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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2023
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: 000-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

The number of shares outstanding of each of the registrant's classes of common stock as of July 27, 2023:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,818,146
Common Stock, $.001 par value	106,740,572

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
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"Altibodies™," "ARCALYST®," "Evkeeza®," "EYLEA®," "Inmazeb®," "Libtayo®," "Praluent®" (in the United States), "REGEN-COV®," "Regeneron®," "Regeneron Genetics Center®," "RGC®," "*Veloci-Bi*®," "*VelociGene*®," "*VelociHum*®," "*VelociMab*®," "*VelocImmune*®," "*VelociMouse*®," "*VelociSuite*®," "*VelociT*®," and "ZALTRAP®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners. This report refers to products of Regeneron Pharmaceuticals, Inc., its collaborators, and other parties. Consult the product label in each territory for specific information about such products.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,937.2	$ 3,105.9
Marketable securities	6,990.5	4,636.4
Accounts receivable, net	5,121.3	5,328.7
Inventories	2,507.7	2,401.9
Prepaid expenses and other current assets	366.3	411.2
Total current assets	16,923.0	15,884.1
Marketable securities	6,327.2	6,591.8
Property, plant, and equipment, net	3,922.6	3,763.0
Intangible assets, net	953.0	915.5
Deferred tax assets	2,138.5	1,723.7
Other noncurrent assets	393.2	336.4
Total assets	$ 30,657.5	$ 29,214.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 547.3	$ 589.2
Accrued expenses and other current liabilities	2,176.0	2,074.2
Deferred revenue	381.1	477.9
Total current liabilities	3,104.4	3,141.3
Long-term debt	1,982.2	1,981.4
Finance lease liabilities	720.0	720.0
Deferred revenue	116.2	69.8
Other noncurrent liabilities	716.8	638.0
Total liabilities	6,639.6	6,550.5
Stockholders' equity:		
Preferred Stock, par value $.01 per share; 30.0 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, par value $.001 per share; 40.0 shares authorized; shares issued and outstanding - 1.8 in 2023 and 2022	—	—
Common Stock, par value $.001 per share; 320.0 shares authorized; shares issued - 131.6 in 2023 and 130.4 in 2022	0.1	0.1
Additional paid-in capital	10,888.5	9,949.3
Retained earnings	25,092.9	23,306.7
Accumulated other comprehensive loss	(197.7)	(238.8)
Treasury Stock, at cost; 24.5 shares in 2023 and 22.6 shares in 2022	(11,765.9)	(10,353.3)
Total stockholders' equity	24,017.9	22,664.0
Total liabilities and stockholders' equity	$ 30,657.5	$ 29,214.5

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Statements of Operations				
Revenues:				
Net product sales	$ 1,772.1	$ 1,754.4	$ 3,440.1	$ 3,393.0
Collaboration revenue	1,316.7	1,043.6	2,694.8	2,276.1
Other revenue	69.3	59.2	185.3	153.2
	3,158.1	2,857.2	6,320.2	5,822.3
Expenses:				
Research and development	1,085.3	794.3	2,186.5	1,638.1
Acquired in-process research and development	—	197.0	56.1	225.1
Selling, general, and administrative	652.0	476.3	1,253.1	926.3
Cost of goods sold	192.4	149.2	400.8	356.5
Cost of collaboration and contract manufacturing	212.5	147.9	461.6	345.5
Other operating (income) expense, net	(0.6)	(17.4)	(1.1)	(37.6)
	2,141.6	1,747.3	4,357.0	3,453.9
Income from operations	1,016.5	1,109.9	1,963.2	2,368.4
Other income (expense):				
Other income (expense), net	85.3	(133.6)	14.6	(317.4)
Interest expense	(18.9)	(13.1)	(36.9)	(26.7)
	66.4	(146.7)	(22.3)	(344.1)
Income before income taxes	1,082.9	963.2	1,940.9	2,024.3
Income tax expense	114.5	111.1	154.7	198.7
Net income	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Net income per share - basic	$ 9.05	$ 7.90	$ 16.69	$ 17.01
Net income per share - diluted	$ 8.50	$ 7.47	$ 15.68	$ 16.07
Weighted average shares outstanding - basic	107.0	107.9	107.0	107.3
Weighted average shares outstanding - diluted	113.9	114.0	113.9	113.6
Statements of Comprehensive Income				
Net income	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Other comprehensive income (loss), net of tax:				
Unrealized (loss) gain on debt securities	(15.7)	(53.7)	41.5	(198.6)
Loss on foreign currency translation	(0.4)	—	(0.4)	—
Unrealized gain on cash flow hedges	—	—	—	1.0
Comprehensive income	$ 952.3	$ 798.4	$ 1,827.3	$ 1,628.0

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, 2022	1.8	$ —	130.4	$ 0.1	$ 9,949.3	$23,306.7	$ (238.8)	(22.6)	$(10,353.3)	$ 22,664.0
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	1.1	—	491.3	—	—	—	—	491.3
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(99.2)	—	—	—	—	(99.2)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	18.9	—	—	—	1.7	20.6
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.9)	(693.9)	(693.9)
Stock-based compensation charges	—	—	—	—	237.4	—	—	—	—	237.4
Net income	—	—	—	—	—	817.8	—	—	—	817.8
Other comprehensive income, net of tax	—	—	—	—	—	—	57.2	—	—	57.2
Balance, March 31, 2023	1.8	—	131.4	0.1	10,597.7	24,124.5	(181.6)	(23.5)	(11,045.5)	23,495.2
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.2	—	80.7	—	—	—	—	80.7
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(14.0)	—	—	—	—	(14.0)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	16.1	—	—	—	2.4	18.5
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.0)	(722.8)	(722.8)
Stock-based compensation charges	—	—	—	—	208.0	—	—	—	—	208.0
Net income	—	—	—	—	—	968.4	—	—	—	968.4
Other comprehensive loss, net of tax	—	—	—	—	—	—	(16.1)	—	—	(16.1)
Balance, June 30, 2023	1.8	$ —	131.6	$ 0.1	$10,888.5	$25,092.9	$ (197.7)	(24.5)	$(11,765.9)	$ 24,017.9

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

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

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

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

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net income	$ 1,786.2	$ 1,825.6
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	202.6	148.7
Stock-based compensation expense	440.7	326.7
Losses on marketable and other securities, net	197.5	370.9
Other non-cash items, net	29.2	138.3
Deferred income taxes	(425.8)	(381.0)
Acquired in-process research and development in connection with asset acquisition	—	195.0
Changes in assets and liabilities:		
Decrease in accounts receivable	207.4	875.1
Increase in inventories	(147.2)	(328.7)
Increase in prepaid expenses and other assets	(8.9)	(288.5)
(Decrease) increase in deferred revenue	(50.4)	109.7
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	158.7	(325.7)
Total adjustments	603.8	840.5
Net cash provided by operating activities	2,390.0	2,666.1
Cash flows from investing activities:		
Purchases of marketable and other securities	(6,271.1)	(3,774.9)
Sales or maturities of marketable and other securities	4,061.5	2,181.4
Capital expenditures	(291.2)	(295.4)
Payments for Libtayo intangible asset	(121.8)	—
Asset acquisition, net of cash acquired	—	(230.3)
Net cash used in investing activities	(2,622.6)	(2,119.2)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	575.9	828.4
Payments in connection with Common Stock tendered for employee tax obligations	(113.1)	(147.7)
Repurchases of Common Stock	(1,399.5)	(717.1)
Net cash used in financing activities	(936.7)	(36.4)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(0.4)	—
Net (decrease) increase in cash, cash equivalents, and restricted cash	(1,169.7)	510.5
Cash, cash equivalents, and restricted cash at beginning of period	3,119.4	2,898.1
Cash, cash equivalents, and restricted cash at end of period	$ 1,949.7	$ 3,408.6

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, 2022 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, 2022.

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

2. Product Sales

Net product sales consist of the following:

(In millions)		Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
EYLEA®	U.S.	$ 1,500.1	$ 1,621.2	$ 2,933.9	$ 3,138.8
Libtayo®[a]	U.S.	130.2	90.9	239.9	169.8
	ROW[b]	79.8	—	147.0	—
Praluent®	U.S.	40.5	31.2	80.7	64.8
Evkeeza®	U.S.	19.3	11.1	34.2	19.6
Inmazeb®	U.S.	2.2	—	4.4	—
		$ 1,772.1	$ 1,754.4	$ 3,440.1	$ 3,393.0

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

[b] Rest of world ("ROW")

As of June 30, 2023 and December 31, 2022, the Company had $3.718 billion and $3.586 billion, respectively, of trade accounts receivable that were recorded within Accounts receivable, net.

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for the three and six months ended June 30, 2023 and 2022. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Besse Medical, a subsidiary of AmerisourceBergen Corporation	51 %	57 %	51 %	56 %
McKesson Corporation	25 %	28 %	25 %	29 %

3. Collaboration, License, and Other Agreements

a. Sanofi

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

(In millions)	Statement of Operations Classification	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Antibody:					
Regeneron's share of profits in connection with commercialization of antibodies	Collaboration revenue	$ 751.1	$ 496.6	$ 1,387.6	$ 911.9
Sales-based milestones earned	Collaboration revenue	$ —	$ —	$ —	$ 50.0
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	$ 192.6	$ 145.5	$ 354.5	$ 306.3
Other	Collaboration revenue	$ —	$ 28.9	$ —	$ 28.9
Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses	(R&D expense)/Reduction of R&D expense	$ (14.5)	$ 37.1	$ (40.9)	$ 63.9
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	$ 130.9	$ 110.8	$ 248.5	$ 202.5
Immuno-oncology[(a)]:					
Regeneron's share of profits in connection with commercialization of Libtayo outside the United States	Collaboration revenue	$ —	$ 3.9	$ —	$ 6.7
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ —	$ 2.6	$ —	$ 4.6
Reimbursement of R&D expenses	Reduction of R&D expense	$ —	$ 21.2	$ —	$ 42.7
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	$ —	$ 22.4	$ —	$ 41.4
Regeneron's obligation for its share of Sanofi commercial expenses	SG&A expense	$ —	$ (10.7)	$ —	$ (19.9)
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ —	$ (37.8)	$ —	$ (70.1)
Amounts recognized in connection with up-front payments received	Other operating income	$ —	$ 17.0	$ —	$ 35.1

[(a)] As described within the "*Immuno-Oncology*" section below, effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide.

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 (the "LCA"), Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. The Company is obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on the Company's share of collaboration profits from commercialization of collaboration products. Under the terms of the LCA, the Company was required to apply 10% of its share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs. On July 1, 2022, an amendment to the LCA became effective, pursuant to which the percentage of the Company's share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%. A portion of the value associated with the increase in reimbursement percentage was deemed to be contingent consideration attributable to the Company's acquisition of the Libtayo (cemiplimab) rights described within the "*Immuno-Oncology*" section below; this portion will be recorded as an increase to the Libtayo intangible asset over time as the Company repays such development costs to Sanofi.

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. The Company is entitled to receive the final sales milestone payment of $50.0 million when such sales outside the United States exceed $3.0 billion on a rolling twelve-month basis.

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

(In millions)	**June 30, 2023**	**December 31, 2022**
Accounts receivable, net	$ 876.0	$ 692.3
Deferred revenue	$ 372.2	$ 415.8

Immuno-Oncology

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

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA"). In connection with the A&R IO LCA, in 2022, the Company made a $900.0 million up-front payment to Sanofi, as well as a $100.0 million regulatory milestone payment. In addition, Sanofi earned a $65.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2022 and is eligible to receive an additional $35.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2023 (aggregate of $100.0 million in sales-based milestones eligible to be earned under the terms of the A&R IO LCA). The Company also pays Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. The transaction was accounted for as an asset acquisition and amounts paid to Sanofi in connection with obtaining the worldwide rights to Libtayo, including the up-front payment and any contingent consideration, are recorded as an intangible asset.

b. Bayer

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA (aflibercept) and aflibercept 8 mg outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits and losses from such sales.

Amounts recognized in the Company's Statements of Operations in connection with its Bayer collaboration are as follows:

(In millions)	Statement of Operations Classification	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	Collaboration revenue	$ 349.5	$ 339.7	$ 681.1	$ 678.1
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ 27.2	$ 17.8	$ 52.5	$ 42.8
One-time payment in connection with change in Japan arrangement	Collaboration revenue	$ —	$ —	$ —	$ 21.9
Regeneron's obligation for its share of Bayer R&D expenses, net of reimbursement of R&D expenses	(R&D expense)/Reduction of R&D expense	$ (12.0)	$ 2.9	$ (25.4)	$ 3.2

The following table summarizes contract balances in connection with the Company's Bayer collaboration:

(In millions)	June 30, 2023	December 31, 2022
Accounts receivable, net	$ 355.6	$ 348.2
Deferred revenue	$ 124.8	$ 131.9

c. Roche

The Company is a party to a collaboration agreement with Roche to develop, manufacture, and distribute the casirivimab and imdevimab antibody cocktail (known as REGEN-COV® in the United States and Ronapreve™ in other countries). Under the terms of the collaboration agreement, the parties jointly fund certain studies, and the Company has the right to distribute the product in the United States while Roche has the right to distribute 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.

Amounts recognized in the Company's Statements of Operations in connection with its Roche collaboration are as follows:

(In millions)	Statement of Operations Classification	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Global gross profit payment from Roche in connection with sales of Ronapreve	Collaboration revenue	$ —	$ 8.2	$ 222.2	$ 224.5
Other	Collaboration revenue	$ (3.8)	$ —	$ (3.8)	$ —

Reimbursement of research and development expenses from Roche was not material for the three and six months ended June 30, 2023 and 2022.

The following table summarizes contract balances in connection with the Company's Roche collaboration:

(In millions)	June 30, 2023	December 31, 2022
Accounts receivable, net	$ —	$ 396.6

d. Alnylam

In 2019, the Company and Alnylam entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference ("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. In connection with entering into the collaboration, the Company made an up-front payment of $400.0 million to Alnylam, and also purchased shares of Alnylam common stock for $400.0 million. For each program, the Company provides Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive two $100.0 million clinical proof-of-principle milestones for each of the eye and CNS programs (an aggregate of $200.0 million in development milestones). Under the terms of the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a co-development/co-commercialization collaboration agreement ("Co-Co Collaboration Agreement") (under which the parties are advancing ALN-APP and ALN-PNP, which are currently in clinical development) or license agreement.

Amounts recognized in the Company's Statements of Operations in connection with its Alnylam collaboration were not material for the three and six months ended June 30, 2023 and 2022. In addition, contract balances in the Company's Balance Sheets were not material as of June 30, 2023 and December 31, 2022.

e. Sonoma Biotherapeutics, Inc.

In March 2023, the Company and Sonoma Biotherapeutics, Inc. entered into a license and collaboration agreement to bring together the Company's *VelociSuite*® technologies with Sonoma's technology platform for the discovery, development, and commercialization of novel regulatory T cell (T_{reg}) therapies for autoimmune diseases. In connection with the agreement, the Company made a $45.0 million up-front payment (which was recorded to Acquired in-process research and development expense in the first quarter of 2023) and, in April 2023, the Company purchased an aggregate of $30.0 million of Sonoma preferred stock. Sonoma is also eligible to receive a $45.0 million development milestone payment. The Company and Sonoma will co-fund research and development activities and share equally any future commercial expenses and profits. The Company will have the option to lead late-stage development and commercialization on all products globally, with Sonoma retaining rights to co-promote all such products in the United States.

f. Checkmate

In May 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. (“Checkmate”) for a total equity value of approximately $250 million. As a result of the transaction, which was accounted for as an asset acquisition, the Company recorded (i) a charge of $195.0 million to Acquired in-process research and development and (ii) net assets of $35.3 million, net of cash, related to the assets acquired (including deferred tax assets and investments) and liabilities assumed.

