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 March 31, 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 April 12, 2022:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,818,146
Common Stock, $.001 par value	108,028,048

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

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,345.7	$ 2,885.6
Marketable securities	3,704.9	2,809.1
Accounts receivable, net	4,839.0	6,036.5
Inventories	1,991.5	1,951.3
Prepaid expenses and other current assets	424.9	332.4
Total current assets	14,306.0	14,014.9
Marketable securities	7,084.0	6,838.0
Property, plant, and equipment, net	3,556.4	3,482.2
Deferred tax assets	1,140.3	876.9
Other noncurrent assets	262.0	222.8
Total assets	$ 26,348.7	$ 25,434.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 470.3	$ 564.0
Accrued expenses and other current liabilities	2,046.0	2,206.8
Finance lease liabilities	—	719.7
Deferred revenue	491.3	442.0
Total current liabilities	3,007.6	3,932.5
Long-term debt	1,980.4	1,980.0
Finance lease liabilities	720.0	—
Deferred revenue	33.5	73.3
Other noncurrent liabilities	692.5	680.2
Total liabilities	6,434.0	6,666.0
Stockholders' equity:		
Preferred Stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,823,823 in 2022 and 2021	—	—
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 127,623,390 in 2022 and 126,244,444 in 2021	0.1	0.1
Additional paid-in capital	8,754.1	8,087.5
Retained earnings	19,941.8	18,968.3
Accumulated other comprehensive loss	(170.1)	(26.2)
Treasury Stock, at cost; 19,940,149 shares in 2022 and 19,392,961 shares in 2021	(8,611.2)	(8,260.9)
Total stockholders' equity	19,914.7	18,768.8
Total liabilities and stockholders' equity	$ 26,348.7	$ 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 March 31,	
	2022	**2021**
Statements of Operations		
Revenues:		
Net product sales	$ 1,638.6	$ 1,724.3
Collaboration revenue	1,232.5	754.4
Other revenue	94.0	50.0
	2,965.1	2,528.7
Expenses:		
Research and development	843.8	742.9
Acquired in-process research and development	28.1	—
Selling, general, and administrative	450.0	405.6
Cost of goods sold	207.3	183.2
Cost of collaboration and contract manufacturing	197.6	124.8
Other operating (income) expense, net	(20.2)	(40.5)
	1,706.6	1,416.0
Income from operations	1,258.5	1,112.7
Other income (expense):		
Other (expense) income, net	(183.8)	154.9
Interest expense	(13.6)	(14.6)
	(197.4)	140.3
Income before income taxes	1,061.1	1,253.0
Income tax expense	87.6	137.8
Net income	$ 973.5	$ 1,115.2
Net income per share - basic	$ 9.12	$ 10.58
Net income per share - diluted	$ 8.61	$ 10.09
Weighted average shares outstanding - basic	106.8	105.4
Weighted average shares outstanding - diluted	113.1	110.5
Statements of Comprehensive Income		
Net income	$ 973.5	$ 1,115.2
Other comprehensive income (loss), net of tax:		
Unrealized loss on debt securities	(144.9)	(13.3)
Unrealized gain on cash flow hedges	1.0	0.2
Comprehensive income	$ 829.6	$ 1,102.1

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
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

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

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net income	$ 973.5	$ 1,115.2
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	74.3	67.4
Stock-based compensation expense	166.9	130.9
Losses (gains) on marketable and other securities, net	204.5	(144.4)
Other non-cash items, net	84.3	28.7
Deferred taxes	(225.0)	10.1
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	1,197.5	(58.3)
Increase in inventories	(88.6)	(252.8)
Increase in prepaid expenses and other assets	(44.8)	(50.0)
Increase (decrease) in deferred revenue	9.5	(143.6)
Decrease in accounts payable, accrued expenses, and other liabilities	(250.4)	(34.7)
Total adjustments	1,128.2	(446.7)
Net cash provided by operating activities	2,101.7	668.5
Cash flows from investing activities:		
Purchases of marketable and other securities	(2,309.8)	(1,360.0)
Sales or maturities of marketable and other securities	746.3	416.3
Capital expenditures	(141.8)	(115.3)
Net cash used in investing activities	(1,705.3)	(1,059.0)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	521.6	95.0
Payments in connection with Common Stock tendered for employee tax obligations	(98.8)	(154.5)
Repurchases of Common Stock	(358.1)	(306.9)
Net cash provided by (used in) financing activities	64.7	(366.4)
Net increase (decrease) in cash, cash equivalents, and restricted cash	461.1	(756.9)
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	$ 3,359.2	$ 1,450.4

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.

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

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 months ended March 31, 2022 would have historically been recorded to Research and development expenses. No such amounts were recorded for the three months ended March 31, 2021.

2. Product Sales

Net product sales consist of the following:

(In millions)	Three Months Ended March 31,	
Net Product Sales in the United States	**2022**	**2021**
EYLEA®	$ 1,517.6	$ 1,347.0
Libtayo®	78.9	69.1
Praluent®	33.6	43.3
REGEN-COV®*	—	262.2
Evkeeza®	8.5	0.5
ARCALYST®	— **	2.2
	$ 1,638.6	$ 1,724.3

* 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.

As of March 31, 2022 and December 31, 2021, the Company had $3.664 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 months ended March 31, 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 March 31,	
	2022	**2021**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	55 %	46 %
McKesson Corporation	30 %	29 %
U.S. government	— %	13 %

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:

		Three Months Ended March 31,	
(In millions)	**Statement of Operations Classification**	**2022**	**2021**
Antibody:			
Regeneron's share of profits in connection with commercialization of antibodies	Collaboration revenue	$ 415.3	$ 260.6
Sales-based milestone earned	Collaboration revenue	$ 50.0	$ —
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	$ 160.8	$ 105.6
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 36.5	$ 30.1
Regeneron's obligation for its share of Sanofi research and development expenses	Research and development expense	$ (9.7)	$ (11.9)
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 91.7	$ 60.4
Immuno-oncology:			
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	Collaboration revenue	$ 2.8	$ (6.1)
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ 2.0	$ 4.7
Reimbursement of research and development expenses	Reduction of Research and development expense	$ 21.5	$ 21.9
Reimbursement of commercialization-related expenses	Reduction of Selling, general, and administrative expense	$ 19.0	$ 18.5
Regeneron's obligation for its share of Sanofi commercial expenses	Selling, general, and administrative expense	$ (9.2)	$ (7.7)
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ (32.3)	$ (30.4)
Amounts recognized in connection with up-front payments received	Other operating income	$ 18.1	$ 22.9

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%–100% of agreed-upon development costs.

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)	March 31, 2022	December 31, 2021
Accounts receivable, net	$ 500.4	$ 504.8
Deferred revenue	$ 380.2	$ 368.7

Immuno-Oncology

The Company is party to a collaboration with Sanofi to research, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration").

Under the terms of the Immuno-oncology License and Collaboration Agreement, the parties are co-developing and co-commercializing Libtayo (cemiplimab). The parties share equally, on an ongoing basis, agreed-upon development and commercialization expenses for Libtayo. The Company has principal control over the development of Libtayo and leads commercialization activities in the United States (see Note 2 for related product sales information), while Sanofi leads commercialization activities outside of the United States. The parties share equally in profits and losses in connection with the commercialization of Libtayo.

