; provided that, solely in the period from and after the A&R Effective Date but prior to the transfer of the applicable Marketing Approval for the IO Licensed Product in a given country, on a country–by-country basis, Sanofi shall continue to manage the foregoing matters on Regeneron's behalf as a Transition Service pursuant to the TSA (subject to the terms of the TSA and PVA), and Sanofi shall have the right to fulfill any obligations owed to any Regulatory Authority in such country (and to timely respond to any requests received therefrom) in respect thereto during such period in accordance with, and subject to, the TSA and PVA. Sanofi shall refer to Regeneron all such questions or inquiries that it receives about the IO Licensed Product in the Territory from and after the A&R Effective Date. Notwithstanding anything to the contrary in this Agreement in the event of termination of Commercialization in any country in the Territory after the A&R Effective Date where applicable Law requires continuation of pharmacovigilance activities or monitoring, receipt or recording of product complaints in that country, the Parties will cooperate in good faith to ensure continued compliance with such pharmacovigilance requirements, as set forth in, and pursuant to the terms of (as applicable), the PVA.

6.9 Expert Arbitration [* * *].

(a) If the Parties are unable to agree to: [* * *], each Party will select (1) individual who: (a) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue, (b) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past [* * *], and (c) has no known personal financial interest or benefit in the outcome or resolution of the dispute (such Person who meets the criteria of (a) through (c), 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 with a single vote.

(b) The Expert Committee will promptly hold a meeting to review the issue under review, at which it will consider memoranda submitted by each Party [* * *] before the meeting, as well as reasonable presentations that each Party may present at the meeting, and will thereafter determine (as applicable) (A) [* * *], (B) [* * *], or (C) [* * *], and in each case of (A) through (C), the Expert Panel shall make such determination taking into account such factors as the Expert Committee sees fit, including, to the extent applicable to (B) and (C): (I) [* * *], and (II) [* * *]; provided that with respect to any determination under (C), the Expert Panel shall take account of any (x) [* * *], (y) [* * *]. The determination of the Expert Committee as to the above matters will be binding on both Parties, [* * *], the Parties shall within [* * *] meet and agree on a true-up payment to be made from one Party to the other equaling the difference between any payments made under ARTICLE IX hereto arising from [* * *]in the period following the first commercial sale of such Combination Product and the date of such determination (the "At-Risk Period"), and the [* * *] if the Expert Committee's determination as to the [* * *] during the whole of such At-Risk Period (and, for clarity, such [* * *] during the At-Risk Period).

(c) The Parties will [* * *] the costs of the Expert Committee and [* * *] in connection with the Expert Committee process pursuant to this Section 6.9. Unless otherwise agreed to by the Parties in writing, the Expert Committee may not decide on issues outside the scope mandated under terms of this Agreement. For clarity, nothing in this Section 6.9 shall be construed as prohibiting or requiring the delay of any launch of a Combination Product in any country in the Territory.

ARTICLE VII
CLINICAL AND REGULATORY AFFAIRS

7.1 Ownership of Approvals and Registration Filings.

(a) Except to the extent prohibited by applicable Law or as otherwise provided in the CTSA or Ancillary Agreements, as between the Parties, from and after the A&R Effective Date, Regeneron or its Affiliate or its or their Sublicensee (or its or their designee) shall (i) have the sole right to address any and all regulatory matters pertaining to the IO Licensed Product, including any and all interactions with any Regulatory Authority in the Territory, (ii) exclusively own (A) all Approvals and Registration Filings with respect to the IO Licensed Product (including the Manufacture, Development, Commercialization and use thereof) in the Territory and (B) any IND(s) for the IO Licensed Product, and (iii) have the rights and obligations set forth in Section 7.2 and Section 7.3 with respect thereto.

(b) To the extent not, and unless and until, fully transferred to Regeneron or its Affiliates pursuant to Section 3.8, Sanofi shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of Regeneron and its Affiliates and its and their Sublicensees.

7.2 Regulatory Responsibility. From and after the A&R Effective Date subject to the TSA, the MSA and the PVA, as between the Parties, Regeneron shall have the sole right and decision-making authority with respect to, and subject to Section 17.2 shall be solely liable for, all regulatory strategy and actions, including preparing communications and filings with and submissions (including supplements and amendments thereto) to, and attending meetings with, the applicable Regulatory Authority(ies), in each case with respect to the Development, Manufacture, Commercialization or use of the IO Licensed Product in the Field in the Territory from and after the A&R Effective Date; provided that, solely in the period from and after the A&R Effective Date but prior to the transfer of the applicable Marketing Approval for the IO Licensed Product in a given country, on a country–by-country basis, Sanofi shall continue to manage the foregoing matters on Regeneron's behalf as a Transition Service pursuant to the TSA (subject to the terms of the TSA and PVA), and Sanofi shall have the right to fulfill any obligations owed to any Regulatory Authority in such country (and to timely respond to any requests received therefrom) in respect thereto during such period in accordance with, and subject to, the TSA and PVA.

7.3 Rights of Reference. Regeneron and its Affiliates shall have, and Sanofi (on behalf of itself and its Affiliates) hereby grants to Regeneron and its Affiliates, the right to access and reference (with the right to grant further rights of reference pursuant to Section 4.4) all relevant regulatory documentation (including all Registration Filings and Approvals) Controlled by Sanofi (or its Affiliates) that is related to the Existing IO Licensed Product as necessary or reasonably useful to exercise Regeneron's rights under the license grants set forth in Section 4.1, including to obtain Approval for use of the IO Licensed Product in combination with other products. Promptly upon the request of Regeneron, Sanofi or its Affiliate shall, to the extent such request is consistent with the foregoing rights to access and reference, prepare a letter of authorization to the applicable Regulatory Authority (and, [* * *], take such actions or make

such other filings) in order to permit any such regulatory documentation (including all Registration Filings and Approvals) to be incorporated by reference by Regeneron, its Affiliates or its or their Sublicensees in their Registration Filings; provided that [* * *].

7.4 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party or its Affiliates or its or their Sublicensees with regard to the IO Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including, with respect to an inspection or audit of Sanofi or its Affiliates or its or their Sublicensees, by allowing, to the extent practicable, a representative of Regeneron to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture, Commercialization or use of the IO Licensed Product for use in the Field under this Agreement. Following receipt by Sanofi or any of its Affiliates or its or their Sublicensees of the inspection or audit observations of the Regulatory Authority (a copy of which Sanofi will promptly provide to Regeneron), Sanofi or its Affiliates or its or their Sublicensees will prepare any appropriate responses; provided that Regeneron shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the IO Licensed Product in the Field in the Territory. In the event the Parties disagree concerning the form or content of a response, Regeneron will decide the appropriate content of the response to the extent specifically and solely related to the IO Licensed Product. Regulatory inspections and audits pertaining to Sanofi's Manufacturing facilities shall be governed by the applicable Quality Agreement. Without limiting the foregoing, Sanofi (and its Third Party subcontractors) shall, for so long as Manufacture under the MSA is ongoing, notify Regeneron within one (1) Business Day after receipt of notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities being used or proposed to be used for the Manufacture of the IO Licensed Product by or on behalf of Sanofi for Regeneron under such MSA.

7.5 Recalls and Other Corrective Actions.

(a) Notice. Each Party shall notify the other Party promptly (but in no event later than [* * *] following its determination (according to each Party's internal standard operating procedures) that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of the IO Licensed Product in the Territory that (i) relates to IO Licensed Product sold before the A&R Effective Date or (ii) is being implemented with respect to either: (A) the Existing Inventory transferred by Sanofi to Regeneron pursuant to (and as such term is defined in) the TDA, or (B) Finished Product supplied by Sanofi to Regeneron under the MSA (any recall, market suspension or market withdrawal described in clauses (i) or (ii), a "Selected Recall"), and shall include in such notice the reasoning behind such determination and any supporting facts.

(b) Implementation. As between the Parties, Regeneron shall have the sole right to make decisions with respect to and to implement any recall, market suspension or market withdrawal related to the IO Licensed Product in the Field in the Territory; provided that [* * *]; provided, further that, Sanofi shall to the extent reasonably practicable and without prejudice to Sanofi's right to timely implement any such recall, market suspension or market withdrawal, discuss with Regeneron in good faith and agree regarding such decisions for such country prior to any such implementation, and provided further that, prior to any implementation of a Selected Recall, the implementing Party shall consult with the other Party and shall consider the other Party's comments in good faith. If Sanofi determines that a recall or market withdrawal of the IO Licensed Product in the Field in the Territory may be required (according to Sanofi's internal SOPs), Sanofi shall, within twenty-four (24) hours of such determination, notify Regeneron.

(c) Recall Costs. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 7.5, (i) to the extent such recall, market suspension or market withdrawal is attributable to acts or omissions occurring prior to the A&R Effective Date, subject to Section 17.1 of the Pre-A&R Terms, and excluding any costs or expenses included as Continued Shared Expenses for the purposes of the True-Up as of the A&R Effective Date in Schedule 2.2, the costs and expenses of such recall, market suspension or market withdrawal will be [* * *], and (ii) subject to any further allocation under the MSA, to the extent such recall, market suspension or market withdrawal is attributable to acts or omissions occurring after the A&R Effective Date and to the extent not constituting Third Party Claims subject to indemnification under Section 17.2, the costs and expenses of such recall, market suspension or market withdrawal will be [* * *].