4. Net Income Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2023**	**2022**	**2023**	**2022**
Net income - basic and diluted	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Weighted average shares - basic	107.0	107.9	107.0	107.3
Effect of dilutive securities:				
Stock options	4.8	4.7	4.9	4.9
Restricted stock awards and restricted stock units	2.1	1.4	2.0	1.4
Weighted average shares - diluted	113.9	114.0	113.9	113.6
Net income per share - basic	$ 9.05	$ 7.90	$ 16.69	$ 17.01
Net income per share - diluted	$ 8.50	$ 7.47	$ 15.68	$ 16.07

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(Shares in millions)	**2023**	**2022**	**2023**	**2022**
Stock options	1.7	2.2	1.7	2.3

5. Marketable Securities

Marketable securities as of June 30, 2023 and December 31, 2022 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	Unrealized		Fair
As of June 30, 2023	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 6,911.3	$ 0.7	$ (221.7)	$ 6,690.3
U.S. government and government agency obligations	4,899.7	0.5	(24.2)	4,876.0
Sovereign bonds	78.6	—	(2.2)	76.4
Commercial paper	300.3	0.1	(0.2)	300.2
Certificates of deposit	259.0	—	(0.2)	258.8
Asset-backed securities	90.5	0.2	(2.4)	88.3
	$ 12,539.4	$ 1.5	$ (250.9)	$ 12,290.0
As of December 31, 2022				
Corporate bonds	$ 6,975.5	$ —	$ (291.1)	$ 6,684.4
U.S. government and government agency obligations	2,945.4	0.9	(6.9)	2,939.4
Sovereign bonds	67.1	—	(3.0)	64.1
Commercial paper	121.1	—	—	121.1
Certificates of deposit	182.1	—	(0.1)	182.0
Asset-backed securities	28.9	—	(1.7)	27.2
	$ 10,320.1	$ 0.9	$ (302.8)	$ 10,018.2

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities as of June 30, 2023 mature at various dates through April 2029. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

(In millions)	June 30, 2023	December 31, 2022
Maturities within one year	$ 6,999.1	$ 4,636.4
Maturities after one year through five years	5,281.1	5,381.4
Maturities after five years	9.8	0.4
	$ 12,290.0	$ 10,018.2

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.

	Less than 12 Months		12 Months or Greater		Total	
(In millions) **As of June 30, 2023**	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 1,567.4	$ (15.7)	$ 4,856.6	$ (206.0)	$ 6,424.0	$ (221.7)
U.S. government and government agency obligations	2,286.8	(19.9)	79.2	(4.3)	2,366.0	(24.2)
Sovereign bonds	12.3	(0.2)	53.1	(2.0)	65.4	(2.2)
Commercial paper	254.8	(0.2)	—	—	254.8	(0.2)
Certificates of deposit	158.4	(0.2)	—	—	158.4	(0.2)
Asset-backed securities	62.6	(0.9)	24.7	(1.5)	87.3	(2.4)
	$ 4,342.3	$ (37.1)	$ 5,013.6	$ (213.8)	$ 9,355.9	$ (250.9)
As of December 31, 2022						
Corporate bonds	$ 2,445.4	$ (73.1)	$ 4,200.4	$ (218.0)	$ 6,645.8	$ (291.1)
U.S. government and government agency obligations	785.2	(2.0)	71.0	(4.9)	856.2	(6.9)
Sovereign bonds	18.6	(1.1)	45.6	(1.9)	64.2	(3.0)
Certificates of deposit	40.2	(0.1)	—	—	40.2	(0.1)
Asset-backed securities	11.5	(0.6)	15.2	(1.1)	26.7	(1.7)
	$ 3,300.9	$ (76.9)	$ 4,332.2	$ (225.9)	$ 7,633.1	$ (302.8)

The unrealized losses on corporate bonds as of June 30, 2023 were primarily driven by increases in interest rates. The Company has reviewed its portfolio of available-for-sale debt securities and determined that the decline in fair value below cost did not result from credit-related factors. In addition, the Company does not intend to sell, and it is not more likely than not that the Company will be required to sell, such securities before recovery of their amortized cost bases.

With respect to marketable securities, for the three and six months ended June 30, 2023 and 2022, amounts reclassified from Accumulated other comprehensive loss into Other income (expense), net were related to realized gains/losses on sales of available-for-sale debt securities.

For the three months ended ended June 30, 2023, realized gains on sales of marketable securities were not material and there were no realized losses. For the six months ended June 30, 2023, and for the three and six months ended June 30, 2022, realized gains and losses on sales of marketable securities were not material.

6. Fair Value Measurements

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

- Level 1 - Quoted prices in active markets for identical assets
- Level 2 - Significant other observable inputs, such as quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable
- Level 3 - Significant other unobservable inputs

(In millions)		Fair Value Measurements at Reporting Date	
As of June 30, 2023	**Fair Value**	**Level 1**	**Level 2**
Cash equivalents	$ 512.5	$ 201.8	$ 310.7
Available-for-sale debt securities:			
Corporate bonds	6,690.3	—	6,690.3
U.S. government and government agency obligations	4,876.0	—	4,876.0
Sovereign bonds	76.4	—	76.4
Commercial paper	300.2	—	300.2
Certificates of deposit	258.8	—	258.8
Asset-backed securities	88.3	—	88.3
Equity securities (unrestricted)	865.8	865.8	—
Equity securities (restricted)	161.9	151.0	10.9
	$ 13,830.2	$ 1,218.6	$ 12,611.6
As of December 31, 2022			
Cash equivalents	$ 1,662.8	$ 88.3	$ 1,574.5
Available-for-sale debt securities:			
Corporate bonds	6,684.4	—	6,684.4
U.S. government and government agency obligations	2,939.4	—	2,939.4
Sovereign bonds	64.1	—	64.1
Commercial paper	121.1	—	121.1
Certificates of deposit	182.0	—	182.0
Asset-backed securities	27.2	—	27.2
Equity securities (unrestricted)	24.6	24.6	—
Equity securities (restricted)	1,185.4	1,185.4	—
	$ 12,891.0	$ 1,298.3	$ 11,592.7

The Company held certain restricted equity securities as of June 30, 2023 which are subject to transfer restrictions that expire at various dates through 2024.

During the three and six months ended June 30, 2023, we recorded $30.9 million and $195.6 million of net unrealized losses, respectively, on equity securities in Other income (expense), net; and during the three and six months ended June 30, 2022, we recorded $163.7 million and $374.9 million of net unrealized losses, respectively, on equity securities in Other income (expense), net.

In addition to the investments summarized in the table above, as of June 30, 2023 and December 31, 2022, the Company had $78.3 million and $48.3 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, which was determined based on Level 2 inputs, was estimated to be $1.476 billion and $1.443 billion as of June 30, 2023 and December 31, 2022, respectively.

7. Inventories

Inventories consist of the following:

(In millions)	June 30, 2023	December 31, 2022
Raw materials	$ 813.3	$ 818.4
Work-in-process	1,069.6	963.1
Finished goods	125.3	98.6
Deferred costs	499.5	521.8
	$ 2,507.7	$ 2,401.9

Inventory balances in the table above are net of reserves of $747.9 million and $720.7 million as of June 30, 2023 and December 31, 2022, 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. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 10.6% and 11.5% for the three months ended June 30, 2023 and 2022, respectively, and 8.0% and 9.8% for the six months ended June 30, 2023 and 2022, respectively. The Company's effective tax rate for the three and six months ended June 30, 2023 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and, to a lesser extent, stock-based compensation and federal tax credits for research activities.

The Company's effective tax rate for the three and six months ended June 30, 2022 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and, to a lesser extent, stock-based compensation.

In August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law in the United States. The IRA created a new corporate alternative minimum tax of 15% on adjusted financial statement income and an excise tax of 1% of the value of certain stock repurchases. The provisions of the IRA became effective for periods beginning after December 31, 2022. The IRA did not have a material impact on the Company's financial statements for the three and six months ended June 30, 2023.

9. Stockholders' Equity

Share Repurchase Programs

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock. As of June 30, 2023, the Company had repurchased the entire $3.0 billion of its Common Stock that it was authorized to repurchase under the program.

In January 2023, 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 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. As of June 30, 2023, $2.332 billion remained available for share repurchases under the January 2023 program.

The table below summarizes the shares of our Common Stock we repurchased and the cost of the shares, which were recorded as Treasury Stock. As described in Note 8, effective January 1, 2023 share repurchases, net of issuances, are subject to a 1% excise tax; such amount, if applicable, is recognized as an additional cost of the shares acquired.

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2023**	**2022**	**2023**	**2022**
Number of shares	1.0	0.7	1.9	1.2
Total cost of shares	$ 722.8	$ 393.6	$ 1,416.7	$ 745.5

10. Statement of Cash Flows

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

	June 30,	
(In millions)	**2023**	**2022**
Cash and cash equivalents	$ 1,937.2	$ 3,395.1
Restricted cash included in Prepaid expenses and other current assets	5.5	—
Restricted cash included in Other noncurrent assets	7.0	13.5
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$ 1,949.7	$ 3,408.6

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

Supplemental disclosure of non-cash investing and financing activities

(In millions)	June 30, 2023	December 31, 2022	June 30, 2022	December 31, 2021
Accrued capital expenditures	$ 107.5	$ 70.8	$ 81.9	$ 74.8
Accrued contingent consideration for Libtayo intangible asset	$ 60.8	$ 135.5	$ —	$ —

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. 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. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of June 30, 2023 and December 31, 2022, the Company's accruals for loss contingencies were not material. There are certain loss contingencies that the Company deems reasonably possible for which the possible loss or range of possible loss is not estimable at this time.

Proceedings Relating to Praluent (alirocumab) Injection

As described 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. In addition, as described below, the Company filed a lawsuit against Amgen alleging that Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of U.S. federal and state laws.

United States

In the United States, Amgen 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 sought 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 4, 2022, the United States Supreme Court granted Amgen's petition for writ of certiorari. An oral hearing was held on March 27, 2023. On May 28, 2023, the United States Supreme Court affirmed the Federal Circuit's decision that certain of Amgen's asserted patent claims are invalid based on lack of enablement.

On May 27, 2022, the Company filed a lawsuit against Amgen in the United States District Court for the District of Delaware, alleging that, beginning in 2020, Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws. The lawsuit seeks damages for harm caused by the alleged scheme, as well as injunctive relief restraining Amgen from continuing its alleged anticompetitive conduct. On August 1, 2022, Amgen filed a motion to dismiss the complaint. On August 11, 2022, Amgen filed a motion to stay these proceedings pending resolution of the patent litigation described in the preceding paragraph. An oral hearing on Amgen's motion to dismiss and motion to stay was held on January 6, 2023. On February 10, 2023, the court denied Amgen's motion to stay; and on March 21, 2023, the court denied Amgen's motion to dismiss. A trial has been scheduled to begin in November 2024.

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, 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 was held on February 21, 2023, at which the '917 Patent was revoked. Amgen filed a notice to appeal to the TBA of the EPO on February 27, 2023.

On June 1, 2023, Amgen filed a lawsuit against the Company and certain of Sanofi's affiliated entities in the Munich Local Division of the Unified Patent Court (the "UPC") alleging infringement of Amgen's European Patent No. 3,666,797 (the "'797 Patent"). The lawsuit seeks, among other things, a permanent injunction in several countries in Europe and monetary damages. The '797 Patent is a divisional patent of the '124 Patent discussed above. Also on June 1, 2023, Sanofi filed an action in the Munich Central Division of the UPC seeking revocation of the '797 Patent.

Proceedings Relating to EYLEA (aflibercept) Injection

Certain of the Company's patents pertaining to EYLEA are subject to post-grant proceedings before the United States Patent and Trademark Office ("USPTO"), EPO, or other comparable foreign authorities, including those described in greater detail below. In addition, the Company has filed patent infringement lawsuits in several jurisdictions alleging infringement of certain Company patents pertaining to EYLEA, including those described in greater detail below.

United States

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

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 was held on August 10, 2022. On November 9, 2022, the USPTO issued final written decisions finding that the claims of the '338 and '069 Patents are unpatentable and,

therefore, invalid. On January 10, 2023, the Company filed notices of appeal of the USPTO written decisions concerning the '338 and '069 Patents with the Federal Circuit.

In 2022, Mylan filed IPR petitions against the Company's U.S. Patent Nos. 10,130,681 (the "'681 Patent") and 10,888,601 (the "'601 Patent") (each filed July 1, 2022) and 10,857,205 (the "'205 Patent") (filed October 28, 2022) seeking declarations of invalidity of each of these patents. On January 11, 2023, the USPTO instituted IPR proceedings concerning the '681 Patent and the '601 Patent. On February 21, 2023, the Company filed a Notice of Disclaimer with the USPTO, disclaiming all claims of the '205 Patent; and, as a result, on March 1, 2023, the USPTO denied institution of Mylan's IPR petition against the '205 Patent. On January 6, 2023 and March 26, 2023, Samsung Bioepis Co., Ltd. filed separate IPR petitions against the Company's '681 Patent and '601 Patent, respectively, seeking declarations of invalidity of such patents. On July 19, 2023, the USPTO instituted an IPR proceeding concerning the '681 Patent.

On September 9, 2022, Apotex filed an IPR petition against the Company's U.S. Patent No. 11,253,572 (the "'572 Patent") seeking a declaration of invalidity of the '572 Patent. On March 10, 2023, the USPTO declined to institute an IPR proceeding concerning the '572 Patent. On April 27, 2023, Samsung Bioepis Co., Ltd. filed a separate IPR petition against the '572 Patent seeking a declaration of invalidity of the '572 Patent.

On January 17, 2023 and February 28, 2023, Celltrion filed IPR petitions against the '992 Patent and the '226 Patent, respectively, seeking declarations of invalidity of such patents. On July 20, 2023, the USPTO instituted an IPR proceeding concerning the '992 Patent.

On August 2, 2022, the Company filed a patent infringement lawsuit against Mylan in the United States District Court for the Northern District of West Virginia alleging that Mylan's filing for a U.S. Food and Drug Administration approval of an aflibercept biosimilar infringes certain Company patents. On April 20, 2023, Mylan filed a motion for summary judgment or partial summary judgment concerning four of the asserted patents. On April 26, 2023, the Company filed a stipulation accepting summary judgment of noninfringement of all asserted claims of the Company's U.S. Patent No. 11,104,715. A trial was held from June 12, 2023 through June 23, 2023 concerning certain claims of the '601 Patent, the '572 Patent, and the Company's U.S. Patent No. 11,084,865. Closing arguments have been scheduled for August 3, 2023.

Europe

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

Between May 5-10, 2023, Amgen and three anonymous parties initiated opposition proceedings in the EPO against the Company's European Patent No. 3,716,992 (the "EP '992 Patent") seeking revocation of the EP '992 Patent in its entirety.

On June 22, 2023, Samsung Bioepis NL B.V. initiated invalidation proceedings in the German Federal Patent Court against the German designation of the Company's European Patent No. 2,364,691 (the "'691 Patent") seeking revocation of the '691 Patent in its entirety.