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

(In millions)	March 31, 2022	December 31, 2021
Accounts receivable, net	$ 4.9	$ (22.5)
Deferred revenue	$ 21.1	$ 16.0
Other liabilities	$ 258.0	$ 276.1

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

The aggregate amount of the estimated consideration under the IO Collaboration related to the Company's obligation that was unsatisfied (or partially unsatisfied) as of March 31, 2022 was $532.8 million. This amount is expected to be recognized over the remaining period in which the Company is obligated to satisfy its obligation in connection with performing development activities.

b. Bayer

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. All agreed-upon development expenses incurred by the Company and Bayer are 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:

		Three Months Ended March 31,	
(In millions)	**Statement of Operations Classification**	**2022**	**2021**
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	Collaboration revenue	$ 338.4	$ 308.9
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ 25.0	$ 13.9
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	$ 11.1	$ 10.8
Regeneron's obligation for its share of Bayer research and development expenses	Research and development expense	$ (10.8)	$ (12.5)

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

(In millions)	**March 31, 2022**	**December 31, 2021**
Accounts receivable, net	$ 344.8	$ 355.5
Deferred revenue	$ 122.4	$ 129.4

c. Teva

The Company and Teva are parties to a collaboration agreement (the "Teva Collaboration Agreement") to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with Mitsubishi Tanabe Pharma Corporation. The Company leads global development activities, and the parties share development costs equally, on an ongoing basis, under a global development plan.

Amounts recognized in our Statements of Operations in connection with the Teva Collaboration Agreement were not material for the three months ended March 31, 2022 and 2021. In addition, contract balances in our Balance Sheets were not material as of March 31, 2022 and December 31, 2021.

The aggregate amount of the estimated consideration under the Teva Collaboration Agreement related to the Company's obligation that was unsatisfied (or partially unsatisfied) as of March 31, 2022 was $83.6 million. This amount is expected to be recognized over the remaining period in which the Company is obligated to satisfy its obligation in connection with performing development activities.

d. 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 2021.

e. 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:

		Three Months Ended March 31,	
(In millions)	**Statement of Operations Classification**	**2022**	**2021**
Global gross profit payment from Roche in connection with sales of Ronapreve	Collaboration revenue	$ 216.3	$ 66.8

Reimbursement of research and development expenses from Roche was $86.8 million for the three months ended March 31, 2021. Such amounts were not material for the three months ended March 31, 2022.

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

(In millions)	**March 31, 2022**	**December 31, 2021**
Accounts receivable, net	$ 204.3	$ —
Accrued expenses and other current liabilities	$ —	$ 268.8

f. 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 months ended March 31, 2022 and 2021. In addition, contract balances in our Balance Sheets were not material as of March 31, 2022 and December 31, 2021.

g. Checkmate

In April 2022, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") to acquire Checkmate Pharmaceuticals, Inc. at a total equity value of approximately $250 million. On May 2, 2022, the Company commenced a tender offer to acquire any and all outstanding shares of common stock of Checkmate at a price of $10.50 per share, to be paid to each shareholder tendering Checkmate shares in cash, without interest, subject to reduction for any applicable withholding taxes. The consummation of the tender offer is subject to certain conditions, including the tender of at least a majority of the outstanding shares of Checkmate common stock, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, and other customary closing conditions. If the tender offer is successfully consummated, the Company will acquire all shares not acquired in the tender offer through a merger that does not require the vote of Checkmate stockholders. The transaction is expected to close in mid-2022.

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 March 31,	
(In millions, except per share data)	**2022**	**2021**
Net income - basic and diluted	$ 973.5	$ 1,115.2
Weighted average shares - basic	106.8	105.4
Effect of dilutive securities:		
Stock options	5.0	4.5
Restricted stock awards and restricted stock units	1.3	0.6
Weighted average shares - diluted	113.1	110.5
Net income per share - basic	$ 9.12	$ 10.58
Net income per share - diluted	$ 8.61	$ 10.09

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

	Three Months Ended March 31,	
(Shares in millions)	**2022**	**2021**
Stock options	2.2	5.0

5. Marketable Securities

Marketable securities as of March 31, 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 March 31, 2022				
Corporate bonds	$ 8,422.3	$ 1.3	$ (207.4)	$ 8,216.2
U.S. government and government agency obligations	385.8	—	(3.9)	381.9
Sovereign bonds	55.2	—	(1.5)	53.7
Commercial paper	712.7	—	(1.3)	711.4
Certificates of deposit	344.2	—	(0.9)	343.3
Asset-backed securities	44.9	—	(1.2)	43.7
	$ 9,965.1	$ 1.3	$ (216.2)	$ 9,750.2
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 March 31, 2022 mature at various dates through March 2027. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

(In millions)	March 31, 2022	December 31, 2021
Maturities within one year	$ 3,704.9	$ 2,809.1
Maturities after one year through five years	6,045.3	5,588.1
	$ 9,750.2	$ 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 March 31, 2022	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 7,269.3	$ (194.2)	$ 212.9	$ (13.2)	$ 7,482.2	$ (207.4)
U.S. government and government agency obligations	326.2	(3.8)	1.2	(0.1)	327.4	(3.9)
Sovereign bonds	44.7	(1.5)	—	—	44.7	(1.5)
Commercial paper	666.5	(1.3)	—	—	666.5	(1.3)
Certificates of deposit	324.5	(0.9)	—	—	324.5	(0.9)
Asset-backed securities	43.7	(1.2)	—	—	43.7	(1.2)
	$ 8,674.9	$ (202.9)	$ 214.1	$ (13.3)	$ 8,889.0	$ (216.2)
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)

For the three months ended March 31, 2022, realized gains and losses on sales of marketable securities were not material. For the three months ended March 31, 2021, realized gains were not material and there were no realized losses on sales of marketable securities.

With respect to marketable securities, for the three months ended March 31, 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.

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 March 31, 2022	**Fair Value**	**Level 1**	**Level 2**
Available-for-sale debt securities:			
Corporate bonds	$ 8,216.2	$ —	$ 8,216.2
U.S. government and government agency obligations	381.9	—	381.9
Sovereign bonds	53.7	—	53.7
Commercial paper	711.4	—	711.4
Certificates of deposit	343.3	—	343.3
Asset-backed securities	43.7	—	43.7
Equity securities (unrestricted)	43.9	43.9	—
Equity securities (restricted)	994.8	994.8	—
	$ 10,788.9	$ 1,038.7	$ 9,750.2
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 March 31, 2022 which are subject to transfer restrictions that expire at various dates through 2024.

During the three months ended March 31, 2022 and 2021, we recorded $211.2 million of net unrealized losses and $143.9 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 March 31, 2022 and December 31, 2021, the Company had $46.7 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 $1.686 billion and $1.887 billion as of March 31, 2022 and December 31, 2021, respectively.

7. Inventories

Inventories consist of the following:

(In millions)	March 31, 2022	December 31, 2021
Raw materials	$ 773.5	$ 721.9
Work-in-process	644.9	707.2
Finished goods	47.3	73.7
Deferred costs	525.8	448.5
	$ 1,991.5	$ 1,951.3

Inventory balances in the table above are net of reserves of $566.5 million and $510.0 million as of March 31, 2022 and December 31, 2021, respectively. Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

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)	March 31, 2022	December 31, 2021
1.750% Senior Notes due September 2030	$ 1,240.2	$ 1,239.9
2.800% Senior Notes due September 2050	740.2	740.1
	$ 1,980.4	$ 1,980.0

Interest expense related to the Notes was $11.1 million for each of the three months ended March 31, 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 March 31, 2022.

10. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 8.3% and 11.0% for the three months ended March 31, 2022 and 2021, respectively. The Company's effective tax rate for the three months ended March 31, 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 stock-based compensation. The Company's effective tax rate for the three months ended March 31, 2021 was positively impacted, compared to the U.S. federal statutory rate, primarily by the reversal of liabilities related to uncertain tax positions, stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and federal tax credits for research activities.

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. During the three months ended March 31, 2021, we repurchased 690,265 shares of our Common Stock under the program and recorded the cost of the shares received, or $323.5 million, as Treasury Stock. 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. During the three months ended March 31, 2022, we repurchased 566,973 shares of our Common Stock under the program and recorded the cost of the shares received, or $352.0 million, as Treasury Stock. As of March 31, 2022, $2.493 billion remained available for share repurchases under the November 2021 program.

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:

	March 31,	
(In millions)	**2022**	**2021**
Cash and cash equivalents	$ 3,345.7	$ 1,437.9
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	$ 3,359.2	$ 1,450.4

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

Supplemental disclosure of non-cash investing and financing activities

(In millions)	**March 31, 2022**	**December 31, 2021**	**March 31, 2021**	**December 31, 2020**
Accrued capital expenditures	$ 80.7	$ 74.8	$ 75.6	$ 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 March 31, 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.

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.

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 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

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.

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.

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 has been scheduled for July 22, 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 February 25, 2022, the Company filed a notice of appeal of the court's decision to dismiss the amended complaint with the U.S. Court of Appeals for the Second Circuit.

Proceedings Related to "Most Favored Nation" Interim Final Rule

On December 11, 2020, the Company filed a lawsuit in the United States District Court for the Southern District of New York against the U.S. Department of Health and Human Services, the Secretary of HHS, the Centers for Medicare & Medicaid Services ("CMS"), and the Administrator of CMS seeking declaratory and injunctive relief related to the interim final rule with comment period entitled "Most Favored Nation (MFN) Model" issued on November 20, 2020 by HHS, acting through CMS (the "MFN Rule"). On the same day, the Company filed a motion for a preliminary injunction and temporary restraining order, seeking to prevent implementation of the MFN Rule. On December 22, 2020, the court heard oral argument on the Company's motion for a preliminary injunction and temporary restraining order. On December 31, 2020, the court granted the Company's motion and issued a preliminary injunction. On February 2, 2021, the government stated to the court that the Solicitor General had determined not to appeal the preliminary injunction. On February 10, 2021, the court entered a 90-day stay of the litigation and subsequently extended the stay, with the most recent 60-day extension granted on March 7, 2022. On December 27, 2021, CMS published a final rule that rescinded the MFN Rule; and, on March 28, 2022, the Company filed a notice of voluntary dismissal of this litigation.

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. An oral hearing has been scheduled for May 6, 2022.

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., Medical Mutual of Ohio, and Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey in the U.S. District Court for the District of Massachusetts on December 20, 2021, February 23, 2022, and April 4, 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. 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.

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), Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn), 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), as well as Regeneron's agreement with Roche relating to the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve™ in other countries), to be cancelled or terminated; the likelihood that any planned or future acquisitions, business combinations, or other related transactions, such as Regeneron's planned acquisition of Checkmate Pharmaceuticals, Inc. discussed in this report, will close within the expected time period or at all and whether and to what extent Regeneron will realize any anticipated benefits of any such transaction; 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 March 31,	
(In millions, except per share data)	**2022**	**2021**
Revenues	$ 2,965.1	$ 2,528.7
Net income	$ 973.5	$ 1,115.2
Net income per share - diluted	$ 8.61	$ 10.09

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[(d)]**
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	✔			
	- Neovascular glaucoma ("NVG")			✔	
Dupixent (dupilumab) Injection[(b)]	- Atopic dermatitis (in adults and adolescents)	✔	✔	✔	✔
	- Atopic dermatitis (in pediatrics 6–11 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[(d)]
Dupixent (dupilumab) Injection[(b)] *(continued)*	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔	✔
Libtayo (cemiplimab) Injection[(b)]	- 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[(c)]	- 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[(e)]	- COVID-19		✔	✔	✔
Kevzara (sarilumab) Solution for Subcutaneous Injection[(b)]	- Rheumatoid arthritis ("RA")	✔	✔	✔	✔
Evkeeza (evinacumab) Injection[(f)]	- HoFH (in adults and adolescents)	✔	✔		
Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn) Injection	- Infection caused by *Zaire ebolavirus*	✔			
ARCALYST® (rilonacept) Injection for Subcutaneous Use[(g)]	- 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[(h)]	- 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)] 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.

[(d)] 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.

[(e)] Known as REGEN-COV in the United States and Ronapreve in other countries

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

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

REGEN-COV - Emergency and Temporary Use Authorizations

REGEN-COV has not been approved by the U.S. Food and Drug Administration ("FDA"), but is currently authorized under an Emergency Use Authorization ("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 Biologics License Application ("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.

Emergency or temporary pandemic use authorizations are also currently in place in numerous other countries outside the United States.

Net Product Sales of Regeneron-Discovered Products

	Three Months Ended March 31,						
	2022			2021			% Change
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,517.6	$ 868.5	$ 2,386.1	$ 1,347.0	$ 811.2 *	$ 2,158.2	11 %
Dupixent[b]	$ 1,325.6	$ 484.8	$ 1,810.4	$ 961.5	$ 301.4	$ 1,262.9	43 %
Libtayo[c]	$ 78.9	$ 45.8	$ 124.7	$ 69.1	$ 31.7	$ 100.8	24 %
Praluent[d]	$ 33.6	$ 77.8	$ 111.4	$ 43.3	$ 61.3	$ 104.6	7 %
REGEN-COV[e]	$ —	$ 635.6	$ 635.6	$ 262.2	$ 176.6	$ 438.8	45 %
Kevzara[b]	$ 57.0	$ 49.4	$ 106.4	$ 30.7	$ 38.4	$ 69.1	54 %
Other products[f]	$ 9.9	$ 20.4	$ 30.3	$ 4.1	$ 23.0	$ 27.1	12 %

* 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] Regeneron records net product sales of Libtayo in the United States and Sanofi records net product sales of Libtayo outside the United States. The parties equally share profits/losses in connection with global sales of Libtayo.
[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 connection with its agreements with the U.S. government. 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 $18.7 million for the fourth quarter of 2021.