(d) Correspondence or Public Announcements. Sanofi shall not, and shall ensure that its Affiliates and its and their Sublicensees do not, except to the extent required by applicable Laws or any applicable rules, regulations or guidelines of any applicable Regulatory Authority (in which case, Sanofi shall use its commercially reasonably efforts to provide Regeneron as much prior advance notice as practicable in the circumstances and shall consider any comments from Regeneron in good faith), make any public statements or disclosures in connection with any recall, market suspension or market withdrawal of the IO Licensed Product without Regeneron's prior written consent (not to be unreasonably withheld, conditioned or delayed). Without limiting the foregoing, each Party shall provide the other Party with copies of any correspondence sent to or received from Regulatory Authorities or any issued public announcement, in each case, related to any Selected Recall.

(e) Miscellaneous. Each Party shall consider any comments made by the other Party pursuant to this Section 7.5 in good faith. Notwithstanding anything herein to the contrary, in the event of any inconsistency between this Section 7.5 and the terms and conditions of any applicable quality agreement that is an exhibit to the MSA or the PVA, the terms of such quality agreement or PVA, as applicable, shall control.

ARTICLE VIII
MANUFACTURING AND SUPPLY

8.1 Manufacture and Supply of Finished Product. On the A&R Execution Date, the Parties or their Affiliates shall execute a Manufacturing Services Agreement (the "MSA") in the form attached as Schedule 8.1 hereto. Subject to and pursuant to the terms of the MSA, Sanofi will perform or cause to be performed those Manufacturing services set forth in the MSA for the periods of time specified in the MSA. Subject to the terms of this Agreement, except as expressly provided for under the MSA, as between the Parties, Regeneron shall have the sole right to Manufacture the IO Licensed Product from and after the A&R Effective Date. Regeneron shall be solely responsible for one hundred percent (100%) of any COGS incurred in connection with any IO Licensed Product sold from and after the A&R Effective Date. For clarity, during the period from the Transition Date until the A&R Effective Date, any and all COGS incurred by Sanofi during such period shall be subject to Section 2.2. Regeneron's obligation to reimburse Sanofi for Manufacturing conducted from or after the A&R Effective Date shall be limited to the Transition Services Fees (as such term is defined in the TSA) payable pursuant to the TSA and any other Manufacturing-related fees payable pursuant to the MSA.

ARTICLE IX
PERIODIC REPORTS; PAYMENTS

9.1 Upfront Payment. Within ten (10) Business Days [* * *] following the A&R Effective Date, Regeneron shall pay to Sanofi a non-refundable, non-creditable amount of nine hundred million Dollars ($900,000,000) (such amount, the "Payment"). [* * *].

9.2 Milestone Payments. In addition to the other payments contemplated herein, subject to the terms and conditions of this Agreement, Regeneron shall pay to Sanofi:

(a) a one-time non-refundable, non-creditable milestone payment in the amount of one hundred million Dollars ($100,000,000) (the "Development Milestone Payment") upon receipt of the first Marketing Approval of the IO Licensed Product from the FDA or the EMA, in either case, for use in the prophylaxis, treatment or amelioration of non-small cell lung cancer in any patient population in combination with chemotherapy (such Marketing Approval, the "Development Milestone"). After the achievement of such Development Milestone, Regeneron: (i) shall promptly (and in any event within [* * *], or if the Development Milestone is achieved prior to the A&R Effective Date, within [* * *] after the A&R Effective Date) provide written notice to Sanofi of the achievement of such Development Milestone, and (ii) shall have [* * *] from the date of electronic receipt of an invoice from Sanofi (which, for clarity, may only be issued following the later of the A&R Effective Date and achievement of such Development Milestone) to pay the amount of the Development Milestone Payment to Sanofi. For purposes of clarification, the Development Milestone Payment shall be made only once and only upon the first (1st) occurrence of the Development Milestone, and no amounts shall be due for subsequent or repeated achievements of such Development Milestone in other jurisdictions in the Territory.

(b) a one-time non-refundable, non-creditable milestone payment in the amount of [* * *] (the "2022 Sales Milestone Payment") in the event that, in the 2022 Calendar Year, worldwide Net Sales of the IO Licensed Product are greater than or equal to [* * *] (the "2022 Sales Milestone"). After the achievement of such 2022 Sales Milestone, Regeneron: (i) shall, within the later of (A) [* * *] after the end of the [* * *] and (B) [* * *] after Sanofi provides Regeneron the Monthly Statement (as defined in the TDA) for such calendar month in which the 2022 Sales Milestone is achieved, provide written notice to Sanofi of the achievement of such 2022 Sales Milestone, if applicable, and (ii) shall have [* * *] from the date of electronic receipt of an invoice from Sanofi (which, for clarity, may only be issued following the calendar month in which such 2022 Sales Milestone is achieved) to pay the amount of the 2022 Sales Milestone Payment to Sanofi. In no event shall payment be due under this Section 9.2(b) with respect to Net Sales in any Calendar Year other than 2022; provided, however, that all Net Sales hereunder shall be booked in accordance with the applicable Party's Accounting Standards and applicable Law.

(c) a one-time non-refundable milestone payment in the amount of [* * *] (the "2023 Sales Milestone Payment") in the event that, in the 2023 Calendar Year, worldwide Net Sales of the IO Licensed Product are greater than or equal to [* * *] (the "2023 Sales Milestone"). After the achievement of such 2023 Sales Milestone, Regeneron: (i) shall, within the later of (A) [* * *] after the end of the calendar month and (B) [* * *] after Sanofi provides Regeneron the Monthly Statement (as defined in the TDA) for such calendar month in which the 2023 Sales Milestone is achieved, provide written notice to Sanofi of the achievement of such 2023 Sales Milestone, if applicable, and (ii) shall have [* * *] from the date of electronic receipt of an invoice (which, for clarity, may only be issued following the calendar month in which such 2023 Sales Milestone is achieved) from Sanofi to pay the amount of the 2023 Sales Milestone Payment to Sanofi. In no event shall payment be due under this Section 9.2(c) with respect to Net Sales in any Calendar Year other than 2023; provided, however, that all Net Sales hereunder shall be booked in accordance with the applicable Party's Accounting Standards and applicable Law.

In no event shall the payments under this Section 9.2 exceed two hundred million Dollars ($200,000,000).

9.3 Royalties.

(a) During the period of time commencing on the Transition Date and ending twelve (12) years thereafter (the "Royalty Term"), Regeneron shall on a Quarterly basis, pay Sanofi a royalty of eleven percent (11%) on the sum of [* * *] all worldwide Net Sales of the IO Licensed Product made during the prior Quarter of the Royalty Term [* * *] (such amounts, the "Royalties"); provided that (x) for clarity, Royalties due for the Interim Period shall be paid pursuant to Section 2.2 and shall not be paid pursuant to this Section 9.3, and (y) no Royalties shall be due with respect to any Net Sales attributable to sales made prior to the Royalty Term; provided, further, that the Parties comply with Section 2.2 with respect to any reconciliations with respect to such Net Sales. By way of illustration, if the first commercial sale of the IO Licensed Product in a particular country of the Territory occurs on the [* * *] of the Transition Date, royalties on the Net Sales of such IO Licensed Product in such particular country shall be payable for [* * *] after such first commercial sale. Following the expiration of the Royalty Term, the grants in Section 4.1 and Section 4.3 shall become fully-paid (subject to any later achievement of the Development Milestone, in which case the Development Milestone Payment shall remain due and payable in accordance with Section 9.2(a)) and royalty-free.

(b) From and after the A&R Effective Date, during the Royalty Term, Regeneron shall deliver to Sanofi: (i) within [* * *] following the end of each Quarter of the Royalty Term, a non-binding estimate of aggregate Net Sales for the IO Licensed Product for such Quarter; and (ii) within [* * *] following the end of each such Quarter, a report setting forth, on a country-by-country basis: (1) Net Sales of the IO Licensed Product by Regeneron, its Affiliates and Sublicensees; (2) the [* * *]; and (3) royalties payable in respect of such Net Sales of the IO Licensed Product and [* * *], in each case ((1) - (3)), during such Quarter (such report, the "Quarterly Royalty Report"). Any amounts in such reports shall be in local currency and in Dollars, where applicable (with the calculation of such amounts to be made pursuant to the exchange methodology specified in Section 9.8).

(c) Following delivery of the Quarterly Royalty Report for a given Quarter, Sanofi shall submit an invoice to Regeneron for the amount of Royalties thereunder, subject to the terms of this ARTICLE IX, and Regeneron shall pay all Royalties due to Sanofi hereunder in respect of such Quarter no later than [* * *] after receipt of Sanofi's invoice therefor.

(d) [* * *]. [* * *].