Canada

On June 15, July 15, August 30, and October 4, 2022, the Company and Bayer Inc. filed patent infringement lawsuits against BGP Pharma ULC d.b.a Viatris Canada ("Viatris Canada") in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept biosimilar would directly or indirectly infringe one or more claims of the Company's Canadian Patent Nos. 2,654,510 (the "'510 Patent") and 3,007,276 (the "'276 Patent") (in the lawsuit filed on June 15, 2022); the Company's Canadian Patent No. 2,965,495 (the "'495 Patent") (in the lawsuit filed on July 15, 2022); the Company's Canadian Patent No. 2,906,768 (the "'768 Patent") (in the lawsuit filed on August 30, 2022, which has been joined with the lawsuit filed on July 15, 2022); and the Company's Canadian Patent No. 3,129,193 (the "'193 Patent") (in the lawsuit filed on October 4, 2022). A trial for the lawsuit concerning the '510 Patent and the '276 Patent (the "Viatris Canada 510/276 Lawsuit") has been scheduled for March 2024; a trial for the lawsuit concerning the '193 Patent has been scheduled for May 2024; and a trial for the lawsuit concerning the '495 Patent and the '768 Patent has been scheduled for November/December 2024. The filing of the Viatris Canada 510/276 Lawsuit resulted in a statutory 24-month stay of regulatory approval of Viatris Canada's aflibercept biosimilar in Canada unless the lawsuit is resolved earlier. On March 27, 2023, in light of the transfer of Viatris Canada's New Drug Submission ("NDS") of its aflibercept biosimilar to Biosimilar Collaborations Ireland Limited ("BCIL"), the Company filed a motion in the Federal Court of Canada seeking termination of the Viatris Canada 510/276 Lawsuit. On June 5, 2023, BCIL was added as a defendant in the Viatris Canada 510/276 Lawsuit.

On March 23, 2023 and June 14, 2023, the Company and Bayer Inc. filed patent infringement lawsuits against BCIL in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept biosimilar would

directly or indirectly infringe one or more claims of the Company's '510 and '276 Patents. The June 14, 2023 lawsuit was filed after BCIL served Bayer Inc. with a statutory notification in relation to the NDS on May 23, 2023.

On May 9, 2023, Amgen Canada Inc. ("Amgen Canada") filed invalidation proceedings against the Company in the Federal Court of Canada seeking revocation of the '510 Patent and the '276 Patent.

South Korea

On October 31, 2022 and December 13, 2022, Samsung Bioepis Co., Ltd. initiated invalidation proceedings before the Intellectual Property Trial and Appeal Board of the Korean Intellectual Property Office against the Company's Korean Patent Nos. 1131429 and 1406811, respectively, seeking revocation of each of such patents in its entirety.

On January 16, 2023, the Company filed patent infringement lawsuits against Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd. before the Seoul Central District Court seeking a declaration that the making, constructing, using, or selling of an aflibercept biosimilar would infringe one or more claims of the Company's Korean Patent No. 659477 (the "'477 Patent"). On July 20, 2023, the Company filed a preliminary injunction petition against Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd. before the Seoul Central District Court seeking a court order enjoining the manufacture, use, and assignment of an aflibercept biosimilar that infringes one or more claims of the '477 Patent.

On March 2, 2023, the Company filed an affirmative scope confirmation action against Samsung Bioepis Co., Ltd. before the Intellectual Property Tribunal and Appeal Board of the Korean Intellectual Property Office seeking a ruling that Samsung Bioepis's aflibercept biosimilar is covered by the claims of the '477 Patent. On March 7, 2023, the action was designated for expedited proceedings.

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 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 Novartis's U.S. Patent No. 9,220,631 (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 November 7, 2022, the Company and Novartis entered into a stipulation staying the lawsuit in light of the decision in the IPR proceeding discussed below.

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 October 26, 2021, the USPTO issued a decision instituting the IPR proceeding. An oral hearing was held on July 21, 2022. On October 25, 2022, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a final written decision invalidating all claims of the '631 Patent. On December 23, 2022, Novartis filed a notice of appeal of the PTAB's decision to the Federal Circuit.

On July 17, 2020, the Company filed an antitrust lawsuit against Novartis and Vetter Pharma International Gmbh ("Vetter") in the United States District Court for the Southern District of New York seeking a declaration that the '631 Patent is unenforceable and a judgment that the defendants' conduct violates Sections 1 and 2 of the Sherman Antitrust Act of 1890, as amended (the "Sherman Antitrust Act"). The Company is also seeking injunctive relief and treble damages. On September 4, 2020, Novartis filed, and Vetter moved to join, a motion to dismiss the complaint, to transfer the lawsuit to the Northern District of New York, or to stay the suit; and on October 19, 2020, Novartis filed, and Vetter moved to join, a second motion to dismiss the complaint on different grounds. On January 25, 2021, the Company filed an amended complaint seeking a judgment that Novartis's conduct violates Section 2 of the Sherman Antitrust Act based on additional grounds, as well as a judgment of tortious interference with contract. On February 22, 2021, Novartis filed, and Vetter moved to join, a motion to dismiss the amended complaint. On September 21, 2021, the court granted Novartis and Vetter's motion to transfer this lawsuit to the Northern District of New York. As a result, this lawsuit was transferred to the same judge that had been assigned to the patent infringement lawsuit discussed above. On November 5, 2021, the Company filed a motion to stay these proceedings in light of the pending IPR proceeding discussed above. On January 31, 2022, the court denied the Company's motion to stay these proceedings and granted Novartis and Vetter's motion to dismiss the amended complaint. On June 10, 2022, the Company filed an appeal of the District Court's decision to dismiss the amended complaint with the U.S. Court of Appeals for the Second Circuit.

Proceedings Relating to REGEN-COV (casirivimab and imdevimab)

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit (as amended on April 8, 2021 and December 12, 2022) 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. On December 28, 2022, the U.S. Attorney's Office for the District of Massachusetts filed a motion for partial summary judgment. On January 31, 2023, the Company filed a motion for summary judgment. An oral hearing on the parties' respective motions for summary judgment was held on July 21, 2023.

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. On July 25, 2023, the court in part granted and in part denied the Company's motion to dismiss.

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 the Centers for Medicare & Medicaid Services. The CID covers the period from January 2011 through June 2021. The Company is cooperating with this investigation.

California Department of Insurance Subpoena

In September 2022, the Company received a subpoena from the Insurance Commissioner for the State of California pursuant to the California Insurance Code. The subpoena seeks information relating to the marketing, sale, and distribution of EYLEA, including (i) discounts, rebates, credit card fees, and inventory management systems; (ii) Regeneron's relationships with distributors; (iii) price reporting; (iv) speaker programs; and (v) patient support programs. The subpoena covers the period from January 1, 2014 through August 1, 2021. The Company is cooperating with this investigation.

Proceedings Initiated by Other Payors Relating to Patient Assistance Organization Support

The Company is party to several lawsuits relating to the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. These lawsuits were filed by UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "UHC") and Humana Inc. ("Humana") in the United States District Court for the Southern District of New York on December 17, 2020 and July 22, 2021, respectively; and by Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively, "BCBS"), Medical Mutual of Ohio ("MMO"), Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey ("Horizon"), and Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund ("Local 464A") in the U.S. District Court for the District of Massachusetts on December 20, 2021, February 23, 2022, April 4, 2022, and June 17, 2022, respectively. These lawsuits allege causes of action under state law and the federal Racketeer Influenced and Corrupt Organizations Act and seek monetary damages and equitable relief. The MMO and Local 464A lawsuits are putative class action lawsuits. On December 29, 2021, the lawsuits filed by UHC and Humana were stayed

by the United States District Court for the Southern District of New York pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. On September 27, 2022, the lawsuits filed by BCBS, MMO, and Horizon were stayed by the U.S. District Court for the District of Massachusetts pending resolution of the proceedings before the same court discussed under "Department of Justice Matters" above; and, in light of these stays, the parties to the Local 464A action have also agreed to stay that matter.

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 plaintiff moved to remand the case to the New York Supreme Court. Also on September 23, 2021, the individual defendants moved to dismiss the complaint in its entirety. On December 19, 2022, the U.S. District Court for the Southern District of New York denied the plaintiff's motion to remand the case and granted a motion to stay the case pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. As a result of the stay, the court also terminated the Company's motion to dismiss the complaint without prejudice. The Company can therefore renew the motion to dismiss upon conclusion of the stay.

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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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), aflibercept 8 mg, pozelimab, odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, 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 and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business; 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 described further in Note 11 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 11 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 advance as an integrated, multi-product biotechnology company that provides patients and medical professionals with important medicines for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	2023	2022	2023	2022
Revenues	$ 3,158.1	$ 2,857.2	$ 6,320.2	$ 5,822.3
Net income	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Net income per share - diluted	$ 8.50	$ 7.47	$ 15.68	$ 16.07

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

Products

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

		Territory			
Product	**Disease**	**U.S.**	**EU**	**Japan**	**Other[e]**
EYLEA (aflibercept) Injection[a]	Neovascular age-related macular degeneration ("wet AMD")	✔	✔	✔	✔
	Diabetic macular edema ("DME")	✔	✔	✔	✔
	Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	✔	✔	✔	✔
	Myopic choroidal neovascularization ("mCNV")		✔	✔	✔
	Diabetic retinopathy ("DR")	✔			
	Neovascular glaucoma ("NVG")			✔	
	Retinopathy of prematurity ("ROP")	✔	✔	✔	✔
Dupixent (dupilumab) Injection[b]	Atopic dermatitis (in adults and adolescents)	✔	✔	✔	✔
	Atopic dermatitis (in pediatrics 6–11 years of age)	✔	✔		✔
	Atopic dermatitis (in pediatrics 6 months–5 years of age)	✔	✔		✔
	Asthma (in adults and adolescents)	✔	✔	✔	✔
	Asthma (in pediatrics 6–11 years of age)	✔	✔		✔
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔	✔

Product *(continued)*	Disease	Territory			
		U.S.	EU	Japan	Other[e]
Dupixent (dupilumab) Injection[b] *(continued)*	Eosinophilic esophagitis ("EoE") (in adults and adolescents)	✔	✔		✔
	Prurigo nodularis	✔	✔	✔	✔
Libtayo (cemiplimab) Injection[c]	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	✔	✔		✔
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	✔	✔		✔
	Metastatic or locally advanced basal cell carcinoma ("BCC")	✔	✔		✔
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔		✔
	Metastatic or recurrent second-line cervical cancer		✔	✔	✔
Praluent (alirocumab) Injection[d]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✔	✔		✔
	Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔		✔
	Homozygous familial hypercholesterolemia ("HoFH")	✔			
REGEN-COV®[f]	COVID-19		✔	✔	✔
Kevzara (sarilumab) Solution for Subcutaneous Injection[b]	Rheumatoid arthritis ("RA")	✔	✔	✔	✔
	Polymyalgia rheumatica ("PMR")	✔			
Evkeeza (evinacumab) Injection[g]	HoFH (in adults and adolescents)	✔	✔		✔
	HoFH (in pediatrics 5–11 years of age)	✔			
Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn) Injection	Infection caused by *Zaire ebolavirus*	✔			
ARCALYST® (rilonacept) Injection for Subcutaneous Use[h]	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	✔			
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults and pediatrics)	✔			
	Recurrent pericarditis (in adults and adolescents)	✔			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[i]	Metastatic colorectal cancer ("mCRC")	✔	✔	✔	✔

Note: Refer to table below (net product sales of Regeneron-discovered products) 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 generally approved for use in adults in the above-referenced diseases.

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

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

[d] The Company is solely responsible for the development and commercialization of Praluent in the United States, and Sanofi is solely responsible for the development and commercialization of Praluent outside of the United States.

[e] A checkmark in this column indicates that the product has received marketing approval in at least one country outside of the United States, European Union ("EU"), or Japan.

[f] Known as REGEN-COV in the United States and Ronapreve™ in other countries.

[g] The Company is solely responsible for the development and commercialization of Evkeeza in the United States and Ultragenyx is responsible for the development and commercialization of Evkeeza outside of the United States.

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

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

Net product sales of Regeneron-discovered products consist of the following:

	Three Months Ended June 30,						
	2023			2022			% Change
(In millions)	U.S.	ROW[g]	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 1,500.1	$ 886.3	$ 2,386.4	$ 1,621.2	$ 869.8	$ 2,491.0	(4 %)
Dupixent[b]	$ 2,105.2	$ 684.2	$ 2,789.4	$ 1,582.1	$ 509.7	$ 2,091.8	33 %
Libtayo[c]	$ 130.2	$ 79.8	$ 210.0	$ 90.9	$ 50.4	$ 141.3	49 %
Praluent[d]	$ 40.5	$ 99.8	$ 140.3	$ 31.2	$ 77.7	$ 108.9	29 %
REGEN-COV[e]	$ —	$ —	$ —	$ —	$ 22.8	$ 22.8	(100 %)
Kevzara[b]	$ 56.9	$ 42.6	$ 99.5	$ 43.0	$ 39.3	$ 82.3	21 %
Other products[f]	$ 22.5	$ 16.9	$ 39.4	$ 12.1	$ 19.0	$ 31.1	27 %

	Six Months Ended June 30,						
	2023			2022			% Change
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA[a]	$ 2,933.9	$ 1,733.4	$ 4,667.3	$ 3,138.8	$ 1,738.3	$ 4,877.1	(4 %)
Dupixent[b]	$ 4,003.3	$ 1,271.1	$ 5,274.4	$ 2,907.7	$ 994.5	$ 3,902.2	35 %
Libtayo[c]	$ 239.9	$ 152.7	$ 392.6	$ 169.8	$ 96.2	$ 266.0	48 %
Praluent[d]	$ 80.7	$ 205.5	$ 286.2	$ 64.8	$ 155.5	$ 220.3	30 %
REGEN-COV[e]	$ —	$ 613.2	$ 613.2	$ —	$ 658.4	$ 658.4	(7 %)
Kevzara[b]	$ 96.1	$ 81.9	$ 178.0	$ 100.0	$ 88.7	$ 188.7	(6 %)
Other products[f]	$ 40.6	$ 33.4	$ 74.0	$ 22.0	$ 39.4	$ 61.4	21 %

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

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

[c] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Refer to "Collaboration, License, and Other Agreements" section below for further details. Included in this line item for the six months ended June 30, 2023 is $6 million of first quarter 2023 net product sales recorded by Sanofi in connection with sales in certain markets outside the United States (Sanofi recorded net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 had been sold through to the end customers).

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

[e] Regeneron records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States. The parties share gross profits from global sales of REGEN-COV and Ronapreve 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. Not included in this line item are net product sales of ARCALYST, which are recorded by Kiniksa; net product sales of ARCALYST were $43 million for the first quarter of 2023.