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 non-proliferative diabetic retinopathy ("NPDR")		–Report results from Phase 3 study in ROP (second half 2022) –FDA decision on supplemental BLA ("sBLA") for every-16-weeks dosing regimen in patients with NPDR (first half 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*		–Peanut allergy –Grass allergy	–Atopic dermatitis in pediatrics (6 months–5 years of age) (Phase 2/3)[d] –Eosinophilic esophagitis ("EoE")[c] in adults[d], adolescents[d], and pediatrics –Chronic obstructive pulmonary disease ("COPD") –Bullous pemphigoid (Phase 2/3)[c] –Chronic spontaneous urticaria ("CSU") –Prurigo nodularis –Allergic bronchopulmonary aspergillosis ("ABPA")	–Atopic dermatitis in pediatrics (6 months–5 years of age) (U.S. and EU) –EoE in adults and adolescents (U.S. and EU) –Prurigo nodularis (U.S. and EU)	–Approved by European Commission ("EC") for severe asthma in pediatrics (6–11 years of age) –Reported that second Phase 3 trial in prurigo nodularis met its primary and key secondary endpoints –Stopped one of the Phase 3 trials in CSU (in patients refractory to omalizumab) due to futility, based on pre-specified interim analysis	–FDA decision on sBLA (target action date of June 9, 2022) and EC decision on regulatory submission (first half 2023) for atopic dermatitis in pediatric patients (6 months–5 years of age) –Submit regulatory application in Japan for atopic dermatitis in pediatric and adolescent patients (6 months–14 years of age) (second half 2022) –FDA decision on sBLA (target action date of August 3, 2022) and EC decision on regulatory submission (first half 2023) for EoE in adults and adolescents –Report results from Phase 3 study for EoE in pediatrics (mid-2022)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*			–Chronic inducible urticaria - cold –Chronic rhinosinusitis without nasal polyposis –Allergic fungal rhinosinusitis –Chronic pruritis of unknown origin			–Report initial results from Phase 3 study in COPD (first half 2023) –FDA decision on sBLA (fourth quarter 2022/first quarter 2023) and EC decision on regulatory submission (first half 2023) for prurigo nodularis –Report results from Phase 3 study in chronic inducible urticaria - cold (second half 2022) –Report results from Phase 2 study in peanut allergy (second half 2022)
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	–First-line NSCLC, chemotherapy combination –Second-line cervical cancer[e] –Adjuvant CSCC	–Second-line cervical cancer (EU and Japan)	–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) and EC decision on regulatory submission for NSCLC, chemotherapy combination (second half 2022)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 Events to Date	Select Upcoming Milestones
Libtayo (cemiplimab)[b][g] *(continued)*		–Second-line cervical cancer, ISA101b combination		–First-line NSCLC, chemotherapy combination (U.S. and EU)		–EC decision on regulatory submission for cervical cancer (second half 2022)
REGN4018[f] *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					–Report results from Phase 1 study in prostate cancer (second half 2022)
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					
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)
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][o]	–B-cell non-Hodgkin lymphoma ("B-NHL")[o] (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 (second half 2022)
REGN5458[f] *Bispecific antibody targeting BCMA and CD3*		–Multiple myeloma (potentially pivotal study)				–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 (2023) –Expand into earlier lines of therapy for multiple myeloma (first 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[m] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][m]			–Submit BLA for CD55-deficient protein-losing enteropathy, monotherapy (second half 2022)
Cemdisiran[m] *siRNA therapeutic targeting C5*		–Immunoglobulin A nephropathy				
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia					
NTLA-2001[l] *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)(k)] *Multi-antibody therapy to SARS-CoV-2 virus*			–COVID-19 treatment in hospitalized patients –COVID-19 prevention	–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; considered Major Amendment to the BLA and target action date extended by three months –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 (target action date of July 13, 2022) for COVID-19 treatment of non-hospitalized patients and prevention –EC decision on regulatory submission for COVID-19 treatment of hospitalized patients (second half 2022)
"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 (mid-2022)
Evkeeza (evinacumab)[(f)(n)] *Antibody to ANGPTL3*		–Acute pancreatitis prevention				
Garetosmab[(f)] (REGN2477) *Antibody to Activin A*		–Fibrodysplasia ossificans progressiva ("FOP")[(c)(d)(e)]				–Initiate Phase 3 study in FOP (second half 2022)
REGN4461[(f)] *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[(e)] –Partial lipodystrophy				
REGN5381/REGN9035 *Agonist antibody to NPR1/reversal agent to REGN5381*	–Heart failure					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[(h)]	2022 Events to Date	Select Upcoming Milestones
ALN-HSD[(m)] *RNAi therapeutic targeting HSD17B13*	–Nonalcoholic steatohepatitis ("NASH")					
ALN-APP[(m)] *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)] Certain trials conducted with the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH")

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

[(l)] In collaboration with Intellia

[(m)] In collaboration with Alnylam

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

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

Additional Information - Clinical Development Programs

REGEN-COV (casirivimab and imdevimab)

In April 2022, the Company announced that the FDA extended by three months (with a new target action date of July 13, 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 is 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.

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 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). 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.

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%–100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30%–50% of worldwide development expenses that were funded by Sanofi based on our share of collaboration profits from commercialization of collaboration products. However, we are only required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs.

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 the next $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

We are collaborating with Sanofi on the development and commercialization of antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). We are obligated to reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the Amended and Restated Immuno-oncology Discovery and Development Agreement from our share of profits from commercialized IO Collaboration products.

Under the terms of the IO License and Collaboration Agreement, the parties are co-developing and co-commercializing Libtayo. We have principal control over the development of Libtayo, and the parties share equally, on an ongoing basis, development and commercialization expenses for Libtayo.

With regard to Libtayo, we lead commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States and the parties equally share profits from worldwide sales. Sanofi has exercised its option to co-commercialize Libtayo in the United States. We will be entitled to a milestone payment of $375.0 million in the event that global sales of Libtayo equal or exceed $2.0 billion in any consecutive twelve-month period.

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. All agreed-upon development expenses incurred by the Company and Bayer are 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 March 31, 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.

We have also granted Ultragenyx an exclusive option to negotiate a separate agreement to collaborate on the development and commercialization of garetosmab outside of the United States under terms to be agreed upon by both companies.

Checkmate

In April 2022, we entered into an Agreement and Plan of Merger (the "Merger Agreement") to acquire Checkmate Pharmaceuticals, Inc. at a total equity value of approximately $250 million. On May 2, 2022, we commenced a tender offer to acquire any and all outstanding shares of common stock of Checkmate at a price of $10.50 per share, to be paid to each shareholder tendering Checkmate shares in cash, without interest, subject to reduction for any applicable withholding taxes. The consummation of the tender offer is subject to certain conditions, including the tender of at least a majority of the outstanding shares of Checkmate common stock, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. If the tender offer is successfully consummated, we will acquire all shares not acquired in the tender offer through a merger that does not require the vote of Checkmate shareholders. The transaction is expected to close in mid-2022.

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 Months Ended March 31, 2022 and 2021

Net Income

	Three Months Ended March 31,	
(In millions, except per share data)	**2022**	**2021**
Revenues	$ 2,965.1	$ 2,528.7
Operating expenses	1,706.6	1,416.0
Income from operations	1,258.5	1,112.7
Other income (expense)	(197.4)	140.3
Income before income taxes	1,061.1	1,253.0
Income tax expense	87.6	137.8
Net income	$ 973.5	$ 1,115.2
Net income per share - diluted	$ 8.61	$ 10.09

Revenues

	Three Months Ended March 31,		
(In millions)	**2022**	**2021**	**$ Change**
Net product sales in the United States:			
EYLEA	$ 1,517.6	$ 1,347.0	$ 170.6
Libtayo	78.9	69.1	9.8
Praluent	33.6	43.3	(9.7)
REGEN-COV	—	262.2	(262.2)
Evkeeza	8.5	0.5	8.0
ARCALYST	— *	2.2	*
Collaboration revenue:			
Sanofi	630.9	364.8	266.1
Bayer	385.3	322.8	62.5
Roche	216.3	66.8	149.5
Other revenue	94.0	50.0	44.0
Total revenues	$ 2,965.1	$ 2,528.7	$ 436.4

* 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 months ended March 31, 2022, compared to the same period in 2021, due to higher sales volume.

During the three months ended March 31, 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 months ended March 31, 2022. Refer to "Agreements Related to COVID-19 - *U.S. Government*" section above for further details.