9.4 IO Development Balance. During the Term, and until such time as the IO Development Balance is zero, Regeneron shall on a Quarterly basis pay Sanofi the Development Compensation Payment specified in, and calculated in accordance with, Exhibit 2 hereto. Regeneron shall deliver to Sanofi within [* * *] of the end of each Quarter, a report detailing in reasonable detail the information necessary to calculate the Development Compensation Payment due under Exhibit 2 for such Quarter, including: (a) the IO Development Balance prior to such Quarter; (b) the Net Sales for such Quarter; (c) the Development Compensation Payment owed for such Quarter, and (d) the remaining IO Development Balance after such Development Compensation Payment has been deducted (such report, the "IO Development Balance Report"). Following delivery of the IO Development Balance Report for a given Quarter, Sanofi shall submit an invoice to Regeneron for the amount of the Development Compensation Payment specified thereunder, subject to the terms of this ARTICLE IX, and Regeneron shall pay to Sanofi such Development Compensation Payment no later than [* * *] after receipt of Sanofi's invoice therefor.

9.5 Financial Obligations under Licenses and Other Agreements. Unless otherwise agreed by the Parties, Regeneron shall be responsible for [* * *] under (a) [* * *]and

(b) any [* * *]. For the avoidance of doubt (i) [* * *] and (ii) [* * *]. Unless otherwise agreed by the Parties or set forth in the TSA, Regeneron shall [* * *]. For clarity, [* * *].

9.6 Reimbursement. For all amounts for which a Party (the "Owing Party") is obligated to reimburse or pay the other Party or its designated Affiliate (the "Owed Party") pursuant to this Agreement for which no specific provision is made hereunder for such payment, the Owed Party shall send to the Owing Party an invoice for such amount within [* * *] 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 9.8; provided, however, that if the Owing Party in good faith disputes any portion of any such invoice, it shall pay the undisputed portion and shall provide the Owed Party with written notice of the disputed portion and its reasons therefor, and the Owing Party shall not be obligated to pay such disputed portion unless and until such dispute is resolved in favor of the Owed Party. The Parties shall use good faith efforts to resolve any such disputes promptly.

9.7 Invoices and Documentation. The Transition Leads (or their designees) shall coordinate and, acting reasonably, mutually agree upon the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder. All payments otherwise due and owing under this Agreement shall be supported by, and, if any such payment is due hereunder within a specified time period, such specified time period shall not start running until receipt by the owing Party of, an invoice delivered (whether electronically or physically) to the Party owing such amount, in such form approved by the Transition Leads (or their designees).

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

9.9 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the [* * *] Term Secured Overnight Financing Rate ("Term SOFR"), as quoted by Bloomberg effective for the date on which the payment was due, [* * *] (such sum being referred to as the "Default Interest Rate").

9.10 Taxes.

(a) Each Party shall be responsible for any taxes imposed on or measured by net income or gross income (including branch profits), gross receipts, capital, ability or right to do business, property and franchise or similar taxes pursuant to applicable Law. Any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party with respect to any payments to such other Party hereunder

shall be deducted from such payments and paid to the appropriate Governmental Authority within the statutory deadline; provided that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. The Parties agree that any taxes so deducted shall for all purposes of this Agreement be deemed to have been paid to the other Party. If and to the extent that this Agreement does not provide for apportionment and the tax withholding base is ambiguous, the Parties will cooperate in good faith to determine the right tax withholding tax base using Net Sales ratio as a proxy. Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees, and to refrain from withholding (or to withhold at a reduced rate) if the Party entitled to claim the benefit of any available treaty on the avoidance of double taxation claims such benefit, provided that the Party provides the timely, correct and complete documentation required to claim such benefit. Notwithstanding anything in this Agreement to the contrary, if any payment due under Section 9.1 through Section 9.6 (inclusive) above becomes subject to any additional tax liability for Sanofi (including any withholding tax to be paid by Regeneron) solely as a result of assignment of this Agreement by Regeneron, then Regeneron shall pay to Sanofi such additional amount so that Sanofi receives the same amount which it would have received had no such additional tax liability been imposed; provided that Sanofi shall use reasonable efforts to obtain a refund or credit of such amounts and shall pay over to Regeneron any amount recovered.

(b) The Parties acknowledge that Sanofi's income may be exempt from taxation under an income tax treaty or an E.U. directive, or that a reduced withholding tax rate may apply. If Sanofi provides Regeneron with a timely, correct and complete tax exemption certificate or other equivalent document certifying that Regeneron may abstain from withholding or may withhold tax at a lower rate in accordance with applicable Law (the "Certificate"), Regeneron shall apply such tax exemption and shall cease withholding or apply the lower tax rate as soon as the Certificate is received. Sanofi will notify Regeneron in a timely manner if the conditions under which the Certificate was issued change, and will do so before they change. The Parties acknowledge that the taxing jurisdiction may permit Regeneron to refrain from withholding, reporting and paying the tax to the appropriate Governmental Authority, even if no Certificate has been issued, provided that Sanofi timely files an application for tax exemption with the appropriate Governmental Authority (the "Post-Approval Procedure"). If such Post-Approval Procedure or similar procedure exists and Sanofi has provided the proper evidence of timely filing the application for the Post-Approval Procedure, the Parties agree that Regeneron shall refrain from withholding, reporting and remitting taxes in accordance with the Post-Approval Procedure. As and when relevant, Regeneron will use reasonable efforts to provide all required documentation and information to Sanofi to enable Sanofi to apply for any reimbursement of withholding taxes with the appropriate Governmental Authority.

(c) Except to the extent provided in the last sentence of clause (a) of this Section 9.10, the Parties agree that withholding tax due on any consideration payable to Sanofi shall in any event be borne by Sanofi. In the event that Regeneron does not withhold such tax, or withholds such tax at a reduced rate, and the applicable Governmental Authority subsequently determines that additional tax should have been withheld by Regeneron, the Parties shall cooperate in good faith to mitigate all financial consequences attached to such tax liability and, in all cases, Sanofi will indemnify and hold Regeneron harmless for any financial consequences and related costs attached thereto. In the case of any overwithholding, Regeneron and Sanofi shall cooperate in good faith to mitigate such overwithholding.

(d) All payments specified or referred to in this Agreement shall exclude any sales, use, value added, levies, import and custom duties, excise or other similar or equivalent taxes (the "Sales Taxes"). The Party receiving a payment under this Agreement shall provide to the other Party an invoice separately stating any Sales Taxes with respect to the relevant payment. Upon receipt of such invoice, the paying Party shall pay such Sales Taxes to

the receiving Party, and the receiving Party shall remit such Sales Taxes to the relevant Governmental Authority.

9.11 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this ARTICLE IX, the Party with the dispute shall have its Transition Lead provide the other Party's Transition Lead with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the respective Transition Leads, will seek to resolve the dispute as promptly as possible, but no later than [* * *] after such written notice is received. In the event that no resolution is reached by the Transition Leads, the matter shall be escalated to the Executive Officers in accordance with Section 10.3. Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount 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.

9.12 Net Sales Calculations. For purposes of calculating whether the 2022 Sales Milestone and the 2023 Sales Milestone have been achieved, any Royalties due pursuant to Section 9.3 or any Development Compensation Payment due pursuant to Section 9.4, any Net Sales made by Sanofi or its Affiliates or its or their Sublicensees (a) for the Interim Period shall not exceed the Net Sales of the IO Licensed Product made by Sanofi or its Affiliates or its or their Sublicensees for purposes of determining the Sanofi Profits for the Interim Period and (b) for any period from and after the A&R Effective Date shall be equal to the Net Sales under the TDA for such period pursuant to the TDA.

ARTICLE X
DISPUTE RESOLUTION

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Resolution of Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in ARTICLE III ("Governance Disputes") shall be resolved pursuant to ARTICLE III, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply.

10.3 Dispute Resolution Process. The Parties agree that, subject to Sections 10.4 and 16.2, they shall use all reasonable efforts to resolve any dispute arising under this Agreement by good faith negotiation and discussion. Either Party may submit in writing any dispute (other than a Governance Dispute or a dispute in respect of any final and binding results of any audit conducted pursuant to Section 14.4) to the Executive Officers for resolution, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within [* * *] of such notice. Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such dispute, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1.

10.4 No Waiver. Nothing in this ARTICLE X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable

relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other Party or any of its Affiliates or its or their Sublicensees.

ARTICLE XI
TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. From and after the A&R Effective Date, as between the Parties, Regeneron shall have the sole right to select any Trademark for use in the Field in the Territory for the IO Licensed Product, including to determine whether a different Trademark should be used in one or more particular countries or regions for the IO Licensed Product, and shall own and retain all right, title and interest in and to the Transferred Domain Names and the Product Trademarks for the IO Licensed Product, together with all associated goodwill related thereto worldwide.

11.3 Prosecution, Maintenance, Enforcement and Defense of the Product Trademark. Regeneron shall, [* * *], have the sole right to register, prosecute (including monitoring and opposition), maintain, enforce and defend the Transferred Product Trademarks and the Transferred Domain Names for the IO Licensed Product worldwide. With respect to the Transferred Product Trademarks and Transferred Domain Names, [* * *].

11.4 Use of the Product Trademark.

(a) Sanofi agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any Trademark or domain names confusingly similar to, or misleading or deceptive with respect to, the registered or pending Trademarks contained within the Transferred Product Trademarks or the registered domain names contained within the Transferred Domain Names, or take any other action that endangers, damages, dilutes, destroys or similarly affects the rights to, or goodwill associated with, the Transferred Product Trademarks or the Transferred Domain Names pertaining thereto or attack, dispute or contest the validity of or ownership of Regeneron in or to the Libtayo brand name or any registrations or pending registration thereof.