[g] Rest of world ("ROW")

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]	2023 Events to Date	Select Upcoming Milestones
Ophthalmology						
EYLEA (aflibercept)[a]					–Approved by U.S. Food and Drug Administration ("FDA") for ROP	
Aflibercept 8 mg[a]			–Wet AMD –DME –RVO	–Wet AMD and DME (U.S., EU, and Japan) –DR (U.S.)	–FDA issued Complete Response Letter ("CRL") for Biologics License Application ("BLA") for wet AMD, DME, and DR due to unresolved observations resulting from an inspection at third-party contract manufacturer –Resubmitted BLA for wet AMD, DME, and DR –Reported positive two-year data from Phase 3 study in DME	–FDA decision on BLA for wet AMD, DME, and DR –European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") decision on regulatory submissions for wet AMD and DME (fourth quarter 2023/first half 2024) –Report two-year data from Phase 3 study in wet AMD (third quarter 2023)
Immunology & Inflammation						
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*		–Ulcerative colitis –Eosinophilic gastroenteritis (Phase 2/3)	–EoE in pediatrics[c] –Chronic obstructive pulmonary disease ("COPD")[d] –Bullous pemphigoid[c] –Chronic spontaneous urticaria ("CSU") –Chronic pruritus of unknown origin	–Atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) (Japan) –CSU in adults and adolescents (U.S. and Japan)	–Approved by EC for atopic dermatitis in pediatrics (6 months–5 years of age) –Approved by EC for EoE in adults and adolescents –Approved by MHLW for prurigo nodularis –Reported that Phase 3 trial in COPD with evidence of type 2 inflammation met its primary and all key secondary endpoints; presented at 2023 American Thoracic Society International Conference and published in *New England Journal of Medicine*	–MHLW decision on regulatory submission for atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) (second half 2023) –Supplemental BLA ("sBLA") filing acceptance and submission of regulatory application in the EU for EoE in pediatrics (second half 2023) –Report results from replicate Phase 3 trial in COPD (mid-2024)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2023 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*					–Phase 3 trial in chronic cold induced urticaria did not meet its required efficacy endpoints –Discontinued further clinical development in allergic fungal rhinosinusitis and chronic rhinosinusitis without nasal polyposis	–FDA decision on sBLA (target action date of October 22, 2023) and MHLW decision on regulatory submission (first half 2024) for CSU in adults and adolescents
Kevzara (sarilumab)[b] *Antibody to IL-6R*		–Polyarticular-course juvenile idiopathic arthritis ("pcJIA") (pivotal study) –Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)			–Approved by FDA for PMR	–Submit sBLA and regulatory application in the EU for pcJIA (second half 2023)
Itepekimab[b] **(REGN3500)** *Antibody to IL-33*			–COPD[e]		–Phase 3 COPD program passed interim futility analysis conducted by Independent Data Monitoring Committee ("IDMC")	–Report results from Phase 3 study in COPD (2025)
REGN5713-5714-5715 *Multi-antibody therapy to Bet v 1*			–Birch allergy			
Solid Organ Oncology						
Libtayo (cemiplimab)[g] *Antibody to PD-1*		–Neoadjuvant CSCC –Second-line cervical cancer, ISA101b combination –First-line NSCLC, BNT116[s] combination	–Adjuvant CSCC		–Approved by EC for first-line NSCLC, chemotherapy combination	

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2023 Events to Date	Select Upcoming Milestones
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–Solid tumors and advanced hematologic malignancies	–First-line advanced NSCLC (Phase 2/3) (pivotal study)	–First-line metastatic melanoma –First-line adjuvant melanoma		–Presented positive data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting	–Initiate potentially pivotal Phase 2 study (in combination with Libtayo) in perioperative melanoma (second half 2023) –Initiate Phase 2 study (in combination with Libtayo) in perioperative NSCLC (second half 2023)
Vidutolimod *Immune activator targeting TLR9*		–Solid tumors				
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*		–Platinum-resistant ovarian cancer				–Report results from Phase 1/2 study (in combination with Libtayo) in platinum-resistant ovarian cancer (second half 2023)
REGN5668[n] *Bispecific antibody targeting MUC16 and CD28*	–Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				–Discontinued enrollment in cohorts in combination with full-dose Libtayo	–Report additional results from Phase 1/2 study (in combination with Libtayo) in prostate cancer (2024)
REGN4336 *Bispecific antibody targeting PSMA and CD3*	–Prostate cancer					
REGN5093 *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC					
REGN5093-M114 *Bispecific antibody-drug conjugate targeting two distinct MET epitopes*	–MET overexpressing advanced cancer					
REGN6569 *Antibody to GITR*	–Solid tumors					
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2023 Events to Date	Select Upcoming Milestones
Hematology						
Odronextamab[i] (REGN1979) *Bispecific antibody targeting CD20 and CD3*	–Certain B-cell malignancies[c][m]	–B-cell non-Hodgkin lymphoma ("B-NHL")[m] (pivotal study)		– Relapsed/refractory FL and DLBCL (EU)		–Initiate Phase 3 studies in follicular lymphoma ("FL") and diffuse large B-cell lymphoma ("DLBCL"), including earlier lines of therapy (second half 2023) –BLA filing acceptance for relapsed/refractory FL and DLBCL (second half 2023)
REGN5837[p] *Bispecific antibody targeting CD22 and CD28*	–B-NHL					
Linvoseltamab[f] (REGN5458) *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma[c][e]	–Multiple myeloma (pivotal study)[c][e]			–Presented updated positive data from pivotal trial in multiple myeloma at ASCO Annual Meeting	–Initiate Phase 3 study in multiple myeloma, including earlier lines of therapy (third quarter 2023) –Present data from pivotal study in multiple myeloma (fourth quarter 2023) –Submit BLA for relapsed/refractory multiple myeloma (fourth quarter 2023)
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 ("CHAPLE"), monotherapy[c][e] (potentially pivotal study)	–Myasthenia gravis, cemdisiran combination[t] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][t]	–CHAPLE, monotherapy (adults and children aged 1 year and older) (U.S.)		–FDA decision on BLA for pozelimab monotherapy for CHAPLE (target action date of August 20, 2023)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2023 Events to Date	Select Upcoming Milestones
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia					
NTLA-2001[j] *TTR gene knockout using CRISPR/Cas9*	–Transthyretin ("ATTR") amyloidosis[c]					
REGN9933 *Antibody to Factor XI*		–Thrombosis				
REGN7508 *Antibody to Factor XI*	–Thrombosis					
REGN7999 *Antibody to TMPRSS6*	–Transfusion dependent iron overload					
General Medicine						
"Next Generation" Covid Antibodies *Antibodies to SARS-CoV-2 variants*						–Initiate clinical development of "next generation" antibody (second half 2023)
Praluent (alirocumab) *Antibody to PCSK9*			–HeFH in pediatrics and adolescents	–HeFH in pediatrics and adolescents (8–17 years of age) (U.S.)		–FDA decision on sBLA for HeFH in pediatrics and adolescents (target action date of March 10, 2024)
Evkeeza (evinacumab)[f][i] *Antibody to ANGPTL3*				–HoFH in pediatrics (5–11 years of age) (EU) –HoFH in adults, adolescents, and pediatrics (5–11 years of age) (Japan)	–Approved by FDA for HoFH in pediatrics (5–11 years of age)	
Garetosmab[f] **(REGN2477)** *Antibody to Activin A*			–Fibrodysplasia ossificans progressiva ("FOP")[c][d][e]			
Mibavademab[f] **(REGN4461)** *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[e] –Partial lipodystrophy				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2023 Events to Date	Select Upcoming Milestones
REGN5381/REGN9035 *Agonist antibody to NPR1/reversal agent to REGN5381*	–Reversal agent in healthy volunteers	–Heart failure			–Paused enrollment in Phase 1 and Phase 2 studies pending protocol amendment	–Report initial data in healthy volunteers (second half 2023)
ALN-HSD[o] *RNAi therapeutic targeting HSD17B13*	–Nonalcoholic steatohepatitis ("NASH")	–NASH				
ALN-PNP[k] *RNAi therapeutic targeting PNPLA3*	–NASH					
ALN-APP[k] *RNAi therapeutic targeting APP*	–Early-onset Alzheimer's disease[q]				–Reported positive interim data from single dose part of Phase 1 trial in early-onset Alzheimer's disease	
DB-OTO[r] *AAV-based gene therapy*	–Hearing loss in pediatrics[c] (Phase 1/2)					

Note: 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.

[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 Zai Lab in mainland China, Hong Kong, Taiwan, and Macau

[j] In collaboration with Intellia

[k] In collaboration with Alnylam

[l] In collaboration with Ultragenyx outside the United States

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

[n] Studied in combination with ubamatamab

[o] Alnylam elected to opt-out of the product candidate. Under the terms of our agreement, Alnylam is entitled to receive royalties on sales of the product, if any.

[p] Studied in combination with odronextamab

[q] Part B of the study (multi-dose regimen) has been placed on partial clinical hold in the U.S. by the FDA due to findings observed in prior non-clinical chronic toxicology studies.

[r] In collaboration with Decibel

[s] BioNTech's BNT116 is an mRNA cancer vaccine

[t] Under the terms of our license agreement for the combination consisting of cemdisiran and pozelimab, Alnylam is entitled to receive royalties on sales of the combination (if any), as well as sales milestones.

Additional Information - Clinical Development Programs

Aflibercept 8 mg

In June 2023, the FDA issued a CRL for the BLA for aflibercept 8 mg for the treatment of patients with wet AMD, DME, and DR. The CRL was issued solely due to unresolved observations resulting from a May 2023 FDA inspection at a third-party contract manufacturing organization, Catalent, that the Company engaged to complete vial-filling for aflibercept 8 mg. The CRL did not identify any issues with the aflibercept 8 mg clinical efficacy or safety profile, trial design, labeling, or drug substance manufacturing, and no additional clinical data or trials have been requested.

The May 2023 inspection was conducted as part of the FDA review process for both the aflibercept 8 mg BLA and the pending BLA for pozelimab, as both product candidates are filled on the same manufacturing line in Catalent's facility. Catalent has already provided certain manufacturing data and other information to the FDA, and expects to be able to provide the remaining required data and information in August 2023. The FDA has stated that its review of the Catalent manufacturing data in the context of the pozelimab BLA will support actions for both the pozelimab BLA and the aflibercept 8 mg BLA resubmission. The FDA has also informed the Company that it will strive to complete its review prior to the target action date for the pozelimab BLA (August 20, 2023), and, if unable to do so, may extend its review by up to 3 months while still continuing to prioritize the review. Based on this information, the Company anticipates the FDA will act on the pozelimab and aflibercept 8 mg BLAs before the end of the third quarter 2023.

In June 2023, the Company announced top-line, two-year (96 weeks) data for aflibercept 8 mg from the pivotal PHOTON trial in patients with DME. In addition, in July 2023, the results were presented at the American Society of Retina Specialists annual meeting. During the trial, aflibercept 8 mg patients were initially randomized to either 12- or 16-week dosing intervals (after three initial monthly doses) and were able to shorten or extend dosing intervals if pre-specified criteria were met. The longer-term data among aflibercept 8 mg patients who completed the trial demonstrated that the vast majority of patients were able to maintain or further extend these dosing intervals through two years with:

- 89% maintaining ≥12-week dosing intervals through two years, compared to 93% through one year (48 weeks);
- 84% maintaining ≥16-week dosing intervals through two years, compared to 89% maintaining a 16-week dosing interval through one year; and
- 44% meeting the criteria for ≥20-week dosing intervals by week 96, including 17% and 27% who were eligible for 20- and 24-week dosing intervals, respectively.

The visual gains for aflibercept 8 mg remained consistent with the first year of the trial. In PHOTON, the safety of aflibercept 8 mg also continued to be similar to EYLEA through two years and remained consistent with the known safety profile of EYLEA from previous clinical trials for DME.

In May 2023, Bayer announced that it initiated a Phase 3 study to evaluate the efficacy and safety of aflibercept 8 mg at extended dosing intervals compared to the standard of care, EYLEA, in RVO to support potential future regulatory submissions outside the United States.

Dupixent

In March 2023, the Company and Sanofi announced that the primary and all key secondary endpoints were met in the BOREAS trial (the first of two Phase 3 trials) in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled COPD and evidence of type 2 inflammation. In this trial, patients receiving Dupixent experienced a 30% reduction in moderate or severe acute COPD exacerbations (rapid and acute worsening of respiratory symptoms) over 52 weeks, while also demonstrating significant improvements in lung function, quality of life, and COPD respiratory symptoms. The safety results were generally consistent with the known safety profile of Dupixent in its approved indications.

REGN5678

In the ongoing Phase 1 study of REGN5678, the Company has observed antitumor activity in combination with Libtayo as well as with REGN5678 monotherapy. Due to the emerging safety profile, including two immune-mediated Grade 5 adverse events (death), one of which occurred in July 2023, the Company has discontinued enrollment of patients receiving the combination of REGN5678 and full-dose Libtayo. The Company plans to explore REGN5678 combinations with lower doses of Libtayo. The Company also plans to enroll patients in a REGN5678 monotherapy cohort, as well as in combination with other immunotherapy modalities.

ALN-APP

In April 2023, the Company and Alnylam Pharmaceuticals, Inc. reported positive interim data from the single dose portion of the Phase 1 study of ALN-APP in early-onset Alzheimer’s disease. Alnylam announced incremental data at the 2023

Alzheimer's Association International Conference ("AAIC") in July 2023. The Phase 1 trial is ongoing, with safety and efficacy trends to be further evaluated as more data are gathered. As described in the "Collaboration, License, and Other Agreements - Alnylam" section below, Alnylam is eligible to receive a $100.0 million development milestone from us upon achieving specified clinical proof-of-principle criteria for a central nervous system ("CNS") program (including the ALN-APP program).

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 (the "LCA"), Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on our share of collaboration profits from commercialization of collaboration products; as of December 31, 2022, the total amount of our contingent reimbursement obligation to Sanofi in connection with such development expenses was approximately $2.9 billion. Under the terms of the LCA, we were required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs. On July 1, 2022, an amendment to the LCA became effective, pursuant to which the percentage of Regeneron's share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-commercialize such products on a country-by-country basis. We co-commercialize Dupixent in the United States and in certain countries outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi equally share profits and losses from sales within the United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and share losses outside the United States at 55% (Sanofi)/45% (us). In each of 2020 and 2021, we 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. In 2022, we earned two additional $50.0 million sales-based milestones, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $2.0 billion and $2.5 billion, respectively, on a rolling twelve-month basis. We are entitled to receive the final sales milestone payment of $50.0 million when such sales outside the United States exceed $3.0 billion on a rolling twelve-month basis.

Immuno-Oncology

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

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA"). In connection with the A&R IO LCA, in 2022, the Company made a $900.0 million up-front payment to Sanofi, as well as a $100.0 million regulatory milestone payment. In addition, Sanofi earned a $65.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2022 and is eligible to receive an additional $35.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2023. We also pay Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. The parties have also entered into a transition services agreement, a transitional distribution agreement, and a manufacturing services agreement, pursuant to which, during certain transitional periods, Sanofi will perform for Regeneron certain transition, distribution, and manufacturing services, respectively.

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

Bayer

We and Bayer are parties to a license and collaboration agreement for the global development and commercialization of EYLEA and aflibercept 8 mg outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits and losses from such 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.

Alnylam

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, in addition to a select number of targets expressed in the liver. In connection with the collaboration, the Company made an up-front payment of $400.0 million to Alnylam, and also purchased shares of Alnylam common stock for $400.0 million. For each program, we provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive two $100.0 million clinical proof-of-principle milestones for each of the eye and CNS programs (an aggregate of $200.0 million in development milestones).

Under the terms of the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a co-development/co-commercialization collaboration agreement ("Co-Co Collaboration Agreement") (under which the parties are advancing ALN-APP and ALN-PNP, which are currently in clinical development) or a license agreement ("License Agreement") structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee of $300.0 million.

For CNS programs and liver programs, under a Co-Co Collaboration Agreement, the party designated as the lead party will lead development and commercialization of the program and the parties will split profits and share costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions. Alnylam is the lead party for ALN-APP, and we are the lead party for ALN-PNP.

In addition, during 2019, the parties entered a License Agreement for a combination consisting of cemdisiran (a small interfering RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam) and pozelimab, with us as the licensee. Under the License Agreement, we as the licensee are responsible for our own costs and expenses.

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 to Intellia.