Collaboration Revenue

Sanofi Collaboration Revenue

(In millions)	Three Months Ended March 31, 2022	2021
Antibody:		
Regeneron's share of profits in connection with commercialization of antibodies	$ 415.3	$ 260.6
Sales-based milestone earned	50.0	—
Reimbursement for manufacturing of commercial supplies[a]	160.8	105.6
Total Antibody	626.1	366.2
Immuno-oncology:		
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	2.8	(6.1)
Reimbursement for manufacturing of ex-U.S. commercial supplies[a]	2.0	4.7
Total Immuno-oncology	4.8	(1.4)
Total Sanofi collaboration revenue	$ 630.9	$ 364.8

[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 months ended March 31, 2022, compared to the same period of 2021, was driven by higher Dupixent profits.

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

(In millions)	Three Months Ended March 31, 2022	2021
Dupixent and Kevzara net product sales	$ 1,916.8	$ 1,332.0
Regeneron's share of collaboration profits	$ 462.2	$ 289.9
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(46.9)	(29.3)
Regeneron's share of profits in connection with commercialization of antibodies	$ 415.3	$ 260.6
Regeneron's share of collaboration profits as a percentage of Dupixent and Kevzara net product sales	22%	20%

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.

Bayer Collaboration Revenue

	Three Months Ended March 31,	
(In millions)	**2022**	**2021**
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 338.4	$ 308.9
Reimbursement for manufacturing of ex-U.S. commercial supplies[(a)]	25.0	13.9
One-time payment in connection with change in Japan arrangement	21.9	—
Total Bayer collaboration revenue	$ 385.3	$ 322.8

[(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 March 31,	
(In millions)	**2022**	**2021**
EYLEA net product sales outside the United States	$ 868.5	$ 811.2*
Regeneron's share of collaboration profit from sales outside the United States	$ 353.4	$ 323.7
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(15.0)	(14.8)
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 338.4	$ 308.9
Regeneron's share of profits as a percentage of EYLEA net product sales outside the United States	39%	38%

[*] 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.

During the three months ended March 31, 2022 and 2021, the Company recorded, within collaboration revenue, $216.3 million and $66.8 million of payments, respectively, from Roche in connection with this agreement. 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 three months ended March 31, 2022 included a $30.0 million up-front payment received from Ultragenyx in connection with our license and collaboration agreement for Evkeeza outside the United States.

Expenses

	Three Months Ended March 31,		
(In millions, except headcount data)	**2022**	**2021**	**Change**
Research and development[(a)]	$ 843.8	$ 742.9	$ 100.9
Acquired in-process research and development	28.1	—	28.1
Selling, general, and administrative[(a)]	450.0	405.6	44.4
Cost of goods sold[(b)]	207.3	183.2	24.1
Cost of collaboration and contract manufacturing[(c)]	197.6	124.8	72.8
Other operating (income) expense, net	(20.2)	(40.5)	20.3
Total operating expenses	$ 1,706.6	$ 1,416.0	$ 290.6
Average headcount	10,492	9,447	1,045

[(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 in the United States (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 for the three months ended March 31, 2022 and 2021 included a total of $166.9 million and $130.9 million, 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 March 31, 2022	2021*	$ Change
Direct research and development expenses:			
Libtayo (cemiplimab)	$ 38.6	$ 39.8	$ (1.2)
Dupixent (dupilumab)	32.1	27.4	4.7
EYLEA	24.4	28.1	(3.7)
REGEN-COV	2.7	208.8	(206.1)
Other product candidates in clinical development and other research programs	97.9	116.0	(18.1)
Total direct research and development expenses	195.7	420.1	(224.4)
Indirect research and development expenses:			
Payroll and benefits	283.8	233.0	50.8
Lab supplies and other research and development costs	38.0	33.4	4.6
Occupancy and other operating costs	120.3	95.1	25.2
Total indirect research and development expenses	442.1	361.5	80.6
Clinical manufacturing costs	271.7	133.7	138.0
Reimbursement of research and development expenses by collaborators	(65.7)	(172.4)	106.7
Total research and development expenses	$ 843.8	$ 742.9	$ 100.9

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

Reimbursement of research and development expenses by collaborators included reimbursements from Roche related to REGEN-COV of $86.8 million for the three months ended March 31, 2021. For the three months ended March 31, 2022, reimbursements from Roche related to REGEN-COV were not material.

Research and development expenses included stock-based compensation expense of $92.4 million and $69.7 million for the three months ended March 31, 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 months ended March 31, 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 months ended March 31, 2022, compared to the same period in 2021, primarily due to higher headcount and headcount-related costs and an increase in commercialization-related expenses for EYLEA. Selling, general, and administrative expenses also included stock-based compensation expense of $60.7 million and $50.8 million for the three months ended March 31, 2022 and 2021, respectively.

Cost of Goods Sold

Cost of goods sold increased for the three months ended March 31, 2022, compared to the same period in 2021, primarily due to $58.0 million of costs related to REGEN-COV, including inventory write-offs and reserves, partly offset by lower REGEN-COV manufacturing costs since there were no net product sales in the United States for the three months ended March 31, 2022.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased for the three months ended March 31, 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 expense (income), 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.

Other Income (Expense)

Other income (expense) was ($197.4) million and $140.3 million for the three months ended March 31, 2022 and 2021, respectively. This change was primarily driven by the recognition of net unrealized losses on equity securities of $211.2 million for the three months ended March 31, 2022 compared to $143.9 million of net unrealized gains for the same period in 2021.

Income Taxes

	Three Months Ended March 31,	
(In millions, except effective tax rate)	**2022**	**2021**
Income tax expense	$ 87.6	$ 137.8
Effective tax rate	8.3 %	11.0 %

Our effective tax rate for the three months ended March 31, 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 stock-based compensation. Our effective tax rate for the three months ended March 31, 2021 was positively impacted, compared to the U.S. federal statutory rate, primarily by the reversal of liabilities related to uncertain tax positions, stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and federal tax credits for research activities.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	March 31, 2022	December 31, 2021	$ Change
Financial assets:			
Cash and cash equivalents	$ 3,345.7	$ 2,885.6	$ 460.1
Marketable securities - current	3,704.9	2,809.1	895.8
Marketable securities - noncurrent	7,084.0	6,838.0	246.0
	$ 14,134.6	$ 12,532.7	$ 1,601.9
Borrowings and finance lease liabilities:			
Long-term debt	$ 1,980.4	$ 1,980.0	$ 0.4
Finance lease liabilities	$ 720.0	$ 719.7 *	$ 0.3
Working capital:			
Current assets	$ 14,306.0	$ 14,014.9	$ 291.1
Current liabilities	3,007.6	3,932.5 *	(924.9)
	$ 11,298.4	$ 10,082.4	$ 1,216.0

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

As of March 31, 2022, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Three Months Ended March 31, 2022 and 2021

	As of March 31,		
(In millions)	2022	2021	$ Change
Cash flows provided by operating activities	$ 2,101.7	$ 668.5	$ 1,433.2
Cash flows used in investing activities	$ (1,705.3)	$ (1,059.0)	$ (646.3)
Cash flows provided by (used in) financing activities	$ 64.7	$ (366.4)	$ 431.1

Cash Flows from Operating Activities

As of March 31, 2022, Accounts receivable had decreased by $1.198 billion, 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 March 31, 2022, deferred tax assets increased by $225.0 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 three months ended March 31, 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 $630 million to $700 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.