(b) Except as otherwise required to perform its obligations under the TSA and TDA, Sanofi its Affiliates and its and their Sublicensees shall (i) have no rights in or to the Transferred Domain Names and (ii) discontinue forthwith all use of the Transferred Product Trademarks.

11.5 Use of Corporate Names.

(a) Except as expressly permitted under Section 4.1(d) or as otherwise required by applicable Law, neither Party shall use any Trademark or domain name of the other Party without such other Party's prior written consent. Neither Party shall, and shall not permit its Affiliates or its or their Sublicensees or distributors to, with respect to its activities under this Agreement, take any action or do any act that endangers, damages, destroys or similarly affects, in any material respect, the other Party's or the other Party's Affiliates' corporate names or logos or the value of goodwill pertaining thereto.

(b) Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, (i) conform to customary industry standards for the protection of, and comply with applicable Law with respect to the use of, the other Party's corporate names and logos and

(ii) adhere to and maintain the highest quality standards of the other Party with respect to goods sold and services provided under the other Party's corporate names or logos.

ARTICLE XII
NEWLY CREATED INVENTIONS; JOINT PATENT RIGHTS

12.1 Ownership of Newly Created Intellectual Property.

(a) Regeneron shall exclusively own all right, title and interest in and to any and all intellectual property (including Know-How, Patents and copyrights) first discovered, invented, authored or otherwise created under or in connection with this Agreement after the Transition Date to the extent [* * *]. The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's intellectual property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's intellectual property (including Know-How, Patents and copyrights), other than the license rights expressly granted hereunder. For inventions first discovered, invented, authored or otherwise created under or in connection with this Agreement after the Transition Date, any remuneration payable under applicable Law to an inventor and costs and expenses associated with determining such remuneration shall be the sole responsibility of Regeneron.

(b) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under this Agreement vests in a Party, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party shall, and hereby does, irrevocably assign, and shall cause its Affiliates and its and their Sublicensees to assign, to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party. Each Party agrees to execute all necessary documentation to reflect the foregoing.

(c) Subject to and without limiting the license grant to Regeneron in Section 4.1, the Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement, [* * *].

12.2 Prosecution and Maintenance of Patent Rights.

(a) [* * *].

(b) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of [* * *] pursuant to this Section 12.2, including the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary.

(c) [* * *] shall determine which, if any, of the [* * *] to seek an extension of the term in the Territory and shall have the right to seek any such extension.

12.3 Interference, Opposition, and Other Administrative Patent Proceedings.

(a) Each Party will notify the other within [* * *] of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition, post-grant review, inter-partes review, derivation proceeding, supplemental examination, reissue or reexamination relating to the [* * *] in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The [* * *] pursuant to Section 12.2 shall have the right to initiate or respond to such

a proceeding, as applicable, and to determine the course of action in such proceeding, including settlement negotiations and terms.

(b) All costs and expenses (including any Out-of-Pocket Costs) incurred from and after the A&R Effective Date in connection with any interference, opposition, reissue, post-grant review, reissue or reexamination proceeding relating to the [* * *] in the Territory for use in the Field shall be [* * *].

ARTICLE XIII
INTELLECTUAL PROPERTY LITIGATION AND LICENSES

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a [* * *], the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known, potential or suspected infringement or unauthorized use. [* * *].

(b) With respect to any such actual, suspected or potential infringement of a [* * *] by virtue of a Third Party's activities in the Field in the Territory, including any generic or potential generic competitor's activities in the Field in the Territory, including any Abbreviated New Drug Application (as defined in the Federal Food, Drug, and Cosmetic Act) filing, Paragraph IV Certification, any regulatory filing based on Section 351(k) of the Public Health Service Act (42 U.S.C. 262) or Article 10(4) of the Directive 2001/83/EC or any other similar regulation promulgated by the FDA, the EMA or by other applicable similar governmental regulatory authorities or other actual or potential infringement by a generic or potential generic competitor anywhere in the Territory, [* * *].

(c) Except as otherwise set forth in this Agreement, all costs and expenses (including Out-of-Pocket Costs) incurred in connection with any litigation under this Section 13.1 shall be the [* * *], subject to the final sentence of Section 13.1(b); provided that, in the case of costs and expenses incurred by Sanofi, [* * *].

(d) [* * *].

13.2 Patent Marking. Unless otherwise mutually agreed to by the Parties in writing, Regeneron shall comply with the Patent marking statutes in each country in which the IO Licensed Product in the Field is made, offered for sale, sold or imported by or on behalf of Regeneron, its Affiliates or Sublicensees.

13.3 Third Party Infringement Claims; New Licenses.

(a) For the period commencing on the A&R Effective Date and ending on the [* * *], if either Party or its Affiliates shall learn of an allegation that the Development, Manufacture, Commercialization or use of the IO Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation.

(b) After the A&R Effective Date, [* * *].

(c) Except as otherwise set forth in this Agreement, all costs and expenses (including any Out-of-Pocket Costs) incurred in connection with any litigation referred to in this Section 13.3 shall [* * *].

(d) [* * *].

(e) License fees, royalties and other payments under Licenses to the extent attributable to, and based on, the Development, Manufacture, Commercialization or use of the IO Licensed Product in the Field in the Territory from and after the Transition Date, shall be governed by Section 9.5.

(f) [* * *].

ARTICLE XIV
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Periods prior to Transition Date. The Parties' respective audit rights under ARTICLE XIV of the Pre-A&R Terms shall continue to apply in respect of any books and records with respect to periods prior to the Transition Date.

14.2 Interim Period Prior to A&R Effective Date. Solely in respect of the period between the Transition Date and the A&R Effective Date, Sanofi shall be obligated to keep records, and Regeneron shall have the right to audit Sanofi, on terms consistent with Sections 14.3 and 14.4. For clarity, Sections 14.3 and 14.4 shall not apply to Sanofi for any periods from and after the A&R Effective Date, and for such periods Sections 14.3 and 14.4 shall be read as applying solely to Regeneron, its Affiliates and its Sublicensees.

14.3 Books and Records. Each Party shall, and shall cause each of its Affiliates and Sublicensees to, keep proper books of record and account in which full, true and correct entries (in conformity with such Party's Accounting Standards) shall be made for the purpose of determining the amounts payable or owed to the other Party pursuant to this Agreement. Each Party shall, and shall cause each of its Affiliates to, permit auditors, as provided in Section 14.4, to visit and inspect, during regular business hours and under the guidance of the employees of such Party, and to examine the books of record and account of such Party or such Affiliate or such Sublicensee (and Regeneron shall cause its Sublicensees to make available such books of record and account to Regeneron) to the extent relating to such payments under this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate or such Sublicensee to the extent relating to this Agreement, with, and be advised as to the same by, its and their officers and independent accountants.

14.4 Audits and Adjustments.

(a) Each Party shall have the right [* * *], upon no less than [* * *] advance written notice and at such reasonable times and intervals and to such reasonable extent as such Party shall request, not more than once during any Calendar Year, to have the books and records of the other Party and its Affiliates and its Sublicensees maintained pursuant to Section 14.1 or Section 14.2 to the extent relating to this Agreement, for the preceding [* * *] to be made available for review at a single location to be audited by an independent "Big Four" (or equivalent) accounting firm of such first Party's choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement (including, for the avoidance of doubt, all information necessary to calculate the royalty payments due under Section 9.3 during the Royalty Term, including, on a month-by-month and country-by-country basis, the total gross invoiced amounts from sales of the IO

Licensed Product by or on behalf of (individually and in aggregate) Regeneron, its Affiliates and Sublicensees, the amount of units sold, broken out by dosage form and unit size, all relevant deductions from gross invoiced amounts to calculate Net Sales, the resulting Net Sales, and the royalties calculated as payable in respect thereto); provided that no period may be subjected to audit more than [* * *] unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within [* * *] of delivery. If the audited Party or its Affiliates have underpaid or overbilled an amount due under this Agreement resulting in a cumulative discrepancy of amounts incurred during any year of more than [* * *], the audited Party shall also reimburse the auditing Party for the costs and expenses of such audit [* * *]. Such accountants 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 Parties shall cause such accountants to enter into a reasonably acceptable confidentiality agreement with the audited Party and obligating such firm to retain all such financial information in confidence pursuant to terms no less stringent than those set forth in ARTICLE XVI.

(c) If any examination or audit of the records described above discloses an overpayment or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 14.4(d), (i) the Party that underpaid shall pay any amounts due plus, if such underpayment is the underpaying Party's fault, interest thereon at the Default Interest Rate accruing from the date of such underpayment, or (ii) the Party that received an overpayment shall refund such overpayment plus, if such overpayment is the fault of the Party refunding such payment, interest thereon at the Default Interest Rate accruing from the date of such overpayment, in each case (i) and (ii) within [* * *] after receipt of the written results of such audit.

(d) Subject to the first (1st) sentence of Section 14.4(b), any disputes with respect to the results of any audit conducted under this Section 14.4 shall be subject to dispute resolution in accordance with ARTICLE X.