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, as well as on whether we are able to obtain regulatory approval for aflibercept 8 mg and are successful in commercializing it. 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. In addition, our research and development activities and related costs 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 from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators; and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

Corporate Information

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

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

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

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

Results of Operations

Three and Six Months Ended June 30, 2023 and 2022

Net Income

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2023**	**2022**	**2023**	**2022**
Revenues	$ 3,158.1	$ 2,857.2	$ 6,320.2	$ 5,822.3
Operating expenses	2,141.6	1,747.3	4,357.0	3,453.9
Income from operations	1,016.5	1,109.9	1,963.2	2,368.4
Other income (expense)	66.4	(146.7)	(22.3)	(344.1)
Income before income taxes	1,082.9	963.2	1,940.9	2,024.3
Income tax expense	114.5	111.1	154.7	198.7
Net income	$ 968.4	$ 852.1	$ 1,786.2	$ 1,825.6
Net income per share - diluted	$ 8.50	$ 7.47	$ 15.68	$ 16.07

Revenues

(In millions)	Three Months Ended June 30, 2023	2022	$ Change	Six Months Ended June 30, 2023	2022	$ Change
Net product sales:						
EYLEA - U.S.	$ 1,500.1	$ 1,621.2	$ (121.1)	$ 2,933.9	$ 3,138.8	$ (204.9)
Libtayo - U.S.	130.2	90.9	39.3	239.9	169.8	70.1
Libtayo - ROW	79.8	—	*	147.0	—	*
Praluent - U.S.	40.5	31.2	9.3	80.7	64.8	15.9
Evkeeza - U.S.	19.3	11.1	8.2	34.2	19.6	14.6
Inmazeb - U.S.	2.2	—	2.2	4.4	—	4.4
Total net product sales	$ 1,772.1	$ 1,754.4	$ 17.7	$ 3,440.1	$ 3,393.0	$ 47.1
Collaboration revenue:						
Sanofi	$ 943.7	$ 677.5	$ 266.2	$ 1,742.1	$ 1,308.4	$ 433.7
Bayer	376.7	357.5	19.2	733.6	742.8	(9.2)
Roche	(3.8)	8.2	(12.0)	218.4	224.5	(6.1)
Other	0.1	0.4	(0.3)	0.7	0.4	0.3
Other revenue	69.3	59.2	10.1	185.3	153.2	32.1
Total revenues	$ 3,158.1	$ 2,857.2	$ 300.9	$ 6,320.2	$ 5,822.3	$ 497.9

* Not meaningful

Net Product Sales

Net product sales of EYLEA in the United States decreased for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily due to a lower net selling price resulting from increased competition.

As described in "Collaboration, License, and Other Agreements - Sanofi - *Immuno-Oncology*" above, effective July 1, 2022, the Company became solely responsible for the research, development, and commercialization of Libtayo worldwide and began recording net product sales of Libtayo outside the United States.

Collaboration Revenue

Sanofi Collaboration Revenue

(In millions)	Three Months Ended June 30, 2023	2022	Six Months Ended June 30, 2023	2022
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	$ 751.1	$ 496.6	$ 1,387.6	$ 911.9
Sales-based milestones earned	—	—	—	50.0
Reimbursement for manufacturing of commercial supplies[(a)]	192.6	145.5	354.5	306.3
Other	—	28.9	—	28.9
Total Antibody	943.7	671.0	1,742.1	1,297.1
Total Immuno-oncology	—	6.5	—	11.3
Total Sanofi collaboration revenue	$ 943.7	$ 677.5	$ 1,742.1	$ 1,308.4

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

Global net product sales of Dupixent and Kevzara are recorded by Sanofi in connection with the Antibody Collaboration. As described above under "Collaboration, License, and Other Agreements - Sanofi - *Antibody*", on July 1, 2022, an amendment to the LCA became effective, pursuant to which the percentage of Regeneron's share of profits in any calendar quarter used to reimburse Sanofi for development costs which were funded by Sanofi increased from 10% to 20%. The increase in our share of profits in connection with commercialization of antibodies during the three and six months ended June 30, 2023, compared to the same periods in 2022, was driven by higher profits associated with Dupixent sales, partly offset by the impact of the amendment to the LCA.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2023**	**2022**	**2023**	**2022**
Dupixent and Kevzara net product sales	$ 2,888.9	$ 2,174.1	$ 5,452.4	$ 4,090.9
Regeneron's share of collaboration profits	$ 857.8	$ 551.7	$ 1,569.2	$ 1,013.9
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(106.7)	(55.1)	(181.6)	(102.0)
Regeneron's share of profits in connection with commercialization of antibodies	$ 751.1	$ 496.6	$ 1,387.6	$ 911.9
Regeneron's share of collaboration profits as a percentage of Dupixent and Kevzara net product sales	26%	23%	25%	22%

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

As the A&R IO LCA became effective July 1, 2022, the three months ended June 30, 2022 was the last period in which Sanofi collaboration revenue was recognized in connection with the IO Collaboration.

Bayer Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2023**	**2022**	**2023**	**2022**
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 349.5	$ 339.7	$ 681.1	$ 678.1
Reimbursement for manufacturing of ex-U.S. commercial supplies[(a)]	27.2	17.8	52.5	42.8
One-time payment in connection with change in Japan arrangement[(b)]	—	—	—	21.9
Total Bayer collaboration revenue	$ 376.7	$ 357.5	$ 733.6	$ 742.8

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

[(b)] 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.

Bayer records net product sales of EYLEA outside the United States. Regeneron's share of profits in connection with commercialization of EYLEA outside the United States is summarized below:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2023**	**2022**	**2023**	**2022**
EYLEA net product sales outside the United States	$ 886.3	$ 869.8	$ 1,733.4	$ 1,738.3
Regeneron's share of collaboration profit from sales outside the United States	$ 363.5	$ 354.5	$ 710.4	$ 707.9
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(14.0)	(14.8)	(29.3)	(29.8)
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 349.5	$ 339.7	$ 681.1	$ 678.1
Regeneron's share of profits as a percentage of EYLEA net product sales outside the United States	39%	39%	39%	39%

Roche Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2023**	**2022**	**2023**	**2022**
Global gross profit payment from Roche in connection with sales of Ronapreve	$ —	$ 8.2	$ 222.2	$ 224.5
Other	(3.8)	—	(3.8)	—
Total Roche collaboration revenue	$ (3.8)	$ 8.2	$ 218.4	$ 224.5

Roche distributes and records net product sales of Ronapreve outside the United States, and the parties share gross profits from worldwide sales.

Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
(In millions, except headcount data)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Research and development[(a)]	$ 1,085.3	$ 794.3	$ 291.0	$ 2,186.5	$ 1,638.1	$ 548.4
Acquired in-process research and development	—	197.0	(197.0)	56.1	225.1	(169.0)
Selling, general, and administrative[(a)]	652.0	476.3	175.7	1,253.1	926.3	326.8
Cost of goods sold	192.4	149.2	43.2	400.8	356.5	44.3
Cost of collaboration and contract manufacturing[(b)]	212.5	147.9	64.6	461.6	345.5	116.1
Other operating (income) expense, net	(0.6)	(17.4)	16.8	(1.1)	(37.6)	36.5
Total operating expenses	$ 2,141.6	$ 1,747.3	$ 394.3	$ 4,357.0	$ 3,453.9	$ 903.1
Average headcount	12,412	10,939	1,473	12,256	10,715	1,541

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

[(b)] Includes costs we incur in connection with producing commercial drug supplies for collaborators and others

Operating expenses included stock-based compensation of $202.0 million and $159.8 million for the three months ended June 30, 2023 and 2022, respectively, and $440.7 million and $326.7 million for the six months ended June 30, 2023 and 2022, respectively. Stock-based compensation expense relates 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 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.

	Three Months Ended June 30,			Six Months Ended June 30,		
(In millions)	**2023**	**2022***	**$ Change**	**2023**	**2022***	**$ Change**
Direct research and development expenses:						
Dupixent (dupilumab)	$ 50.1	$ 40.1	$ 10.0	$ 99.3	$ 72.2	$ 27.1
Aflibercept 8 mg	27.9	13.6	14.3	53.6	33.8	19.8
Linvoseltamab	26.3	11.7	14.6	41.1	17.1	24.0
Libtayo (cemiplimab)	25.4	37.2	(11.8)	58.3	75.8	(17.5)
Odronextamab	19.6	13.9	5.7	41.8	25.3	16.5
Fianlimab	18.1	4.6	13.5	52.9	8.0	44.9
Other product candidates in clinical development and other research programs	153.8	105.0	48.8	296.6	189.6	107.0
Total direct research and development expenses	321.2	226.1	95.1	643.6	421.8	221.8
Indirect research and development expenses:						
Payroll and benefits	362.9	285.5	77.4	761.8	569.3	192.5
Lab supplies and other research and development costs	58.5	47.3	11.2	108.4	85.3	23.1
Occupancy and other operating costs	122.1	122.1	—	244.0	242.4	1.6
Total indirect research and development expenses	543.5	454.9	88.6	1,114.2	897.0	217.2
Clinical manufacturing costs	274.0	196.2	77.8	524.1	467.9	56.2
Reimbursement of research and development expenses by collaborators	(53.4)	(82.9)	29.5	(95.4)	(148.6)	53.2
Total research and development expenses	$ 1,085.3	$ 794.3	$ 291.0	$ 2,186.5	$ 1,638.1	$ 548.4

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

Total research and development expenses increased for the three and six months ended June 30, 2023, compared to the same periods in 2022, partially due to the impact of the amendments to the Sanofi collaboration agreements (which were effective July 1, 2022) described under the "Collaboration, License, and Other Agreements" section above, as (i) Sanofi is no longer reimbursing us for 50% of Libtayo development costs (such reimbursements were previously included in Reimbursement of research and development expenses by collaborators in the table above) and (ii) we recognize our 50% share of research and development expenses in connection with the Sanofi Antibody Collaboration. Clinical manufacturing costs for the three and six months ended June 30, 2023 increased due to manufacturing activity associated with our earlier-stage product candidates.

Research and development expenses included stock-based compensation expense of $109.1 million and $89.7 million for the three months ended June 30, 2023 and 2022, respectively, and $248.6 million and $182.1 million for the six months ended June 30, 2023 and 2022, 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 six months ended June 30, 2023 included a $45.0 million up-front payment in connection with our collaboration agreement with Sonoma Biotherapeutics, Inc. Acquired IPR&D for the three and six months ended June 30, 2022 included a $195.0 million charge related to the Company's acquisition of Checkmate Pharmaceuticals, Inc. Additionally, Acquired IPR&D for the six months ended June 30, 2022 included a $20.0 million opt-in payment in connection with a product candidate under our collaboration agreement with Adicet Bio, Inc.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily due to an increase in commercialization-related expenses and integration costs for Libtayo outside the United States (as effective July 1, 2022, the Company became solely responsible for the commercialization of Libtayo worldwide), higher headcount and headcount-related costs, and higher contributions to an independent not-for-profit patient assistance organization. Selling, general, and administrative expenses included stock-based compensation expense of $73.3 million and $57.5 million for the three months ended June 30, 2023 and 2022, respectively, and $150.1 million and $118.2 million for the six months ended June 30, 2023 and 2022, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily due to the recognition of costs in connection with manufacturing commercial supplies of Dupixent. Cost of collaboration and contract manufacturing for the six months ended June 30, 2023 also increased due to the recognition of costs in connection with manufacturing commercial supplies for Sanofi related to Praluent outside the United States.

Other Operating (Income) Expense

Other operating (income) expense, net, for the three and six months ended June 30, 2022 included recognition of amounts previously deferred in connection with up-front and development milestone payments, as applicable, received in connection with our Sanofi IO, Teva, and Mitsubishi Tanabe Pharma Corporation ("MTPC") collaborative arrangements. As the A&R IO LCA became effective July 1, 2022, the three months ended June 30, 2022 was the last period in which such amounts were recognized in connection with our Sanofi IO Collaboration. In addition, during the three months ended September 30, 2022, the Company discontinued further clinical development of fasinumab, and, as a result, we deemed our obligation to provide development services in connection with the Teva and MTPC collaborative arrangements to be complete.

Other Income (Expense)

Other income (expense) consists of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions)	**2023**	**2022**	**2023**	**2022**
Unrealized (losses) gains on equity securities, net	$ (30.9)	$ (163.7)	$ (195.6)	$ (374.9)
Interest income	118.3	28.2	213.5	46.7
Other	(2.1)	1.9	(3.3)	10.8
Other income (expense), net	85.3	(133.6)	14.6	(317.4)
Interest expense	(18.9)	(13.1)	(36.9)	(26.7)
Total other income (expense)	$ 66.4	$ (146.7)	$ (22.3)	$ (344.1)

Income Taxes

(In millions, except effective tax rate)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Income tax expense	$ 114.5	$ 111.1	$ 154.7	$ 198.7
Effective tax rate	10.6 %	11.5 %	8.0 %	9.8 %

The Company's effective tax rate for the three and six months ended June 30, 2023 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and, to a lesser extent, stock-based compensation and federal tax credits for research activities.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	June 30, 2023	December 31, 2022	$ Change
Financial assets:			
Cash and cash equivalents	$ 1,937.2	$ 3,105.9	$ (1,168.7)
Marketable securities - current	6,990.5	4,636.4	2,354.1
Marketable securities - noncurrent	6,327.2	6,591.8	(264.6)
	$ 15,254.9	$ 14,334.1	$ 920.8
Working capital:			
Current assets	$ 16,923.0	$ 15,884.1	$ 1,038.9
Current liabilities	3,104.4	3,141.3	(36.9)
	$ 13,818.6	$ 12,742.8	$ 1,075.8
Borrowings and finance lease liabilities:			
Long-term debt	$ 1,982.2	$ 1,981.4	$ 0.8
Finance lease liabilities	$ 720.0	$ 720.0	$ —

As of June 30, 2023, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Six Months Ended June 30, 2023 and 2022

(In millions)	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	$ Change
Cash flows provided by operating activities	$ 2,390.0	$ 2,666.1	$ (276.1)
Cash flows used in investing activities	$ (2,622.6)	$ (2,119.2)	$ (503.4)
Cash flows used in financing activities	$ (936.7)	$ (36.4)	$ (900.3)

Cash Flows from Investing Activities

Capital expenditures during the six months ended June 30, 2023 included costs incurred in connection with the expansion of our Tarrytown, New York campus, as well 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). Additionally, capital expenditures for the six months ended June 30, 2023 is net of grant proceeds of $60.0 million primarily related to the expansion of our facilities in New York. We expect to incur capital expenditures of $760 million to $830 million for the full year of 2023 primarily in connection with the continued expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown campus and our Rensselaer manufacturing facility (including the fill/finish facility).

Payments for Libtayo intangible asset of $121.8 million during the six months ended June 30, 2023 were related to contingent consideration in connection with our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide (as described in "Collaboration, License, and Other Agreements - *Sanofi - Immuno-Oncology*" above).

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

Cash Flows from Financing Activities

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $575.9 million during the six months ended June 30, 2023, compared to $828.4 million during the six months ended June 30, 2022. For information related to repurchases of Common Stock, see "*Share Repurchase Programs*" section below.

Share Repurchase Programs

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock. As of June 30, 2023, the Company had repurchased the entire $3.0 billion of its Common Stock it was authorized to repurchase under the program.

In January 2023, 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 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.

As of June 30, 2023, $2.332 billion remained available for share repurchases under the program.