Cash Flows from Financing Activities

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $521.6 million during the three months ended March 31, 2022, compared to $95.0 million during the three months ended March 31, 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 three months ended March 31, 2022, we repurchased 566,973 shares of our Common Stock under the program and recorded the cost of the shares received, or $352.0 million, as Treasury Stock. As of March 31, 2022, $2.493 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 March 31, 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 three months ended March 31, 2022.

Future Impact of Recently Issued Accounting Standards

As of March 31, 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 March 31, 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 March 31, 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 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.

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 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, 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. Such disruptions could divert healthcare resources away from, or materially delay, FDA review and potential approval of our product candidates and new indications for our marketed products. 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. 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. 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.

In addition, our internal and contracted manufacturing capacity may not be sufficient to cover any potential future demand for our COVID-19 monoclonal antibodies. While we have entered into a collaboration agreement with Roche to develop, manufacture, and distribute outside the United States REGEN-COV, we cannot be certain that our current manufacturing and distribution capacity for REGEN-COV and the increased manufacturing and distribution capacity through our collaboration with Roche will be sufficient if there is significant future demand for REGEN-COV. In addition, we rely entirely on third parties for filling and finishing services for REGEN-COV and, in the future, may rely entirely on such providers for filling and

finishing services for our other COVID-19 monoclonal antibodies. Our third-party fill/finish providers may not have sufficient capacity or may otherwise not be able to provide such services on a timely basis in the quantities requested (such as because they devote their capacity to other drugs or vaccines against COVID-19), which we previously experienced. The ability of our third-party providers to deliver such services to us may further be adversely impacted by the imposition of government restrictions or limitations (including those that may be imposed under the Defense Production Act). If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms or at all, we may experience delays in the development, manufacturing, and distribution of our COVID-19 monoclonal antibodies.

We and 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 three months ended March 31, 2022 and 2021, EYLEA net sales in the United States represented 51% and 53% 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) and would redesign the Medicare Part D benefit to limit patient out-of-pocket drug costs and shift liabilities among stakeholders, including manufacturers. 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), as well as Samsung Bioepis Co., Ltd. and Biogen Inc.'s biosimilar referencing Lucentis. In addition, Genentech/Roche recently announced the approval of Vabysmo™ (faricimab-svoa), a bispecific antibody targeting both VEGF and Ang2, for the treatment of wet AMD and DME in the United States. 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 several topical ointments or agents either approved or in development. There are also 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, 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. 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, as in effect from time to time) for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, under the terms of our Antibody Collaboration and our IO Collaboration, we and Sanofi co-commercialize Dupixent and Libtayo in the United States. As a result, we rely in part on Sanofi's sales and marketing organization in the United States for these products. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively,

sales of any of such products may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent in the United States. For example, Sanofi records product sales for Dupixent in the United States and leads negotiations with payors relating to this product. We also rely on Sanofi for sales, marketing, and distribution of Dupixent and Libtayo in countries outside the United States. 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, our Antibody Collaboration, or our IO Collaboration would create substantial new and additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see "Risks Related to Our Reliance on Third Parties - *If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed*" below and "Risks Related to Our Reliance on Third Parties - *If our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, 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 and IO 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 three months ended March 31, 2022 and 2021, our gross product sales of such products to two customers accounted on a combined basis for 85% and 75% 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 commercial capabilities outside the United States for any new product we decide to 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 commercial capabilities for Dupixent in such jurisdictions. There may be other circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to commercialize a particular product independently; we are unable to find an appropriate collaborator; or our existing collaborator decides not to opt in, decides to opt out, or breaches its obligations to us with respect to a particular product.

In order to commercialize or co-commercialize any products outside the United States, we must build our sales, marketing, distribution, managerial, and other non-technical capabilities in the relevant markets or make arrangements with third parties to perform these services, 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) 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 postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products. 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. 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 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 a proposal formulated in connection with the COVID-19 pandemic for a waiver of certain intellectual property rights under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights; the ultimate timing and scope of this waiver is unknown and 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 waiver.

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. For example, our internal and contracted manufacturing capacity may not be sufficient if there is significant demand for REGEN-COV and our other COVID-19 monoclonal antibodies (if successfully developed and authorized for use). In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. For example, as described in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations," in August 2020, we announced a collaboration agreement with Roche to develop, manufacture, and distribute REGEN-COV (known as Ronapreve in other countries outside the United States). We cannot be certain that our current manufacturing and distribution capacity for REGEN-COV or the increased manufacturing and distribution capacity through our collaboration with Roche will be sufficient if there is significant future demand for REGEN-COV. As we increase our production in anticipation of potential regulatory approval for our product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. We 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 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. Recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal anti-kickback statute.

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 a civil complaint filed 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. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the PPACA. The final regulation 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.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. Implementation of this regulation 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 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. 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 10 to our Condensed Consolidated Financial Statements included in this report). 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 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 Third Parties

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

Under our IO Collaboration, Sanofi also funds half of the development expenses incurred in connection with the clinical development of Libtayo, subject to an agreed-upon development budget. We also rely on Sanofi to lead commercialization efforts outside the United States for Libtayo and to assist us to comply with the necessary requirements related to Libtayo's regulatory approvals in the EU.

If Sanofi terminates the Antibody Collaboration or the IO Collaboration or fails to comply with its payment obligations under any of our collaborations, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. If Sanofi does not perform its obligations with respect to the product candidates 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 or our IO Collaboration (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Antibody Collaboration or the IO Collaboration would create substantial new and additional risks to the successful development and commercialization of the products subject to such collaborations, particularly outside the United States.

If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed.

We rely heavily on Bayer with respect to the commercialization of EYLEA outside the United States. Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen pursuant to a Co-Promotion and Distribution Agreement, as in effect from time to time, with Bayer's Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to commercialize EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant issues for the commercialization of EYLEA outside the United States and result in substantial additional costs and/or lower revenues to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA outside the United States.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi and Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third-party manufacturers, fill/finish providers, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of our marketed products and our product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner (including as a result of its inability to perform due to financial or other relevant constraints, 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.

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 March 31, 2022, we had an aggregate of $2.700 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 March 31, 2022, we had $3.346 billion in cash and cash equivalents and $10.789 billion in marketable securities (including $1.039 billion 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 U.K. Financial Conduct Authority, which regulates LIBOR, has announced that it intends to phase out LIBOR. 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 April 12, 2022, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 37.3% 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 April 12, 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 $2.493 billion remained available as of March 31, 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 April 12, 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 April 12, 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 April 12, 2022, and 18.5% 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 April 12, 2022; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 37.3% 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 April 12, 2022. In addition, these five shareholders plus our Chief Executive Officer held approximately 44.7% 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 April 12, 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 and our 2014 PDGFR-beta 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 March 31, 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)*
1/1/2022–1/31/2022	240,319	$ 613.11	240,000	$ 2,697.8
2/1/2022–2/28/2022	184,306	$ 618.22	184,200	$ 2,584.0
3/1/2022–3/31/2022	142,773	$ 636.92	142,773	$ 2,493.0
Total	567,398 [(a)]		566,973 [(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*	Second Amended and Restated Participation Agreement, dated as of March 2, 2022, by and among Old Saw Mill Holdings LLC, as lessee, Bank of America, N.A., as administrative agent, BA Leasing BSC, LLC, as lessor, and the rent assignees party thereto from time to time. (Incorporated by reference from the Form 8-K for the Registrant, filed March 8, 2022.)
10.2*	Second Amended and Restated Lease and Remedies Agreement, dated as of March 2, 2022, between Old Saw Mill Holdings LLC, as lessee, and BA Leasing BSC, LLC, as lessor. (Incorporated by reference from the Form 8-K for the Registrant, filed March 8, 2022.)
10.3*	Second Amended and Restated Guaranty, dated as of March 2, 2022, made by Regeneron Pharmaceuticals, Inc. (the "Registrant"), Regeneron Healthcare Solutions, Inc., and Regeneron Genetics Center LLC, as guarantors. (Incorporated by reference from the Form 8-K for the Registrant, filed March 8, 2022.)
10.4	Modification No. 1 to Base Agreement, dated as of January 26, 2022, by and between the Registrant and Advanced Technology International.
10.5**	Modification No. 5 to Project Agreement, dated as of March 22, 2022, by and between the Registrant and Advanced Technology International.
10.6**	Modification P00006 to Supply Agreement, dated as of February 24, 2022, by and between the Registrant and the U.S. Army Contracting Command, New Jersey.
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 March 31, 2022 and December 31, 2021; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three months ended March 31, 2022 and 2021; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2022 and 2021; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 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 of the exhibits and/or schedules to this exhibit were omitted in accordance with Item 601(a)(5) of Regulation S-K