14.5 GAAP/IFRS. Except as otherwise provided herein, all of a Party's costs and expenses and other financial determinations with respect to this Agreement and the Pre-A&R Terms shall be determined in accordance with such Party's Accounting Standards, as generally and consistently applied.

ARTICLE XV
REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 Due Organization, Valid Existence and Due Authorization; Financial Capability. Each Party represents and warrants to the other Party, as of the A&R Execution Date and A&R Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents or any other agreement by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting the licenses granted to the other under ARTICLE IV hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in

connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder.

15.2 Knowledge of Pending or Threatened Litigation or Adverse Agreements. Each Party represents and warrants to the other Party that, [* * *], and except as otherwise set forth on Schedule 15.2, as of the A&R Execution Date and A&R Effective Date, there is no (a) claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator or Governmental Authority or (b) to such Party's knowledge, no agreement entered into by such Party or its Affiliates that, in each case ((a) and (b)), individually or in the aggregate, could reasonably be expected to (i) materially impair the ability of such Party to perform any of its obligations under this Agreement or (ii) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. Each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Sanofi Representations, Warranties and Covenants. Sanofi additionally represents and warrants to Regeneron, except as set forth on Schedule 15.2, as of the A&R Execution Date and, except as set forth on Schedule 15.3 (provided that, upon written notice to Regeneron prior to the A&R Effective Date, Sanofi shall have the right to update (x) Schedule 1.78 and Schedule 1.88 and (y) Schedule 15.3 solely with respect to clauses (d), (e) and (j) and solely as such representations are made as of the A&R Effective Date), as of the A&R Effective Date, that:

(a) [* * *].

(b) [* * *].

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

(d) [* * *].

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

(f) Each of the Transferred Product Contracts represents a legal, valid and binding obligation of Sanofi or its Affiliate(s) that are party thereto and is enforceable against Sanofi or such Affiliate(s), in accordance with its terms, and is in full force and effect, subject to (A) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors' rights generally and (B) general equitable principles (whether considered in a proceeding in equity or at Law).

(g) To Sanofi's Knowledge, the Transferred Domain Names assigned pursuant to the Domain Name Assignment represent all material domain names owned or controlled by Sanofi and its Affiliates as of the A&R Execution Date, related to the Existing IO Licensed Product.

(h) [* * *].

(i) Sanofi and its Affiliates have conducted, and its and their respective Sublicensees, contractors and consultants have conducted, all Development and Commercialization of the IO Licensed Product in accordance with all applicable Law.

(j) To Sanofi's Knowledge, no actions have been taken by a Governmental Authority or Regulatory Authority that would prohibit or adversely affect in a material manner Regeneron's right and ability to Commercialize the IO Licensed Product in accordance with this Agreement.

15.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. 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, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as follows: (a) it will not during the Term grant any right or license to any Third Party in the Territory which would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) [* * *]; and (c) from and after the A&R Effective Date, in the course of the transition of Development and Commercialization of the IO Licensed Product in the Field to Regeneron under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

15.6 Sanofi Covenants. From the A&R Execution Date and until the A&R Effective Date, except as consented to in writing by Regeneron, (a) Sanofi shall conduct its business with respect to the IO Licensed Product in the ordinary course of business consistent with past practice and in accordance with all applicable Law with respect to the performance of its obligations under this Agreement, including with respect to its activities under any Existing Trials, and (b) [* * *].

ARTICLE XVI
CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Sanofi and Regeneron acknowledges (subject to Section 16.1(b) and the provisions of ARTICLE XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement, the Pre-A&R Terms or the Ancillary Agreements is confidential and proprietary to such other Party or its Affiliates. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this ARTICLE XVI) that all New Information is confidential and proprietary to both Parties (and both Parties shall be deemed to be the receiving Party with respect thereto). Notwithstanding anything in ARTICLE XVI to the contrary, [* * *].

(b) Notwithstanding anything provided in Section 16.1(a), the restrictions provided in this ARTICLE XVI shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; provided that this clause (ii) shall not apply with respect to [* * *]; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information and not, with respect to [* * *]; (iv) similar in nature to the purported [* * *] but has been independently created outside of this [* * *], as evidenced by written or electronic documentation, without any aid, application or use of the [* * *].

(c) Notwithstanding anything provided in Section 16.1(a), each Party may use or disclose Party Information of the other Party and New Information to the extent that use or disclosure is (i) [* * *]; (ii) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the receiving Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information that is required by Governmental Authority, applicable Law or court order to be disclosed; (iii) to enforce the terms of this Agreement, the Pre-A&R Terms or any Ancillary Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information; or (iv) to the Regulatory Authorities as required in connection with obtaining or maintaining any application of the IO Licensed Product in the Field in the Territory pursuant to the terms of this Agreement; provided that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law; provided, further, that this exception shall not apply to Party Information that does not specifically relate to the IO Licensed Product.

(d) Notwithstanding anything provided in this Section 16.1 or elsewhere in this Agreement, each Party and its Affiliates shall have the right to use and disclose any New Information directly related to the IO Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.

(e) Notwithstanding anything in Section 16.1 to the contrary, to the extent any use or disclosure by Regeneron of any Party Information of Sanofi specifically relating to the IO Licensed Product or the Development, Manufacture, Commercialization or use thereof (to the extent previously disclosed to Regeneron pursuant to the Pre-A&R Terms) would require Regeneron to provide notice to, or seek the consent of, Sanofi pursuant to this Section 16.1, Sanofi hereby waives any requirement for the provision of such notice or the seeking of such consent, to the extent such use or disclosure by Regeneron is for the purposes of the Development, Manufacture or Commercialization of the IO Licensed Product.

16.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties under this ARTICLE XVI are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in

accordance with the provisions of this ARTICLE XVI, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this ARTICLE XVI, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

16.3 Disclosures Concerning this Agreement. The Parties will mutually agree on the contents of their respective press releases with respect to the amendment and restatement of this Agreement, which press releases shall be issued by each Party at a time mutually agreed by the Parties, but no later than [* * *] following the A&R Execution Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement, the Pre-A&R Terms or any Ancillary Agreements or any actions or activities contemplated hereunder or thereunder without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's securities (or the securities of its parent entity) are traded); provided that the Party intending to disclose such information shall (a) use reasonable efforts to (i) provide the other Party advance notice of such required disclosure and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and (ii) assist the other Party to protect such information and (b) limit the disclosure to the information that is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements that incorporate information concerning this Agreement, the Pre-A&R Terms or any of the Ancillary Agreements or any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure that was previously disclosed under the terms of this Agreement, the Pre-A&R Terms or any such Ancillary Agreements or which contains only non-material factual (non-financial) information regarding the Collaboration or this Agreement. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's securities (or the securities of its parent entity) are traded), or in connection with the enforcement of this Agreement, the Pre-A&R Terms or any Ancillary Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement, the Pre-A&R Terms or any Ancillary Agreement, in each case, that have not been previously disclosed publicly pursuant to this ARTICLE XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least [* * *]. The Parties, through the Transition Leads, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the IO Licensed Product in the Field. Each Party acknowledges that the other Party, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement and certain or all of the Ancillary Agreements with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of this Agreement or the applicable Ancillary Agreement(s) marked to show provisions for which the filing Party intends to seek

confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

16.4 Residuals. A Party shall not be restricted under, and shall not be in breach of, this Agreement from using, within or outside this Agreement or any Ancillary Agreement and for any purpose, any general knowledge, skill and expertise acquired by its employees (or its Affiliates' employees) in their performance of this Agreement, the Pre-A&R Terms or any Ancillary Agreement ("Residuals") solely to the extent such Residuals shall have been retained in the unaided memory (without intentional memorization) of such employees in intangible form and without use by the Party or such employees of tangible copies of any Party Information of the other Party or New Information; [* * *]; provided, further, that a Party's use of such Residuals is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at such Party's sole risk. This Section 16.4 shall survive indefinitely the termination of this Agreement in its entirety or expiration of this Agreement for any reason.

ARTICLE XVII
INDEMNITY

17.1 Indemnity Prior to A&R Effective Date. The Parties' respective rights and obligations under Section 17.1 of the Pre-A&R Terms shall continue to apply in respect of any acts or omissions occurring prior to the A&R Effective Date and, for clarity, each Party shall continue to have an obligation to indemnify the other Party for Third Party Claims for which it has an obligation to indemnify the other Party under Section 17.1 of the Pre-A&R Terms.

17.2 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, Sublicensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' or experts' fees and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement (a "Third Party Claim") against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Sanofi or its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of (A) this Agreement, or (B) any Ancillary Agreement other than the Service Agreements;

(ii) material breach by Sanofi (or conduct or omission by any of its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf), which if performed or failed to be performed by Sanofi would be a material breach by Sanofi) of the terms of, or the representations and warranties made by it in, (A) this Agreement, (B) any Ancillary Agreement other than the Service Agreements or (C) any Product Contract or Master Agreement;

(iii) (A) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Sanofi or its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of the TSA, (B) material breach by Sanofi (or conduct or omission by any of its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) of the TSA; or

(iv) any Sanofi Product Agreement, except to the extent that the applicable Third Party Claim is due to or based upon any change in the terms of such Sanofi Product Agreement implemented by Sanofi or any of its Affiliates at Regeneron's direction under the TSA; provided, however, that Regeneron shall be liable for payments or reimbursement of rebates, fees, chargebacks and other payments to be made pursuant to such Sanofi Product Agreements in respect of sales of the IO Licensed Product made after the A&R Effective Date subject to and in accordance with the TDA;

except in each case ((i), (ii), (iii) and (iv)), to the extent that Damages arise out of the [* * *] committed by Regeneron or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement, the Pre-A&R Terms or any Ancillary Agreement or the material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of this Agreement, the Pre-A&R Terms or any Ancillary Agreement.