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

	Six Months Ended June 30,	
(In millions)	**2023**	**2022**
Number of shares	1.9	1.2
Total cost of shares	$ 1,416.7	$ 745.5

Critical Accounting Estimates

A summary of critical accounting estimates is 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, 2022 (filed February 6, 2023). There have been no material changes to critical accounting estimates during the six months ended June 30, 2023.

Future Impact of Recently Issued Accounting Standards

As of June 30, 2023, 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, 2022 (filed February 6, 2023). There have been no material changes to our market risks or to our management of such risks as of June 30, 2023.

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) or 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) or 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2023 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 11 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.

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 enacted or 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 established or 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 U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines.
- We face risks from the improper conduct of our employees, agents, contractors, or collaborators, including those relating to potential non-compliance with relevant laws and regulations such as the Foreign Corrupt Practices Act and the U.K. Bribery Act.
- Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials.
- Changes in laws and regulations affecting the healthcare industry could adversely affect our business.
- Tax liabilities and risks associated with our operations outside of the United States could adversely affect our business.
- We face risks related to the personal data we collect, process, and share.

Risks Related to Our Reliance on or Transactions with Third Parties

- If our collaborations with Sanofi or Bayer or other third parties are terminated or breached, our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.
- Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.
- We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions could adversely affect our business, operating results, and financial condition.

Other Risks Related to Our Business 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.
- Public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) have adversely affected and may in the future 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 substantial influence over matters requiring shareholder approval and over our management.

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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 product sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the six months ended June 30, 2023 and 2022, EYLEA net product sales in the United States represented 46% and 54% of our total revenues, respectively. For the six months ended June 30, 2023, EYLEA U.S. net product sales decreased by 7%, compared to the same period in 2022, as discussed in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations." 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, if EYLEA net product sales experience a sustained decline in or outside the United States, 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 stay profitable at the levels we previously achieved or at all, and our business, prospects, operating results, and financial condition may be materially harmed. 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) will expire after May 17, 2024. See "Risks Related to Intellectual Property and Market Exclusivity - *Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products*" below. As a result, we face the risk of lower EYLEA net product sales due to biosimilar competition following such expiration, which may have a material adverse impact on our results of operations. While we are planning to commercialize aflibercept 8 mg, the potential approval of this product candidate has been delayed following issuance by the FDA of a Complete Response Letter ("CRL") concerning the aflibercept 8 mg BLA (as previously reported and further discussed in this report). 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.*" In addition, the degree to which any future net product sales of aflibercept 8 mg (if approved) may offset any potential decrease in EYLEA net product sales, resulting from the factors discussed above or otherwise, is uncertain.

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 may 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):

- 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 enacted or 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 (such as aflibercept 8 mg); 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 and globally, including measures requiring the U.S. government in the future to negotiate the prices of certain drugs and price reporting and other disclosure requirements 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 and REGEN-COV (described further in Note 11 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 11 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, 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 ("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.

Further, there have been several recent U.S. Congressional inquiries and recently approved or 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. Notably, in 2022 the U.S. Congress passed the Inflation Reduction Act ("IRA"), which includes, among other items, provisions regarding the following:

- *Implementation of a Medicare Drug Price Negotiation Program* (the "Medicare Drug Price Negotiation Program"). The Medicare Drug Price Negotiation Program requires the government to set prices for select high-expenditure drugs covered under Medicare Parts B and D. Starting in 2023 and 2026, the government is authorized to select Part D and Part B drugs, respectively, for inclusion in the Medicare Drug Price Negotiation Program, with established prices to go into effect for selected Part D drugs in 2026 and for selected Part B drugs in 2028, in each case absent certain disqualifying events.
- *Medicare Inflation Based Rebates*. The IRA includes measures penalizing manufacturers that raise prices of drugs covered under Medicare Parts B and D at a rate that exceeds the rate of inflation.
- *Medicare Part D Program Redesign*. The IRA implements changes to the Medicare Part D benefits to limit patient out-of-pocket drug costs and shift program liabilities from patients to other stakeholders, including health plans, manufacturers, and the government.

While enacted into law, it is currently unclear how many of the provisions of the IRA (including the Medicare Drug Price Negotiation Program with respect to Part B drugs and biologics) will be implemented and the extent to which the policy changes will ultimately impact reimbursement levels of our marketed products, including those covered under Medicare Part B (such as EYLEA) or our product candidates that may be covered under Medicare Part B (such as aflibercept 8 mg) or Medicare Part D in the future.

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 legislation, 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 many 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. As discussed below under "*If we are unable to establish commercial capabilities outside the United States for Libtayo, Dupixent, or any other 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 will need to manage these and other commercialization-related risks in order for us to successfully develop commercial capabilities outside the United States (including those necessary for our successful commercialization and co-commercialization of Libtayo and Dupixent, respectively).

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 and (if approved) aflibercept 8 mg. EYLEA faces and, if approved, aflibercept 8 mg will face, significant competition in the marketplace. For example, EYLEA competes in one or more of its approved indications with other VEGF inhibitors, including Genentech/Roche's Vabysmo® (faricimab-svoa) and Susvimo® (ranibizumab ocular implant), Novartis and Genentech/Roche's Lucentis® (ranibizumab), and Novartis' Beovu® (brolucizumab), as well as biosimilar versions of Lucentis commercialized in the United States by Biogen Inc. and Coherus BioSciences, Inc. 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. If approved, we expect that aflibercept 8 mg will be entering a highly competitive environment; and our success in potentially commercializing aflibercept 8 mg will depend on a number of factors, including the relative timing of any commercial launch of aflibercept 8 mg as compared to relevant competition, the extent to which we and our collaborators are able to differentiate aflibercept 8 mg from competitive products, and the applicability of any restrictions imposed by payors at the time, such as step therapy.

Dupixent. The market for Dupixent's current and potential future indications is also increasingly competitive. In atopic dermatitis, there are topical and systemic JAK inhibitors and an antibody against IL-13 approved for atopic dermatitis and others are in development. In addition, a number of companies are developing antibodies against IL-4Ra, IL-13Ra1, OX40(L), and/or IL-31R that may compete with Dupixent in atopic dermatitis and other indications (including asthma and/or prurigo nodularis), as applicable. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or thymic stromal lymphopoietin ("TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP and EoE. There are several other potentially competitive products in development that may compete with Dupixent in asthma, as well as potential future indications, including antibodies against the IL-33 ligand or receptor. Dupixent also faces competition from inhaled products in asthma and potential future indications.

Libtayo. 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).

Other marketed products. There is also significant actual and potential future competition for other products marketed or otherwise commercialized by us and/or our collaborators under our collaboration agreements with them. For example, there are several companies that are marketing and/or developing antibodies or other molecules (such as small interfering RNA molecules, or siRNAs) against PCSK9, ANGPTL3 and IL-6 and/or IL-6R, which currently (or, for product candidates in development, may in the future if approved) compete with Praluent, Evkeeza, and Kevzara, respectively.

Product Candidates

Our *VelocImmune*® technology, other antibody generation technologies, and late-stage and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies, including antibody generation technologies and other approaches such as RNAi, chimeric antigen receptor T cell (CAR-T cell), and gene therapy technologies. For example, we are aware of other pharmaceutical and biotechnology companies actively engaged in the

research and development of antibody-based products against targets that are also the targets of our early- and late-stage product candidates. We are also aware of other companies developing or marketing small molecules or other treatments that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our product candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

We rely on our collaborations with Bayer and Sanofi for commercializing some of our marketed products.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA outside the United States. Under the terms of our license and collaboration agreement with Bayer (which is terminable by Bayer at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination), we rely on Bayer (and, in Japan, Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate) for sales, marketing, and distribution of EYLEA (and, if approved, will rely on Bayer for such activities relating to aflibercept 8 mg) in countries outside the United States.

In addition, under the terms of our Antibody Collaboration, we and Sanofi co-commercialize Dupixent in the United States and, as further discussed below, certain jurisdictions outside the United States. As a result, we rely in part on Sanofi's sales and marketing organization for Dupixent. If we and Sanofi fail to coordinate our sales and marketing efforts effectively, sales of Dupixent may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent. For example, Sanofi records product sales for Dupixent in the United States and leads negotiations with payors relating to this product. We also rely on Sanofi for sales, marketing, and distribution of Dupixent in countries outside the United States. While we exercised our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, we will continue to rely in part on Sanofi's sales and marketing organization in such jurisdictions.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see "Risks Related to Our Reliance on or Transactions with Third Parties - *If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed*" below and "Risks Related to Our Reliance on or Transactions with Third Parties - *If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed*" below.

Sales of our marketed products recorded by us and our collaborators could be reduced by imports from countries where such products may be available at lower prices.

Our sales of products we commercialize in the United States and our collaborators' sales of products they commercialize or co-commercialize with us under our collaboration agreements with them in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under the relevant collaboration agreements and, therefore, our results of operations) may be reduced if the applicable product is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or otherwise alter the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. Similarly, under our Antibody Collaboration with Sanofi, pricing and reimbursement for the products commercialized or co-commercialized thereunder outside the United States are the responsibility of Sanofi. Prices for our marketed products in jurisdictions outside the United States are based on

local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United States. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations.

We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payors and on our and our collaborators' ability to successfully manufacture, market, and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payors, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.

We sell our marketed products for which we record net product sales in the United States to several distributors and specialty pharmacies, as applicable, which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the six months ended June 30, 2023 and 2022, our gross product sales of such products to two customers accounted on a combined basis for 76% and 85% 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 Libtayo, Dupixent, and any other products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and do not currently have a fully established organization for the sales, marketing, and distribution of marketed products outside the United States. We will need to establish some or all of these capabilities outside the United States for any product we decide to independently commercialize or co-commercialize outside the United States. For example, in 2022, we and Sanofi amended the IO Collaboration to transfer all rights to develop, commercialize, and manufacture Libtayo exclusively to our Company, on a worldwide basis, over the course of a defined transition period, and we will need to fully establish certain sales, marketing, distribution, and/or manufacturing capabilities for Libtayo to support markets outside the United States. We will also need to obtain and/or maintain regulatory approvals and secure pricing and reimbursement for Libtayo in many jurisdictions outside of the United States, including Europe and Japan. In addition, following the exercise of our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, we have established certain co-commercialization capabilities for Dupixent in some of

these jurisdictions and are in the process of establishing these capabilities in others. There may be other circumstances in which we need to establish further commercial capabilities outside the United States, including because we decide to commercialize a particular product independently; we are unable to find an appropriate collaborator; or an existing collaborator decides to opt out or breaches its obligations to us with respect to a particular product.

In order to commercialize or co-commercialize any products outside the United States beyond what we have done so far, we must build our sales, marketing, distribution, regulatory, managerial, and other capabilities in the relevant markets or make arrangements with third parties to perform these services, any of which will likely be expensive and time consuming and could delay product launch or the co-commercialization of a product in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop commercial capabilities outside the United States (particularly as it relates to Libtayo, for which we plan to expand our global commercialization footprint as noted above) 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 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 for a new drug or indication 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. The FDA has the explicit authority to require post-marketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are

perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products. Obligations equivalent in scope, but which can vary widely in application, apply in foreign countries.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. The FDA's goal for a standard review is to review the application within a 10-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity ("NME") New Drug Application ("NDA") and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within six months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending, and may be delayed for reasons beyond our control. For example, in 2022, an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe delayed by nearly two months the FDA's approval of our sBLA for the combination treatment of Libtayo with chemotherapy in NSCLC.

If we believe we meet eligibility requirements, we may apply for various regulatory incentives in the United States, such as breakthrough therapy designation, fast track designation, accelerated approval, or priority review, where available, that serve to expedite drug development and/or review, and we may also seek similar designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits, and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by the FDA or other regulatory agencies. Even if obtained, such designations may not result in faster development processes, reviews, or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meets the conditions for a beneficial regulatory designation (including due to factors beyond our control, such as intervening competitive developments) or decide that the time period for FDA review or approval will not be shortened. Recent FDA draft guidance relating to accelerated approval of oncology therapeutics indicates that a confirmatory trial for a particular oncology product candidate should be underway when the related BLA is submitted to the FDA and also states that the FDA may require that a confirmatory trial for a particular oncology product candidate be well underway, if not fully enrolled, by the time of the accelerated approval action. Application of this guidance to our product candidates may result in a delay of the FDA review and approval process despite any earlier beneficial regulatory designation such product candidates may have received.

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 example, in June 2023, the FDA issued a CRL concerning the Company's BLA for aflibercept 8 mg for the treatment of wet AMD, DME, and DR due to unresolved observations resulting from an inspection at the contract manufacturing organization Catalent. This has resulted in a delay of the potential FDA approval of aflibercept 8 mg, and may also impact the FDA's upcoming decision on the BLA for

pozelimab monotherapy for the ultra-rate CHAPLE disease (which is filled on the same manufacturing line in Catalent's facility that is used to fill vials with aflibercept 8 mg). While we have since resubmitted the BLA for aflibercept 8 mg, the BLA resubmission still needs to be supplemented with the Catalent manufacturing data and other information and it is uncertain whether and how timely the issues identified in the aflibercept 8 mg CRL will be resolved. 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 the U.S. Department of Health and Human Services ("HHS") may authorize the issuance of, and the FDA Commissioner may issue, an Emergency Use Authorization ("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. 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 previously granted for REGEN-COV to exclude its use in geographic regions (currently including all U.S. states, territories, and jurisdictions) 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. 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 each of the years ended December 31, 2022 and 2021, we recorded a charge to write down inventory related to REGEN-COV.

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; this will be the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) once we complete the transition from Sanofi pursuant to the amendment to the IO Collaboration discussed above. 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, we are subject to pharmacovigilance reporting and other pharmacovigilance requirements, which may differ in the numerous countries in which we conduct clinical trials or commercialize a product. Failure to comply with any such requirements may result in the premature closure of the clinical trials and other enforcement actions by the relevant regulatory authorities. For example, 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 in the European Economic Area ("EEA"), 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.

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 other 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/or safety concerns, and clinical trials evaluating our product candidates have failed to meet the relevant endpoints. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. If concerns arise about the safety of a product candidate or non-compliance with the protocol or applicable regulatory requirements, the FDA or other regulatory authorities can delay or suspend a clinical trial by placing it on a full or partial "clinical hold" pending receipt of additional data or the satisfaction of other conditions. A clinical hold may require us to spend significant resources to address the underlying causes of the clinical hold and may result in a delay in the clinical program, which may be significant. In addition, if we are not able to successfully address such underlying causes or our response is not deemed adequate to lift the clinical hold, the clinical program may have to be terminated. Any such clinical program delays or terminations may adversely affect our business.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, we previously discontinued actively treating patients with fasinumab following a recommendation from the responsible IDMC that the program be terminated based on available evidence at that time; and we later discontinued further clinical development of fasinumab. 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 11 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. Our ability to protect our trade secrets may be impaired by a number of risks and uncertainties, including those discussed under "Other Regulatory and Litigation Risks - *Increasing use of social media and artificial intelligence-based platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage*" and "Other Risks Related to Our Business - *Significant disruptions of information technology systems or breaches of data security could adversely affect our business*" below. 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 11 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 Europe and are costly to defend. For example, in 2021, anonymous parties initiated opposition proceedings in the European Patent Office ("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 11 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. We cannot be certain that our intellectual property rights related to any current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such change or other rulemaking.

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

We also currently hold issued trademark registrations and have trademark applications pending in the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering, or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected.