** 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: May 4, 2022

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

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

January 26, 2022

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

Attention:

Subject: Modification No. 01

Reference: MCDC Base Agreement No. 2020-504

Dear :

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

DESCRIPTION OF MODIFICATION

1) Article V, Section 5.03, Accounting System Requirements, of the MCDC Base Agreement is hereby amended to read as indicated in bold italics below:

Section 5.03 Accounting System Requirements:

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

For expenditure-based or resource-sharing projects, the capability of the MCDC Member's accounting system will be considered prior to award. Although the Government will not impose requirements that will cause a MCDC Member to revise or alter its existing accounting system, the Government will not enter into a PA that provides for payment based on amounts generated from the MCDC Member's financial or cost records, if the MCDC Member does not have an accounting system capable of identifying the amounts/costs to individual agreements/contracts.

Allowable Costs: Although OTAs are not subject to the FAR, the principles included in FAR Part 31 may be applied to determine price reasonableness for individual projects. MCDC Members who are selected for awards under the Base Agreement may refer to FAR Part 31 for guidance on allowable costs in preparing their final cost proposal for a project award.

2) Article VI, NONTRADITIONAL DEFENSE/COST SHARING of the MCDC Base Agreement is hereby replaced with APPROPRIATE USE OF OTHER TRANSACTION AUTHORITY as indicated below:

Article VI. APPROPRIATE USE OF OTHER TRANSACTION AUTHORITY

In accordance with provisions of 10 USC 2371b, the DoD has authority to enter into transactions *other than* contracts, grants, or cooperative agreements. The DoD has the authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the DoD, or the improvement of platforms, systems, components, or materials in use by the armed forces.

Per 10 U.S.C. § 2371b, each prototype project awarded under this Base Agreement must meet one of the following conditions:

- There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- All significant participants in the transaction, other than the Federal Government, are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.
- At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.
- The senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a contract, or would provide an opportunity to expand the defense supply base in a manner that would not be practical or feasible under a contract.

Throughout the period of performance of any PA, the AO and AOR will actively monitor projects to ensure compliance with this statutory requirement. The Government will take into account any implementation guidance from the Department of the Army and the Office of the Under Secretary of Defense for Acquisition and Sustainment, which includes but is not limited to, the most recent Other Transactions Guide. The MCDC Member awarded a PA will be given the opportunity to become compliant with this statutory requirement should they be found non-compliant by the AO and AOR and as communicated to the PAH by the CMF. Failure to comply may result in termination.

If significant nontraditional / nonprofit participation cannot be fulfilled, the PAH must provide at least one third cost share of the value of the PA awarded to the PAH. Proposals that fail to comply with this requirement, will not be awarded under the OTA.

Cost Sharing is not required under the OTA for projects that contain significant nontraditional / nonprofit participation. Where both Partiesthe Government and MCDCPAH agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by the Partiesthem, and in accordance with the most recent Other Transactions Guide.

3) Article XXI, Section 21.14, Duty-Free Entry, of the MCDC Base Agreement is hereby amended as indicated in bold italics below:

Section 21.14 Duty-Free Entry

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

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

(b) Except as provided in Paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a PA or the applicable subcontract, the price of this PA shall not include any amount for duty on-

(1) End items that are eligible products or qualifying country end products;
(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated into U.S – made end products to be delivered under an PA; or
(3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States.

(c) The PAH shall –

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

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –

(1) For which no duty is included in the PA price in accordance with Paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in Paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –

(1) Consign the shipments to the appropriate –
(i) Military department in care of the PAH, including the PAH's delivery address; or

(ii) Military installation; and

(2) Include the following information:

(i) Prime agreement number and, if applicable, delivery order number.

(ii) Number of the subcontract for foreign supplies, if applicable.

(iii) Identification of the carrier.

(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 201 ***Varick Street, Room 905C, New York***, New York, 10014, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."

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

(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)

(vi) Estimated value in U.S. dollars.

(vii) Activity address number of the contract administration office administering the prime agreement, e.g., for DCMA Dayton, S3605A.

(f) *Preparation of customs forms.*

(1)(i) Except for shipments consigned to a military installation, the PAH shall –

(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this agreement; and

(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.

(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.

(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –

(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two (2) of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;

(2) Consign the shipment as specified in Paragraph (e) of this clause; and

(3) Mark on the exterior of all packages –

(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and

(ii) The activity address number of the contract administration office administering the prime agreement.

(h) The PAH, through the MCDC CMF, shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH, through the MCDC CMF, shall furnish the notice to the ACO immediately upon award to the supplier, and shall include in the notice –

(1) The PAH's name, address, and Commercial and Government Entity (CAGE) code;
(2) Prime agreement number and PA number;
(3) Total dollar value of the prime agreement or PA number;
(4) Date of the last scheduled delivery under the prime agreement or PA number;
(5) Foreign supplier's name and address;
(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
(i) Scrap of salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this agreement if –

(1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
(2) It is not economical or feasible to account for such supplies, so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this agreement.

(j) The PAH shall —

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

4) Article XXI, Section 21.16, Public Readiness and Emergency Preparedness Act (PREP Act), of the MCDC Base Agreement is hereby incorporated as indicated below:

Section 21.16 Public Readiness and Emergency Preparedness Act (PREP Act)

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting

from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

Prior to award of individual projects under the program, current declarations will be reviewed by the Government via PHE.gov. If upon review, it is determined that a current declaration is applicable to the project to be awarded, appropriate PREP Act language will be incorporated into the SOW in coordination with the prospective PAH.

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.	**Advanced Technology International**
By: /s/ Robert Landry	By: /s/
Name: Robert Landry	Name:
Title: Executive Vice President - CFO	Title:
Date: February 24, 2022	Date: February 25, 2022

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.

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”

[* * *]

[* * *]63/034,865, filed June 4, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *][* * *]

[* * *][* * *]

[* * *][* * *][* * *]

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

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

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

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

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

submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

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

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

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

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

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

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

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the

right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

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

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

e. Action to Protect the Government's Interest

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

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

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

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

f. Lower Tier Agreements

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

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Regeneron also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Regeneron.