For clarity, Sanofi's liability, other than Third Party Claims addressed in Section 17.2(c), for any Damages arising from or occurring as a result of a Third Party Claim against a Regeneron Indemnitee that is due to or based upon (x) any actions or omissions by or on behalf of Sanofi for Regeneron in connection with the TDA or the MSA or (y) any breach by Sanofi, any of its Affiliates or its or their Sublicensees of its obligations, covenants or representations and warranties under the TDA or the MSA, in each case ((x) and (y)), shall be governed by the TDA or the MSA, as applicable.

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

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Regeneron or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement or any Ancillary Agreement other than the Service Agreements;

(ii) material breach by Regeneron (or conduct or omission by any of its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf), which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of, or the representations and warranties made by it in, this Agreement or any Ancillary Agreement other than the Service Agreements;

(iii) (A) Sanofi or its Affiliates furnishing the Transition Services in accordance with the terms of the TSA and the instructions provided by Regeneron thereunder, (B) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Regeneron or its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of the TSA, or (C) material breach by Regeneron (or conduct or omission by any of its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) of the TSA; or

(iv) the Development, Manufacture, Commercialization or use of the IO Licensed Product (including, for clarity, any product liability Third Party Claims) by Regeneron and its Affiliates (or its or their respective agents, contractors (excluding by or on

behalf of Sanofi for Regeneron in connection with any Ancillary Agreement), Sublicensees, distributors, representatives or other Persons or entities working on their behalf) from and after the A&R Effective Date, excluding, (A) for clarity, any actions or omissions related to the Development, Manufacture, Commercialization or use of the IO Licensed Product prior to the A&R Effective Date and (B) any Damages to the extent arising out of the negligence committed by Sanofi or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement, the Pre-A&R Terms, any Ancillary Agreement, any Product Contract or any Master Agreement;

except in each case ((i), (ii), (iii) and (iv)), to the extent that Damages arise out of (1) the [* * *] committed by Sanofi or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement, the Pre-A&R Terms or any Ancillary Agreement, (2) the material breach by Sanofi (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Sanofi would be a material breach by Sanofi) of the terms of this Agreement, the Pre-A&R Terms, any Ancillary Agreement or any Product Contract or Master Agreement, or (3) any Sanofi Product Agreement (except to the extent that the applicable Third Party Claim is due to or based upon any change in the terms of such Sanofi Product Agreement implemented by Sanofi or any of its Affiliates at Regeneron's direction under the TSA).

For clarity, Regeneron's liability, other than Third Party Claims addressed in Section 17.2(c) for any Damages arising from or occurring as a result of a Third Party Claim against a Sanofi Indemnitee that is due to or based upon (x) any actions or omissions by or on behalf of Regeneron for Sanofi in connection with the TDA or the MSA or (y) any breach by Regeneron, any of its Affiliates or its or their Sublicensees of its obligations, covenants or representations and warranties under the TDA or the MSA, in each case ((x) and (y)), shall be governed by the TDA or the MSA, as applicable.

(c) Mutual Indemnification.

(i) To the extent any Third Party Claim alleges that the [* * *].

(ii) To the extent any product liability Third Party Claim alleges that the Development, Manufacture, Commercialization or use of the IO Licensed Product prior to the A&R Effective Date causes damages for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other for fifty percent (50%) of all Damages therefrom that are allocable to acts or omissions of either Party that occurred prior to the A&R Effective Date [* * *].

(d) Regeneron will (i) use commercially reasonable efforts to procure and maintain commercial general liability and product liability insurance in an amount not less than [* * *] per occurrence and in the annual aggregate or (ii) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or any of its Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party under Section 17.1 or Section 17.2 with respect to such Damages. The Pre-A&R Terms shall continue to govern with respect to the Parties respective insurance obligations with respect to the period prior to the A&R Effective Date; provided that, consistent with such terms, Sanofi shall have an obligation to maintain the applicable insurance for [* * *] after the A&R Effective Date.

(e) Notwithstanding anything to the contrary in this Section 17.2, subject to Section 17.2(c), neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Sanofi Indemnitees, as the case may be) from Third Party Claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture the IO Licensed Product (or any intermediaries or inputs thereto), pursuant to the MSA or otherwise; provided that nothing in this Section 17.2(e) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party manufacturer(s)

17.3 Indemnity Procedure. The Party entitled to indemnification under this ARTICLE XVII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within [* * *] of being notified of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party. For the avoidance of doubt, the indemnification procedures in this Section 17.3 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages under the terms of Section 17.2(c), and the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending or prosecuting any Third Party Claims subject to Section 17.2(c).

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

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.3 and [* * *]; provided that the Indemnifying Party shall [* * *]if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.

(c) Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 17.3, the Indemnified Party shall, and shall use reasonable efforts to cause each indemnitee to, reasonably cooperate in the defense or prosecution thereof and, if the Indemnifying Party assumes the defense of any such claim, the Indemnified Party shall, and shall use reasonable efforts to cause each indemnitee to, furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals, in each case, as may be reasonably requested in connection therewith. Such cooperation shall include access upon reasonable notice during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and to the extent the Indemnified Party is entitled to indemnification pursuant to this ARTICLE XVII, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection with providing such assistance.

ARTICLE XVIII
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, sanctions, trade restrictions, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance, and only if the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances. For clarity, Sanofi and Regeneron acknowledge and agree that either Party's ability to perform its obligations under this Agreement after the A&R Effective Date may be affected by the COVID-19 pandemic. As such, both Parties understand and acknowledge and agree that any change in response related to the COVID-19 pandemic by a Governmental Authority or Regulatory Authority (e.g., another mandatory shelter in place or stay at home order or changes to essential business rules) may constitute a Force Majeure. If a Party is prevented from performing any of its obligations under this Agreement due to a change in circumstances as a result of the COVID-19 pandemic after the A&R Effective Date, such non-performing Party will provide written notice to the other Party of such change in circumstances, and from and after such notice, will not be liable for breach of this Agreement with respect to such non-performance during the period of such Force Majeure. Without limiting the foregoing, the Parties will agree on extensions to timeframes set forth in this Agreement and any Ancillary Agreement to account for delays in carrying out activities and obligations hereunder to the extent such delays are a result of disruptions to business caused by the COVID-19 pandemic or related laws or regulations.

ARTICLE XIX
TERM

The "Term" shall commence on the first day of the month immediately following the month in which the final Antitrust Clearance is received (the "A&R Effective Date") and thereafter remain in full force and effect in perpetuity and may not be terminated; provided that the last sentence of Section 2.6, Section 3.1(a), the penultimate sentence of Section 3.8, Section 3.11(a), Section 5.4, the first sentence of Section 8.1, the last sentence of Section 9.5, Section 15.6, Section 16.3, Section 20.7 and this ARTICLE XIX shall be effective as of the A&R Execution Date. For

clarity, the Pre-A&R Terms shall be effective from the Effective Date until the A&R Effective Date.

ARTICLE XX
MISCELLANEOUS

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Subject to the procedures established in ARTICLE X, each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts. Each Party further agrees that service of any process, summons, notice or document delivered by reputable international overnight courier service to its address set forth in Section 20.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

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

20.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Exhibit 3 attached hereto and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand or one (1) Business Day after it is sent via a reputable international overnight courier service. Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement and the Ancillary Agreements contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof; provided that (a) the amendment and restatement of the Pre-A&R Terms as of the A&R Effective Date shall not constitute a novation or waiver of any rights or obligations owing under the Pre-A&R Terms based on facts or events occurring or exiting prior to the A&R Effective Date and, except as otherwise expressly provided in this Agreement, shall be without prejudice to any rights or obligations that have arisen, or relate to acts or omissions, prior to the A&R Effective Date and the Pre-A&R Terms shall survive to give effect to the foregoing; (b) certain terms of the Pre-A&R Terms shall survive as they existed prior to the A&R Effective Date solely to the extent expressly set forth herein, including in Section 14.1 (with respect to ARTICLE XIV of the Pre-A&R Terms) and Section 17.1 (with respect to Section 17.1 of the Pre-A&R Terms); and (c) the foregoing shall not affect the continuing validity of the CTSA, which the Parties each acknowledge and agree shall remain in full force and effect notwithstanding the amendment and restatement of this Agreement on the A&R Effective Date. For the avoidance of doubt, the Existing License and Collaboration Agreement shall remain in full force and effect in accordance with its terms and conditions and any variation between a provision of this Agreement and a corresponding or similar provision of the Existing License and Collaboration Agreement shall

not be considered in the interpretation of this Agreement or the Existing License and Collaboration Agreement.