We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to awards of damages if we are found to have infringed such patents or rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others (including those relating to trademarks, copyrights, and trade secrets). Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody-based products made using our *VelocImmune* technology, or any other of our technologies, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we are currently party to patent infringement and other proceedings relating to EYLEA and REGEN-COV, as described in Note 11 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 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) extends through May 17, 2024 following the pediatric exclusivity granted by the FDA. 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 or if there is greater demand than currently expected for our marketed products. In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract

manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. As we increase our production in anticipation of potential regulatory approval for our product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. The COVID-19 pandemic has exacerbated and may in the future further exacerbate certain of these risks. For example, the impact of prioritizing certain manufacturing-related resources for our COVID-19 monoclonal antibodies has included and may in the future include, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products, our ability to re-establish successfully our customary manufacturing cadence, and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient quantities to satisfy our commercial and development needs. We also rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity and establishing fill/finish capabilities will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures, time, and various regulatory approvals and permits. This also holds true for establishing fill/finish capabilities in the future, for which we are in the process of constructing fill/finish facilities (refer to Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for information about expected capital expenditures relating to this and other projects). In addition, we may need to develop or acquire additional manufacturing capabilities to the extent we or our collaborators pursue the development of drugs generated by means other than our existing "Trap" or *VelociSuite*® technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill/finish activities. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities and any future fill/finish activities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing or any future fill/finish capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, and it could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture products may be impaired if any of our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future (including our ability to conduct any fill/finish activities in the future), the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other

parties may allege that our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as described in Note 11 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 each of the years ended December 31, 2022 and 2021, we recorded a charge to write down inventory related to REGEN-COV.

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.

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, or other public health outbreaks, epidemics, or pandemics or geopolitical developments). 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. For example, in June 2023, the FDA issued a CRL concerning the Company's BLA for aflibercept 8 mg for the treatment of wet AMD, DME, and DR due to unresolved observations resulting from an inspection at a third-party fill/finish provider, the contract manufacturing organization Catalent. This has resulted in a delay of the potential FDA approval of aflibercept 8 mg and may also impact the FDA's upcoming decision on the BLA for pozelimab monotherapy for the ultra-rare CHAPLE disease (with a target action date of August 20, 2023), which is filled on the same manufacturing line in Catalent's facility that is used to fill vials with aflibercept 8 mg. While Catalent has been working closely with the FDA to address the findings and we have since resubmitted the BLA for aflibercept 8 mg, the BLA resubmission still needs to be supplemented with the Catalent manufacturing data and other information (collectively, "supplemental Catalent information") and it is, therefore, uncertain whether and how timely the issues identified in the aflibercept 8 mg CRL will be resolved. The FDA has informed us that its review of the supplemental Catalent information in the context of the pozelimab BLA will support actions for both the pozelimab BLA and the aflibercept 8 mg BLA resubmission and that it will prioritize its review. However, the FDA has also noted that it may not be able to complete its review by the pozelimab BLA target action date and that it may consider the supplemental Catalent information submission to constitute a major amendment to the pozelimab BLA, thereby extending the review of the pozelimab BLA by up to three months from the pozelimab BLA target action date and also further delaying the FDA's decision on the aflibercept 8 mg BLA resubmission. In addition, if the FDA concludes that the supplemental Catalent information is insufficient to resolve the issues identified in the aflibercept 8 mg CRL, the FDA may require in its sole discretion additional quality-related studies, data, facility reinspections, or other information demonstrating compliance with applicable cGMP regulations and FDA guidance, further extending the timing of the FDA's review beyond what is discussed above. Therefore, the timing and outcome of the completion of the FDA's review of the aflibercept 8 mg BLA resubmission and the pozelimab BLA are uncertain, and the potential FDA approval of aflibercept 8 mg and pozelimab may be delayed beyond what is currently expected. Significant noncompliance with the requirements discussed in this paragraph 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 U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.

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

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

The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Pharmaceutical companies have been investigated and/or prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal fraud and false statement statutes that extend to non-government health benefit programs.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, damages, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment for individuals and the curtailment or restructuring of operations. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws. As described further in Note 11 to our Condensed Consolidated Financial Statements included in this report, we are party to civil litigation initiated in 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. Applicable manufacturers also are required to report information 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. In addition, several states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities; restrict when pharmaceutical companies may provide meals or gifts to prescribers or engage in other marketing-related activities; require identification or licensing of sales representatives; and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

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

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

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

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

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

In addition, the final regulation issued by HRSA regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities has affected our obligations and potential liability under the 340B program. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. Moreover, under a final regulation effective January 13, 2021, HRSA 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. On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process. 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. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

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

Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract-based requirements under the VA/FSS and/or Tricare programs can subject a manufacturer to civil monetary penalties. These program and contract-based obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and/or response to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside the United States (which have recently increased, and are expected to continue to increase, due to, in part, our efforts to establish our commercialization and co-commercialization capabilities in certain jurisdictions outside the United States) are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to expand internationally, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a fully integrated biotechnology company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations. For example, in March 2022, the SEC proposed new rules for extensive and prescriptive climate-related disclosure in annual reports and registration statements, which would also require inclusion of certain climate-related financial metrics in companies' audited financial statements. In July 2023, the SEC adopted new 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 prescription drugs or other healthcare products, 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. federal or state governments could carry out other significant changes in legislation, regulation, or government policy, including with respect to government reimbursement changes or 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*") or the PPACA or other healthcare reform laws. 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 in several countries outside the United States and we plan to significantly expand the scope of these activities in existing and/or additional countries. For example, as discussed above, we will need to establish commercial capabilities related to Libtayo in many jurisdictions outside the United States following the amendment to the IO Collaboration; and we perform 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, particularly those in which we have not previously established operations, and many of these risks will increase as we expand our activities in such jurisdictions. These risks 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.

We have large-scale manufacturing operations in Limerick, Ireland and have also established offices in the United Kingdom, Germany, and other countries outside the United States. Changes impacting our ability to conduct business in the those 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 foreign jurisdictions in which we operate. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from the applicable statutory tax rates and relative earnings in each taxing jurisdiction. We record liabilities for uncertain tax positions that involve significant management judgment as to the application of law. 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. Consequently, tax assessments or judgments in excess of accrued amounts that we have estimated in preparing our financial statements may materially and adversely affect our reported effective tax rate or our cash flows. Further, other factors may adversely affect our effective tax rate, 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). For example, the IRA has created a corporate alternative minimum tax of 15% on adjusted financial statement income and an excise tax of 1% of the value of certain stock repurchases that apply to certain corporations for tax years beginning after December 31, 2022. Further, actions taken by the Organization for Economic Co-operation and Development and the EC could also influence tax laws in countries in which we operate, including the implementation of a global minimum tax. Changes to these or other laws and regulations or their interpretations could materially adversely impact our effective tax rate or cash flows.

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 EC introduced new standard contractual clauses required to be incorporated into certain 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 many research institutions, 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 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 ("CCPA") and influenced by the GDPR. The CCPA 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. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. These laws and regulations are constantly evolving and may impose limitations on our business activities. Additional state consumer privacy laws are expected to come into effect in 2023 and in 2024-2025. Notably, these state laws provide more restrictions on the use of sensitive personal data, including health information. These states require robust consent and authorizations prior to any collection or use of this data, which may have a large impact on our ability to market to individuals in these jurisdictions based on their health conditions. At the federal level, Section 5 of the FTC 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 FTC has brought legal actions against organizations that have violated consumers' privacy rights or have misled them by failing to maintain appropriate security. For example, in 2023 to date the FTC issued several enforcement actions related to privacy in the healthcare space, under both Section 5 of the FTC Act and the Health Breach Notification Rule, involving companies allegedly using consumer health data for marketing purposes in violation of their own policies and assurances.

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 and artificial intelligence-based platforms could give rise to liability, breaches of data security and privacy laws, 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. Additionally, artificial intelligence ("AI")-based platforms, including generative AI platforms, are increasingly being used in the biopharmaceutical industry. The use of public AI platforms by our employees or third parties on which we rely with access to our proprietary and confidential information, including trade secrets, may continue to increase and may lead to the public disclosure of such information, which may impact our ability to realize the benefit of our intellectual property or comply with data security and privacy laws. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Risks Related to Our Reliance on or Transactions with Third Parties

If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.

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

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

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

We rely heavily on Bayer with respect to the commercialization of EYLEA outside the United States (and, if approved, will rely on Bayer with respect to any potential future commercialization of aflibercept 8 mg outside the United States, including the activities discussed below). Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to commercialize EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant issues for the commercialization of EYLEA outside the United States and result in substantial additional costs and/or lower revenues to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for Libtayo, Dupixent, or any other 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 and, if approved, any potential future commercialization of aflibercept 8 mg outside the United States.

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

We depend upon third-party collaborators, including Sanofi and Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third-party manufacturers, fill/finish providers, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these or other third parties in connection with the commercialization of our marketed products and our product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner (including as a result of its inability to perform due to financial or other relevant constraints, such as due to Russia's invasion of Ukraine) or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates. 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.*"

We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators' arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

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

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

or equity financing to acquire any businesses, products, or product candidates, which may result in dilution for shareholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, businesses, products, or product candidates or to enter into other significant transactions, we will conduct business, legal, and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we have consummated or may consummate in the future, whether as a result of unidentified risks or liabilities, integration difficulties, regulatory setbacks, litigation with current or former employees and other events, our business, operating results, and financial condition could be adversely affected. For any acquired product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, and the market for any such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

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

Other Risks Related to Our Business

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 and other key members of our senior management team. 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 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.

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. 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 and in compliance with U.S. and foreign laws, 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 U.S. and foreign laws that protect the privacy of personal information, disruptions to our operations, government investigations, breach of contract claims, and damage to our reputation (in each case in the U.S. or globally), which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) have adversely affected and may in the future adversely affect our business.

The COVID-19 pandemic previously adversely affected, and the COVID-19 pandemic or other actual or threatened public health outbreaks, epidemics, or pandemics may in the future 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. These and other adverse effects may result from various developments including the following:

- The imposition of various restrictions and mandates to reduce the spread of outbreaks, epidemics, or pandemics, 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 test results.
- Negative impacts on productivity, disruptions to our business, and delays to our clinical programs and development timelines caused by the imposition of various government-imposed or private-sector measures relating to outbreaks, epidemics, or pandemics. Such restrictions and limitations could also negatively impact our access to regulatory authorities (which may be affected, among other things, by 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 loss of key personnel, either temporarily or permanently.
- Negative impacts to our sales and marketing efforts due to the 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.
- Reduced demand for some or all of our marketed products due to, among other factors, shelter-in-place, social distancing, or similar orders.
- Supply chain strains or disruptions (such as port closures and government or other restrictions or limitations, whether resulting from a public health outbreak, epidemic, pandemic, or otherwise, such as those that may be imposed under the Defense Production Act) that result in reduced availability or increased cost of materials produced by or purchased from our suppliers or other third parties on which we rely.
- Microbial, viral, or other contamination of 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), which could result in the closure of or other impact to the affected facilities for an extended period of time, or could result in other delays or disruptions in our direct or indirect supply chain.
- Disruptions to the healthcare and healthcare regulatory systems, which could among other matters, divert healthcare resources away from, or materially delay, regulatory review and potential approval of our product candidates and new indications for our marketed products.
- Pricing pressures, rebates, clawbacks, and other changes in reimbursement policies and programs resulting from the financial strain of a public health outbreak, epidemic, or pandemic on government-funded healthcare systems.
- Risks related to any therapies we may have developed or be in the process of developing in response to any such public health outbreak, epidemic, or pandemic (such as REGEN-COV and our "next generation" monoclonal antibodies targeting SARS-CoV-2), including heightened regulatory scrutiny; restrictions on administration that limit widespread and timely access to any such therapies; fluctuations in, or elimination of, demand for any such therapies (including due to the availability of superior or competitive therapies or preventative measures); mutations of the disease-causing pathogen impacting efficacy; and revocations of or restrictions on any emergency use authorizations.
- Impacts on our clinical trials due to delays in site initiation and patient enrollment as a result of prioritization of hospital resources to address the public health outbreak, epidemic, or 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. Similarly, our ability to recruit and retain patients and principal

investigators and site staff could be delayed or disrupted. Any such disruptions could negatively impact the progress of our clinical trials, including the readouts of trial results, the timing of regulatory review, and any anticipated program milestones.
- Significant disruption to the global financial markets or economy, which may make it more difficult for us to access capital if needed. In addition, a recession or market correction resulting from a public health outbreak, epidemic, or pandemic could materially affect the value of our Common Stock.

These and similar, and perhaps more severe, disruptions in our operations may materially adversely impact our business, prospects, operating results, and financial condition. To the extent a public health outbreak, epidemic, or 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 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 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. Our ability to refinance or to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of our marketed products, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

Our indebtedness could adversely impact our business.

We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of June 30, 2023, we had an aggregate of $2.702 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, Chinese yuan, 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. For example, as previously reported, the amount of our share of profits we earned in connection with commercialization of antibodies outside the United States was adversely impacted in 2022 by the U.S. dollar strengthening against foreign currencies, including the Japanese yen and the euro.

Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.

As of June 30, 2023, we had $1.937 billion in cash and cash equivalents and $13.318 billion in marketable securities (including $1.028 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.

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 (such as aflibercept 8 mg) 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) (such as aflibercept 8 mg) 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;
- 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;
- impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

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

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

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of June 30, 2023, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2023. 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 January 2023, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock (of which $2.332 billion remained available as of June 30, 2023). There can be no assurance of any future share repurchases or share repurchase program authorizations. Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, if at all.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of June 30, 2023, holders of Class A Stock held 14.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to substantially influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of June 30, 2023:

- our current executive officers and directors beneficially owned 6.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2023, and 17.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of June 30, 2023; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2023. In addition, these five shareholders plus our Chief Executive Officer held approximately 46.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of June 30, 2023.

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 substantial influence over matters requiring shareholder approval and over our management.*"

Further, certain of our collaborators are currently bound by "standstill" provisions under their respective agreements with us. These include the January 2014 amended and restated investor agreement between us and Sanofi, as amended, and our 2016 ANG2 license and collaboration agreement with Bayer, which contractually prohibit Sanofi and Bayer, respectively, 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 and 20% in the case of Bayer).

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 programs, as well as Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock granted under one of our long-term incentive plans, during the three months ended June 30, 2023. 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 programs.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs *(in millions)*
4/1/2023–4/30/2023	130,235	$ 809.73	127,012	$ 2,948.5
5/1/2023–5/31/2023	397,322	$ 744.81	397,322	$ 2,652.6
6/1/2023–6/30/2023	431,567	$ 746.07	429,269	$ 2,332.3
Total	959,124 [(a)]		953,603 [(a)]	

[(a)] The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced programs 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 5. Other Information

As disclosed in the table below, during the three months ended June 30, 2023, certain of our directors and/or executive officers adopted plans for trading arrangements intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

Name	Position	Date of Plan Adoption	Scheduled End Date of Trading Arrangement[(a)]	Total Number of Securities to Be Sold Under the Plan
Bonnie L. Bassler, Ph.D.	Director	5/11/2023	7/31/2024	3,969
Andrew J. Murphy, Ph.D.	Executive Vice President, Research	5/9/2023	12/31/2024	80,000
Huda Y. Zoghbi, M.D.	Director	5/5/2023	2/10/2024	2,117

[(a)] In each case, the trading arrangement may expire on an earlier date if and when all transactions under the arrangement are completed.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
3.2	Amended and Restated By-Laws. (Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. (the "Registrant") filed December 21, 2016.)
3.2.1	Amendment to the Amended and Restated By-Laws effective June 9, 2023. (Incorporated by reference from the Form 8-K for the Registrant filed June 14, 2023.)
10.1*	First Amendment to Amended and Restated License and Collaboration Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 1, 2013.
10.2*	Amendment No. 1 to Master Agreement, dated as of April 10, 2023, by and between the Registrant and Alnylam Pharmaceuticals, Inc.
10.3 +	Waiver and Consent, dated as of April 14, 2023, pursuant to the Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Condensed Consolidated Balance Sheets as of June 30, 2023 and December 31, 2022; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2023 and 2022; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2023 and 2022; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2023 and 2022; and (v) the notes to the Registrant's Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Certain confidential portions of this Exhibit were omitted in accordance with Item 601(b)(10) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of all confidential portions of this Exhibit that were omitted to the Securities and Exchange Commission upon its request.