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

h. Compulsory Licensing Rights

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

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

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement

(including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights following the expiration of such ten (10)- year period. For Data produced under this Project Agreement, excluding Computer Software, to the extent developed with private funds and for other Data designated by Regeneron as "Limited Rights Data", Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

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

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

b. Proprietary Manufacturing Data

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

c. Identification and Disposition of Data

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

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

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

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

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

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

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activities related to medical countermeasures against COVID-19. To the extent DoD or BARDA is authorized to do so as an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that, 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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. Contract ID Code Firm Fixed Price	Page 1 Of 6

2. Amendment/Modification No. P00006	3. Effective Date	4. Requisition/Purchase Req. No. SEE SCHEDULE	5. Project No. (If applicable)

6. Issued By	Code W58P05	7. Administered By (If other than Item 6)	Code
U.S. ACC, APG , NCD NATICK, MA 01760-5011 EMAIL:			

8. Name and Address of Contractor (No., Street, City, Country, State and Zip Code)			
REGENERON PHARMACEUTICALS, INC. 777 OLD SAW MILL RIVER RD TARRYTOWN, NY 10591-6717		£	9A. Amendment Of Solicitation No.
			9B. Dated (See Item 11)
		S	10A. Modification Of Contract/Order No. W15QKN-21-C-0014
Code 544P9	Facility Code		10B. Dated (See Item 13) 2021JAN12

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

£ The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers £ is extended, £ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing items 8 and 15, and returning _____ copies of the amendments: (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. Accounting and Appropriation Data (If required)

NO CHANGE TO OBLIGATION DATA

13. THIS ITEM ONLY APPLIES TO MODIFICATIONS OF CONTRACTS/ORDERS
It Modifies The Contract/Order No. As Described In Item 14.

£ A. This Change Order is Issued Pursuant To: The Changes Set Forth in Item 14 Are Made In The Contract/Order No. In Item OA.

£ B. The Above Numbered Contract/Order Is Modified To Reflect The Administrative Changes (such as changes in paying office, appropriation data, etc.) Set Forth In Item 14, Pursuant To The Authority of FAR 43.103(b).

S C. This Supplemental Agreement Is Entered Into Pursuant To Authority Of: FAR 43.103(a)

£ D. Other (Specify type of modification and authority)

E. IMPORTANT: Contractor £ is not, S is required to sign this document and return _____ copies to the Issuing Office.

14. Description Of Amendment/Modification (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

SEE SECOND PAGE FOR DESCRIPTION

Except as provided herein, all terms and conditions of the document referenced In item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. Name And Title Of Signer (Type of print)		16A. Name And Title Of Contracting Officer (Type or print)	
Robert Landry - Executive Vice President			
15B. Contractor/Offeror /s/ Robert Landry (Signature of person authorized to sign)	15C. Date Signed 2/24/2022	16B. United States Of America By /s/ (Signature of Contracting Officer)	16C. Date Signed 02/25/2022

SECTION A - SUPPLEMENTAL INFORMATION

Buyer Name:
Buyer Office Symbol/Telephone Number: CCAP-CR/
Type of Contract 1: Firm Fixed Price
Kind of Contract: Other
Kind of Modification: G
Type of Business: Large Business Performing in U.S.
Surveillance Criticality Designator: A
Weapon System: No Identified Army Weapons Systems
Contract Expiration Date: 2022JUL31

Paying Office: HQ0490
DFAS-INDY VP GFEBS
8899 E. 56TH STREET
INDIANAPOLIS IN 46249-3800

*** End of Narrative A0000 ***

The purpose of this modification is to rescind the Health Resource Priority and Allocations Systems (HRPAS) Rating of DO-HR from Section H.

*** END OF NARRATIVE A0007 ***

SECTION H - SPECIAL CONTRACT REQUIREMENTS

As this is a commercial contract, any special requirements contained in this section and throughout the contract, are incorporated by addendum.

1. OWS REQUIRED CLAUSE

I. Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least [* * *] prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the CO and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than [* * *], the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the CO. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Reference Regeneron's Technical Proposal dated 29 December 2020, Section 2.3.1.1, Program Management, for a listing of key personnel

II. Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made, except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the CO to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The CO or authorized representative (TPOC) will evaluate such requests and promptly notify the Contractor of his approval or disapproval thereof.

The Contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this contract.

III. Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Governments rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractors employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activitys security or interrupt the continuity of its operations.

No information related to data obtained from the Government under this contract shall be released or publicized without the prior written consent of the TPOC, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any Government entity for submission to any securities exchange on which the Contractors (or its parent corporations) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

IV. Publications and Publicity

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the Contractor may publish the results of its work under this contract. The Contractor shall promptly send a copy of each submission to the TPOC for security review prior to submission. The Contractor shall also inform the TPOC when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the Contractor shall not display Government logos, including Operating Division or Staff Division logos on any publications.

(c) The Contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The Contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Contract No. W15QKN-21-C-0014. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

V. Confidentiality of Information

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The CO and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the CO and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the CO prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all sub-contractors.

VI. Organizational Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an Organizational Conflict of Interest (OCI). This provision shall apply to the prime Contractor and all sub-contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractors performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the CO immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the CO to either avoid or mitigate any such OCI. The CO will have sole discretion in accepting the Contractors mitigation plan. In the event the CO unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractors proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to,

for example to provide assistance during technical evaluation of other Contractors offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within [* * *] of execution.

2. HEALTH RESOURCE PRIORITY AND ALLOCATIONS SYSTEM (HRPAS)

Rescinded

3. ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

1. In recognition of the Governments need to provide sufficient quantities of a COVID-19 therapeutic to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

(a) Regeneron gives written notice, required to be submitted to the Government no later than [* * *], of:

i. any formal management decision to terminate manufacturing of this product therapeutic prior to delivery of the minimum required doses to the U.S. Government under this contract, as well as all additional orders accepted by the Contractor, other than as a result of clinical failure, or serious technical or safety reasons

or;

ii. any formal management decision to discontinue sale of this product therapeutic to the Government prior to delivery of the minimum required doses to the U.S. Government under this contract, as well as all additional orders accepted by the Contractor, other than as a result of clinical failure, or serious technical or safety reasons; or any filing that anticipates Federal bankruptcy protection; and

(b) Regeneron has submitted an Emergency Use Authorization application under Section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics license application under the provisions of Section 351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Regeneron, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this therapeutic product with a third party for exclusive sale to the U.S. Government:

(a) a writing, evidencing a non-exclusive, non-transferable, irrevocable (except for cause), royalty-free paid- up license to practice or have practiced for on behalf of the U.S. Government, any Regeneron Background Patent, Copyright, other Regeneron Intellectual Property, Regeneron Know-How, and Regeneron Technical Data rights necessary to manufacture doses of the SARS-CoV2 medical countermeasure neutralizing monoclonal antibodies, designated as casirivimab and imdevimab; necessary FDA regulatory filings or authorizations owned or controlled by Regeneron related to this therapeutic product, and any confirmatory instrument pertaining thereto; and

(b) any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract, and the license rights and items may only be used by the Government and its contractors to the extent needed to manufacture the number of doses that are not received under this contract, including with respect to any additional orders that are accepted by the Contractor.

4. DONATION OF EXCESS PRODUCT

A. In the event the Government determines that does of REGN10987 and REGN10933 (casirivmab and imdevimab) funded under the contract 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 requirment 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 REGN 10933 (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 C.3.1 shall not apply.

D. The parties acknowledge that PREP Act coverage may not apply to the provision of any doses under this Section 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, and that the Government shall cooperate with any such collaborators.

*** END OF NARRATIVE H0001 ***

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: May 4, 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: May 4, 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 March 31, 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)
May 4, 2022

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
May 4, 2022