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

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

20.7 Registration and Filing of this Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.3. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom. [* * *].

20.8 Assignment, Divestment, Sublicensing and Transfers. Except as otherwise expressly provided herein, until such time as each of the MSA, the TDA and TSA have been fully and finally performed, or have expired or terminated pursuant to their respective terms (such date, the "Transition Completion Date"), neither: (a) this Agreement nor any of the rights or obligations hereunder, or (b) any rights in and to the IO Licensed Product or IO Licensed Product business, in each case of (a) and (b), may be assigned, sold, disposed of, divested, sublicensed or otherwise transferred, in whole or in part, by either Sanofi or Regeneron without the prior written consent of the other Party, except that (i) either Party may assign this Agreement (or any rights or obligations hereunder): (x) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet a Party's obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (y) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement and (ii) Regeneron shall have the right to grant sublicenses of its rights hereunder and to enter into collaboration, distribution or other similar agreements with respect to the IO Licensed Product; provided, further, that Sanofi will have no obligation to transition any specific activity pursuant to this Agreement or pursuant to the TSA in a particular country or jurisdiction to more than one party without its prior written consent and, once transition of such specific activity (under this Agreement or under the TSA) in such country or jurisdiction has been initiated (to a Person designated by Regeneron), Sanofi will have no obligation to transition such activity to any other party in such country or jurisdiction without its prior written consent. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any assignment of this Agreement by Regeneron shall preserve in full Sanofi's rights under this Agreement to receive the payments described in Sections 9.1, 9.2, 9.3 and 9.4 above. For clarity, after the Transition Completion Date, Regeneron shall have the right to freely assign, sell, dispose of, divest, sublicense or otherwise transfer (a) its rights and obligations under this Agreement or (b) any rights, in or to the IO Licensed Product or the IO Licensed Product

business, subject to the requirements of Section 4.4. Any attempted assignment, sale, disposal, divestment, sublicense or transfer in violation hereof shall be void.

20.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 20.12.

20.10 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 when due and at all times thereafter 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. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of the IO Licensed Product under this Agreement, then such Party shall ensure that such Affiliate complies with the obligations of such Party hereunder. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement which restricts or prohibits a Party from taking any specified action.

20.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but 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 hereto as if they were original signatures.

20.12 Third Party Beneficiaries. Except as provided below in this Section 20.12, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. 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 any Party hereto. Notwithstanding the foregoing, ARTICLE XVII is intended to benefit, and to be enforceable by, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is only enforceable by the Parties.

20.13 Relationship of the Parties. [* * *] Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.14 Limitation of Damages. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR

CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM THAT IS COVERED BY THE INDEMNIFICATION OBLIGATIONS IN ARTICLE XVII.

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

20.16 Construction.

(a) The use of words in the singular or plural, or with a particular gender, shall not limit the scope or exclude the application of any provision of this Agreement to such person or persons or circumstances as the context otherwise permits. The words "will" and "shall" shall have the same meaning and, unless the context otherwise requires, the use of the word "or" is used in the inclusive sense (and/or). The term "including," "include" or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used with "without limitation" or "without limiting" throughout this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The use of the term "the IO Licensed Product" shall not be deemed to limit any rights of Regeneron with respect to all IO Licensed Products and shall refer to any and all IO Licensed Products. Except for the use of "this Agreement" in the second WHEREAS clause hereof, the use of the term "this Agreement" means this Agreement as amended and restated as of the A&R Effective Date and does not include the Pre-A&R Terms unless expressly included.

(b) The captions of this Agreement are for convenience or reference only and in no way define, describe, extend or limit the scope of intent of this Agreement or in the intent of any provision contained in this Agreement. Unless otherwise specified, (i) the

references in this Agreement to any Article, Section, Exhibit, Schedule or Appendix means references to such Article, Section, Exhibit, Schedule or Appendix of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section and (iii) unless the context otherwise requires, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement within a specified time period and notification of such approval or consent is not delivered within such time period, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. This Agreement has been prepared jointly and the provisions contained herein shall not be construed or interpreted for or against any Party to this Agreement because such Party drafted or caused such Party's legal representative to draft any provision contained herein.

(d) In the event of any conflict between this Agreement and the Schedules, Exhibits or Appendices hereto, this Agreement shall prevail. In the event of any conflict between this Agreement and any of the TSA, TDA or MSA (collectively, the "Service Agreements"), as between this Agreement and the Service Agreements, (i) the terms of the applicable Service Agreement shall govern with respect to any obligation of Sanofi to perform services (but not, for clarity, to transfer the Transferred Items, which shall be governed by this Agreement) and (ii) except as provided in clause (i), this Agreement shall govern.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Amended and Restated Immuno-Oncology License and Collaboration Agreement to be executed by their duly authorized representatives as of the A&R Execution Date.

SANOFI BIOTECHNOLOGY SAS

By: /s/ Alban De-La-Sabliere

Name: Alban De-La-Sabliere

Title: President

REGENERON PHARMACEUTICALS, INC.

By: /s/ Robert E. Landry

Name: Robert E. Landry

Title: EVP - Finance & CFO

EXHIBIT 1

NOT USED

EXHIBIT 2

DEVELOPMENT COMPENSATION PAYMENT

The "IO Development Balance" as of the end of a Quarter shall mean (a) Thirty-Five Million United States Dollars (US$ 35,000,000), less (b) the aggregate amount of Development Compensation Payments made hereunder from and after the Transition Date.

If both the IO Development Balance as of the end of a Quarter is greater than zero and the worldwide Net Sales of the IO Licensed Product for the Quarter are greater than zero, the "Development Compensation Payment" for such Quarter shall equal the lower of (a) zero point five percent (0.5%) of the worldwide Net Sales of the IO Licensed Product for the Quarter and (b) the then-current IO Development Balance. Otherwise, the Development Compensation Payment for the Quarter shall equal zero.

Two examples of a calculation of the Development Compensation Payment in a Quarter would be:

Example 1: (If IO Development Balance is greater than 0.5% of Net Sales)

IO Development Balance at the end of the Quarter	US$35M
Net Sales	US$500M
0.5% of the Net Sales	US$2.5M
Development Compensation Payment	US$2.5M
IO Development Balance at the beginning of the next Quarter	US$32.5M

Example 2: (If IO Development Balance is less than 0.5% of Net Sales)

IO Development Balance at the end of the Quarter	US$4M
Net Sales	US$1B
0.5% of the Net Sales	US$5M
Development Compensation Payment	US$4M
IO Development Balance at the beginning of the next Quarter	Zero

EXHIBIT 3

NOTICES

(a) If to Sanofi:

Sanofi Biotechnology SAS
54, rue La Boétie
75008 Paris
France
Attn: President

Copy (which shall not constitute notice) to:

Sanofi
54, rue La Boétie
75008 Paris France
Attn: Executive Vice President and General Counsel

(b) If to Regeneron:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President

Copy: General Counsel

Schedule 1.7

Form Bill of Sale

Schedule 1.21

Form Domain Name Assignment

Schedule 1.78

[* * *]

Schedule 1.86

Form Transferred Trademark Assignment Agreement

Schedule 1.88

Transferred Product Trademarks

[* * *]

Schedule 2.2

TRUE-UP AS OF A&R EFFECTIVE DATE

Regeneron shall be entitled to all Aggregate Profits (and shall be liable for any and all worldwide Development Costs and Shared Commercial Expenses) arising from worldwide Development and Commercialization of the IO Licensed Product for the period commencing on the Transition Date and ending on the A&R Effective Date (such period, the "Interim Period"). Sanofi shall be entitled to any payments due from Regeneron pursuant to Section 9.2(b) (if applicable), Section 9.3 or Section 9.4 in respect of the worldwide Net Sales of the IO Licensed Product during the Interim Period (such payments, the "Interim Period Payments").

During the Interim Period, each of Sanofi and Regeneron will continue to comply with the information exchange and reporting obligations set forth in the Pre-A&R Terms (including pursuant to ARTICLE IX thereof). Within [* * *] after the A&R Effective Date, the Parties will exchange a report in the form as described in Section 9.6(c) and Section 9.6(d) of the Pre-A&R Terms, with such report to cover the Interim Period. Within [* * *] after the A&R Effective Date, the Parties will exchange Consolidated Payment Reports (in the manner described in Section 9.6(f) of the Pre-A&R Terms) with such report to cover the Interim Period, together with any other information necessary to calculate the net payment one Party shall be required to make to the other Party pursuant to this Schedule 2.2 (the "True-Up as of the A&R Effective Date"), after having reconciled Regeneron's entitlement to the Aggregate Profits, and Sanofi's entitlement to any such payments arising under ARTICLE IX, in each case arising from the worldwide Development and Commercialization of the IO Licensed Product during the Interim Period, in the manner set forth below. Within [* * *] after the exchange of such Consolidated Payment Reports, the Parties shall meet and agree on the calculation of the True-Up as of the A&R Effective Date. If Regeneron is the Party owing the True-Up as of the A&R Effective Date based on the calculations described in this Schedule 2.2, Sanofi shall submit an invoice to Regeneron for an amount equal to the True-Up as of the A&R Effective Date within [* * *] after the exchange of such Consolidated Payment Reports, and Regeneron shall make such payment to Sanofi within [* * *] of the receipt of such invoice. If Sanofi is the Party owing the True-Up as of the A&R Effective Date based on the calculations described in this Schedule 2.2, Regeneron shall submit an invoice to Sanofi for an amount equal to the True-Up as of the A&R Effective Date within [* * *] after the exchange of such Consolidated Payment Reports, and Sanofi shall make such payment to Regeneron within [* * *] of the receipt of such invoice. The Parties will calculate such True-Up as of the A&R Effective Date as follows:

(A) The True-Up as of the A&R Effective Date shall be equal to (a) the Aggregate Profits True-Up (calculated as set forth below), *minus* (b) any Interim Period Payments.

(B) If the True-Up as of the A&R Effective Date is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron in accordance with the terms set forth in ARTICLE IX.

(C) If the True-Up as of the A&R Effective is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi in accordance with the terms set forth in ARTICLE IX.

(D) If the True-Up as of the A&R Effective amounts to zero, then no payment shall be made by either Sanofi or Regeneron.

AGGREGATE PROFITS TRUE-UP

The calculation of the "Aggregate Profits True-Up" shall be determined by [* * *].

If The A&R Effective Date Occurs Before [* * *]

"Aggregate Profits True-Up" shall mean the [* * *].

If The A&R Effective Date Occurs After [* * *]

"Aggregate Profits True-Up" shall mean: the [* * *].

EXAMPLES OF CALCULATING TRUE-UP AS OF THE A&R EFFECTIVE DATE

If The A&R Effective Date Occurs Before [* * *]

In this illustrative example, because the A&R Effective Date occurs before the Quarterly True-Up payment corresponding to [* * *], then the Aggregate Profits True-Up will correspond to [* * *]. In this example, [* * *]. For the purposes of the True-Up as of the A&R Effective Date, only an Aggregate Profits True-Up will be calculated (but, for clarity, the Parties shall still be obligated to perform such calculations and make such payments as set forth in, and pursuant to, Section 9.2(b) (if applicable), Section 9.3 or Section 9.4 of the Agreement, with respect to the Interim Period).

In the below example, the A&R Effective Date is assumed to be [* * *].

	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
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[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]

In the above example, Aggregate Profits True Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron.

Following this illustration above, the True-Up as of the A&R Effective Date would be:

[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

Where the True Up at A&R Effective Date is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi.

For the avoidance of doubt, [* * *].

If The A&R Effective Date Occurs After [* * *]

In this illustrative example, because the A&R Effective Date occurs after [* * *] corresponding to [* * *] has been made, then [* * *]. [* * *] shall be performed pursuant to the Pre-A&R Terms in respect of [* * *].

In this example, Regeneron Profits are [* * *]than Sanofi Profits. In the below example A&R Effective Date is assumed to be [* * *].

[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
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[* * *]	[* * *]	[* * *]	[* * *]
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[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]

In the above example, Aggregate Profits True Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron.

Following this illustration above, the True-Up as of the A&R Effective Date would be:

[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

Where the True Up at A&R Effective Date is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi.

For the avoidance of doubt, [* * *].

DEFINITIONS

For the purposes of this Schedule 2.2, the following terms shall have the meanings described below:

"Aggregate Profits" in a period shall mean the Regeneron Profits for such period plus the Sanofi Profits in such period.

"Continued Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 7.6, Section 13.3(b) and Section 17.1(c) (except in each case to the extent allocated between the Parties as a "Development Cost"), in each case, of the Pre-A&R Terms.

"Development Compensation Payment as per Pre-A&R Terms" shall have the meaning set forth in the Pre-A&R Terms (schedule 2, part II) for the Development Compensation Payment.

"Development Cost True-Up" shall have the meaning set forth in the Pre-A&R Terms (schedule 2, part III).

"Global Product Expenses" shall mean [* * *].

"Other Shared Expenses" shall have the meaning set forth in the Pre-A&R Terms.

"Profit Split" shall mean [* * *].

"Profit Split True-Up" means [* * *].

"Profits" shall mean [* * *].

"Regeneron Profits" shall mean [* * *].

"ROW Territory" shall mean [* * *].

"Sanofi Profits" shall mean [* * *].

"Shared Commercial Expenses" shall have the meaning set forth in the Pre-A&R Terms but, for clarity, [* * *].

"U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

Schedule 2.6

Preliminary List of Licenses

1. [* * *]
2. [* * *]

Schedule 3.1(a)(i)

Form TSA

Schedule 3.1(a)(ii)

Form TDA

Schedule 5.2(a)

Existing Trials[1]

[* * *]

[1] [* * *]

Schedule 5.2(a)-2

[* * *]

[* * *]

Schedule 8.1

Form MSA

Schedule 15.2

A&R Execution Date Exceptions

[* * *]

Schedule 15.3

A&R Effective Date Exceptions

EXECUTION VERSION
CONFIDENTIAL

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.

FIFTH AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

THIS FIFTH AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT (this "Fifth Amendment"), dated as of June 1, 2022 (the "Execution Date"), is by and between Sanofi Biotechnology SAS, a société par actions simplifiée, organized under the laws of France, as successor in interest to Aventis Pharmaceuticals Inc., having a principal place of business at 54, rue La Boétie, 75008 Paris, France ("Sanofi"), Sanofi, a société anonyme organized under the laws of France with its principle headquarters at 54, rue La Boétie, 75008 Paris, France ("Sanofi Parent"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of the state of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties").

RECITALS

WHEREAS, Regeneron, Sanofi and Sanofi Parent are parties to that certain Amended and Restated License and Collaboration Agreement dated as of November 10, 2009, as amended as of May 1, 2013, July 1, 2015, April 5, 2020 and October 6, 2021 (the "LCA") for the Development, Manufacture and Commercialization of Licensed Products (as such terms are defined therein);

WHEREAS, Regeneron and Sanofi are parties to that certain Immuno-Oncology License and Collaboration Agreement dated as of July 1, 2015 and executed as of July 27, 2015 (the "IO LCA");

WHEREAS, Regeneron and Sanofi are amending and restating the IO LCA pursuant to that certain Amended and Restated Immuno-Oncology License and Collaboration Agreement by and between Sanofi and Regeneron dated as of June 1, 2022 (the "A&R IO LCA");

WHEREAS, in addition to executing the A&R IO LCA, the Parties desire to amend the LCA to modify certain terms set forth therein relating to the Development Compensation Payment and the Development Balance (as such terms are defined therein).

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

AGREEMENT

1. **Effectiveness**. This Fifth Amendment is entered into the Execution Date but shall be effective as of and after the date the A&R IO LCA becomes effective.

2. **Definitions**. All capitalized terms used in this Fifth Amendment which are not otherwise defined herein shall have the meanings ascribed to them in the LCA.

3. Amendments to Certain Provisions of the LCA. The Parties acknowledge and agree that:

3.1 The third paragraph of Section III of Schedule 2 to the LCA is hereby amended to read in its entirety as follows:

"From and after April 1, 2022, if both the Development Balance as of the end of a Quarter is greater than zero and the Regeneron Profit Split for the Quarter is greater than zero, the "Development Compensation Payment" for such Quarter shall equal the lower of (a) twenty percent (20%) of the Regeneron Profit Split for the Quarter and (b) the Development Balance. Otherwise, the Development Compensation Payment for the Quarter shall equal zero.

The Development Compensation Payment in a given quarter will be applied first towards Development Costs added to the Development Balance after April 1, 2022 and any remaining amount of the Development Compensation Payment in such Quarter will be applied towards Development Costs added to the Development Balance prior to April 1, 2022."

3.2 The fourth paragraph of Section III of Schedule 2 to the LCA is hereby amended to read in its entirety as follows:

"From and after April 1, 2022, an example calculation of the Development Compensation Payment in a Quarter would be:

[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

For the avoidance of doubt [* * *]."

4. Acknowledgements and Agreements with respect to the Development Balance:

4.1 The Parties hereby acknowledge and agree that as of April 1, 2022, the Development Balance shall be [* * *].

5. Miscellaneous Provisions.

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

5.2 **Miscellaneous**. The provisions of Sections 20.1, 20.3, 20.5, 20.6, 20.7, 20.8, 20.11, 20.12 and 20.17 of the LCA shall apply *mutatis mutandis* to this Fifth Amendment as though set out in full in this Fifth Amendment.

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

[*Signature Page Follows*]

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

SANOFI BIOTECHNOLOGY SAS

By: /s/ Alban De-La-Sabliere

Name: Alban De-La-Sabliere
Title: President

SANOFI

By: /s/ Alban De-La-Sabliere

Name: Alban De-La-Sabliere
Title: Sanofi Partnering Head

REGENERON PHARMACEUTICALS, INC.

By: /s/ Robert E. Landry

Name: Robert E. Landry
Title: EVP - Finance & CFO

Exhibit 31.1

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

I, Leonard S. Schleifer, certify that:

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

Date: August 3, 2022

/s/ Leonard S. Schleifer

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

Exhibit 31.2

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

I, Robert E. Landry, certify that:

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

Date: August 3, 2022

/s/ Robert E. Landry

Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

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

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

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
August 3, 2022

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
August 3, 2022