\+ Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: August 3, 2023

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

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [****], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(b)(10)(iv). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

FIRST AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

This First Amendment to the Amended and Restated License and Collaboration Agreement (this "First Amendment") dated as of May 1, 2013 (the "First Amendment Effective Date"), is by and between Regeneron Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of New York and having its principal office at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") and Aventis Pharmaceuticals Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807 ("Sanofi"), an indirect wholly-owned subsidiary of sanofi-aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75013 Paris, France, with each of Sanofi and Regeneron being sometimes referred to herein individually or as a “Party” and collectively as the “Parties”.)

INTRODUCTION

WHEREAS, Regeneron and Sanofi are Parties to an Amended and Restated License and Collaboration Agreement, having an Effective Date of November 10, 2009 (the "LCA"); and

WHEREAS, Regeneron and Sanofi have determined that it is desirable to amend the LCA and document further agreements between them as set forth herein.

NOW, THEREFORE, in consideration of the following mutual promises and obligations and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. **Definitions**. Capitalized terms used in this First Amendment and not defined herein shall have the meanings ascribed to them in the LCA. For the purposes of this First Amendment the following terms shall have the meanings ascribed herein:

   1.1 “ANG2 Combination Product” shall mean a combination product containing an ANG2 Product and one or more other active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price). For the avoidance of doubt, for the purposes of this First Amendment, Immunoconjugates (as such term is defined in the Discovery Agreement) shall not be deemed ANG2 Combination Products.

   1.2 “ANG2 Formulated Bulk Product” shall have the meaning set forth in Section 5.

   1.3 “ANG2 Licensed Product” shall mean any ANG2 Product or ANG2 Combination Product.

   1.4 “ANG2 Manufacturing Cost” shall have the meaning set forth in Section 5.

1.5 "ANG2 Product" shall mean (a) any Antibody to angiopoietin 2 (also known as ANGPT2 or ANG2), including without limitation the Licensed Product known as REGN 910 and (b) any [****].

1.6 "ANG2 Product Drug Substance" shall mean drug substance that is manufactured for ANG2 Licensed Product for use in the Field that is also used in the manufacture of Excluded Ocular ANG2 Product.

1.7 "ANG2 Ocular Royalties" shall have the meaning set forth in Section 4.

1.8 "ANG2 Royalty Term" shall be the period beginning with the First Commercial Sale of any Excluded Ocular ANG2 Product, to a non-sublicensee Third Party in a country in the Territory following receipt of marketing approval in the applicable country, and ending [****].

1.9 "Collaboration Shared Excluded Ocular ANG2 Product Development Costs" shall mean fifty percent (50%) of the Shared Excluded Ocular ANG2 Product Development Costs.

1.10 "Excluded Field" shall mean the treatment or diagnosis of any ocular disease or disorder.

1.11 "Excluded Ocular ANG2 Product" shall mean any ANG2 Licensed Product for use in the Excluded Field.

1.12 "Field" shall have the meaning in Section 1.44 of the LCA but excluding the Excluded Field.

1.13 "First Commercial Sale" shall have the meaning in Section 1.46 of the LCA except that the use of the term "Licensed Product" shall mean Excluded Ocular ANG2 Product in Section 1.46 or the defined terms therein.

1.14 "Net Sales" shall have the meaning in Section 1.76 of the LCA, except that (a) solely for the purposes of calculating ANG2 Ocular Royalties the term Licensed Products shall mean the applicable ANG2 Licensed Product as the case may be, and (b) solely for the purposes of this First Amendment, the last three (3) sentences of Section 1.76 of the LCA shall be deleted in their entirety.

1.15 "Regeneron Shared ANG2 Product Development Costs" shall mean fifty percent (50%) of the Shared ANG2 Product Development Costs.

1.16 "Shared ANG2 Product Development Costs" shall mean costs and expenses of the type described in Section 1.36(d) of the LCA that are incurred by a Party directly in connection with the Development of an ANG2 Product in accordance with the LCA and the applicable Global Development Plan and Global Development Budget, but only to the extent that such costs and expenses are incurred in connection with activities required for any IND, BLA, Registration Filing and/or Approval of any Excluded Ocular ANG2 Product.

1.17 "Shared Excluded Ocular ANG2 Product Development Costs" shall mean those costs and expenses of the type described in Section 1.36(d) of the LCA that are incurred by Regeneron directly in connection with the

development of an Excluded Ocular ANG2 Product, but only to the extent that such costs and expenses are incurred under a budget that has been approved by the Joint Steering Committee and to the extent that such costs are incurred in connection with activities required for any IND, BLA, Registration Filing and/or Approval of any ANG2 Licensed Product outside the Excluded Field.

1.18 "[****]" shall have the meaning set forth in Section 4.

1.19 [****]

1.20 "Upfront Payment" shall have the meaning set forth in Section 4.

2. **Ophthalmology Program and Exclusions.** Effective as of First Amendment Effective Date, the scope of the Collaboration shall exclude all Excluded Ocular ANG2 Products. Except to the extent required by Sanofi to fulfill its obligations under this First Amendment, all licenses and rights granted by Regeneron to Sanofi and its Affiliates under the LCA or the Discovery Agreement, as the case may be, with respect to Excluded Ocular ANG2 Products shall automatically terminate and revert to Regeneron. In furtherance thereof, the definitions of "Licensed Products" in Section 1.69 of the LCA shall be amended by adding the following sentences at the end thereof: "Notwithstanding anything herein to the contrary, effective as of May 1, 2013 this definition shall specifically exclude Excluded Ocular ANG2 Products." For the avoidance of doubt, Regeneron and Sanofi shall continue to collaborate on the Development and Commercialization of ANG2 Products in the Territory outside the Excluded Field under the terms of the LCA and such ANG2 Products in the Territory outside the Excluded Field shall be Licensed Products under the LCA. For the further avoidance of doubt, after the First Amendment Effective Date, except with regard to payment due under this First Amendment, neither Sanofi nor its Affiliates shall have any right, title, or interest in the Excluded Ocular ANG2 Products and Regeneron shall have the sole discretion to undertake (or not undertake) any further Development or Commercialization of all Excluded Ocular ANG2 Products, either on its own or with or through any Third Party. To further clarify, and by way of example, for the purpose of determining the occurrence of a milestone event delineated in Schedule 3, the Excluded Ocular ANG2 Products shall not be considered Licensed Products.

3. **Confidentiality.** Sanofi shall promptly collect and destroy, and cause its Affiliates to collect and destroy, all documents containing Party Information or New Information relating solely to the Excluded Ocular ANG2 Products, and shall immediately cease and cause its Affiliates to cease all further use of any such Party Information or New Information with respect to Excluded Ocular ANG2 Products. Each of Sanofi and Regeneron reaffirm their commitment under Article 16 of the LCA to keep confidential all New Information and all Party Information of the other Party. In accordance therewith, the rights granted to Sanofi under Section 2 of this First Amendment do not provide Sanofi with any rights to use or disclose New Information or Regeneron Party Information, unless otherwise provided under Article 16 of the LCA. However, notwithstanding anything provided in Section 16.1 to the contrary, as of the First Amendment Effective Date, Regeneron shall have the right to use and disclose, any New Information and/or any Regeneron Party Information for use in the manufacture, development, use, and commercialization of Excluded Ocular ANG2 Products anywhere in the world; provided, however, that any such disclosure of confidential New Information to a Third Party (other than a Governmental Authority or as part of a public disclosure in the interest of patient safety) shall be subject to confidentiality obligations to Regeneron on the part of such Third Party at least as stringent as those set forth in the LCA, except that the term of such confidentiality obligation shall not be less than five (5) years.

4. **Consideration.** In consideration for Sanofi's agreement to enter into this First Amendment, Regeneron shall pay to Sanofi, within five (5) Business Days of the First Amendment Effective Date, a nonrefundable, non-creditable payment of Ten Million US Dollars (US $10,000,000.00) (which shall not be reduced by any withholding or similar taxes) (the "Upfront Payment").

   In addition, Regeneron shall pay to Sanofi a non-refundable, non-creditable performance based milestone of Five Million US Dollars (US $5,000,000) (which shall not be reduced by any withholding or similar taxes) within five (5) Business Days of [****] (the "[****]"). For purposes of clarification, the foregoing milestone payment shall be made only once and only upon the first occurrence of such milestone, regardless of the number of [****].

   Notwithstanding the foregoing, no adjustment shall be made to the Maximum Annual Discovery Program Costs for any Contract Year in connection with any of the actions contemplated under this First Amendment. In addition, notwithstanding any other payment terms in the LCA, Regeneron shall pay to Sanofi royalties on Net Sales in the following amounts (the "ANG2 Ocular Royalties") through the end of the applicable ANG2 Royalty Term:

   (a) For sales of an Excluded Ocular ANG2 Product as a single agent, [****]% of Net Sales;

   (b) For sales of an Excluded Ocular ANG2 Product as an ANG2 Combination Product, [****]% of Net Sales.

   ANG2 Ocular Royalties shall be paid within sixty (60) days after the end of each full or partial Quarter during the ANG Royalty Term in which sales subject to ANG2 Ocular Royalties occur. No other royalties or payments whatsoever of any kind will be due or owing to Sanofi relating in any way to Excluded Ocular ANG2 Products. Nothing in this First Amendment or the LCA shall entitle Sanofi or its Affiliates to any consideration, royalties, fees or payments of any kind based on the development, commercialization or other marketing and sales of any kind of any Excluded Ocular ANG2 Products other than the Upfront Payment and ANG2 Ocular Royalties. During the ANG2 Royalty Term, Regeneron shall deliver to Sanofi with each payment of ANG2 Ocular Royalties a report detailing in reasonable detail the information necessary to calculate the ANG2 Ocular Royalties due hereunder for such calendar quarter, including the following information, specified on a country-by-country basis: (a) total gross invoiced amount from sales of each Excluded Ocular ANG2 Products; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) ANG2 Ocular Royalties payable. Subject to Section 6 below, effective as of 05 November 2012, the Parties have agreed that any costs incurred in connection with the Development of any ANG2 Product in the Excluded Field shall be borne directly by Regeneron and shall no longer be considered Development Costs.

5. **Purified Bulk Drug Substance.** Regeneron shall be entitled to [****]. In addition, upon at [****], Regeneron shall be entitled to [****]. Regeneron shall submit a request to [****]. "ANG2 Formulated Bulk Product" shall mean an ANG2 Product formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form. "ANG2 Manufacturing Cost" shall be the manufacturing costs for the relevant ANG2 Product calculated using the methodology ascribed to calculating Manufacturing Cost for Licensed Products in the LCA. For the avoidance of doubt, costs incurred for the reprocessing of purified bulk ANG2 Product Drug Substance for use solely in the Excluded Field shall not be considered Development Costs and shall be borne solely by Regeneron. Further, all cost directly related to [****] shall be considered Shared ANG2 Product Development Costs.

For the further avoidance of doubt, the Parties shall retain their option under Section 8.3(a) of the LCA to [****].

6. **Payment of Regeneron Shared ANG2 Product Development Costs and Collaboration Shared Excluded Ocular ANG2 Product Development Costs**. Beginning with the First Amendment Effective Date, Regeneron Shared ANG2 Product Development Costs, if any, and Collaboration Shared Excluded Ocular ANG2 Product Development Costs, if any, shall be included in the calculation of the Quarterly True-Up and the Development Balance. Specifically, any Regeneron Shared ANG2 Product Development Costs shall be subtracted from the amount otherwise payable to Regeneron as a Regeneron Reimbursement Amount, and if the total Regeneron Reimbursement Amount, after such subtraction, is negative, the Regeneron Reimbursement Amount shall be a negative number in the calculation of the Quarterly True-Up. Any Collaboration Shared Excluded Ocular ANG2 Product Development Costs shall be added to the amount payable to Regeneron as a Regeneron Reimbursement Amount. In addition, for purposes of calculating the Development Balance, any Regeneron Shared ANG2 Product Development Costs shall be subtracted from Development Costs and any Collaboration Shared Excluded Ocular ANG2 Product Development Costs shall be added to Development Costs. An example of these calculations is set forth in Exhibit A to this First Amendment.

7. **Limitation on Sanofi's Rights to Develop or Commercialize Excluded Ocular ANG2 Products.** Beginning with the First Amendment Effective Date and continuing for as long as Regeneron is paying ANG2 Ocular Royalties, neither Sanofi nor its Affiliates, either alone or through any Third Party directly or indirectly, shall develop, manufacture, market, promote, commercialize, or sell, any Excluded Ocular ANG2 Product anywhere in the Territory. In the event that during the period that Regeneron is paying ANG2 Ocular Royalties (i) Sanofi or one of its Affiliates acquires, directly or indirectly, Control (as such term is defined below) of a Third Party, and (ii) the Third Party or one of its Affiliates is the owner of or is holding license rights to Patents relating to or has any marketing or sales rights relating to any Excluded Ocular ANG2 Product anywhere in the Territory, and (iii) such Excluded Ocular ANG2 Product, at the moment of acquiring Control, is in any stage of discovery, development or commercialization, then Sanofi shall notify Regeneron of such acquisition of Control within ten (10) days of such acquisition and shall divest or cease the development or the commercialization of that Excluded Ocular ANG2 Product within twelve (12) months. For the purpose of this paragraph, the term "Control" shall mean the ownership of more than fifty (50) percent of the voting stock or similar interest. Notwithstanding anything contained herein to the contrary, Sanofi and its Affiliates shall be entitled to (i) initiate, sponsor and/or conduct a clinical trial in a country and/or (ii) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical trial, initiated, sponsored and/or conducted by any Third Party in a country; in each of the foregoing cases with respect to the combination of any Sanofi (or its Affiliate's) products, together with any Excluded Ocular ANG2 Product that has been granted a marketing approval for at least one indication in the applicable country. For purposes of clarity, to the extent such Sanofi product may be covered under the LCA, the terms of the LCA remain in effect.

8. **Post-Amendment License.** Regeneron shall have a fully paid-up and royalty free, worldwide, exclusive license (which shall include the right to grant sublicenses) from Sanofi and its Affiliates under Sanofi Patent Rights and Sanofi Know-How solely in connection with the development, manufacturing, marketing, promotion, commercialization, or sale of any Excluded Ocular ANG2 Product anywhere in the Territory, either (i) existing as of the time of the First Amendment Effective Date (together with and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and all counterparts thereof in any

country which arise on or after the First Amendment Effective Date), or (ii) discovered, created or reduced to practice in connection with Collaboration activities.

9. ANG2 Product Labeling. To the extent permitted by relevant regulations in the Territory, and as required by the Regulatory Authorities, Regeneron and Sanofi shall include appropriate cautionary safety language in approved labeling for ANG2 Products or Excluded Ocular ANG2 Products related to appropriate use in the Excluded Field, or the Field, as the case may be. Further, to the extent permitted by relevant regulations in the Territory, Regeneron and its licensees shall have the sole responsibility for education of ophthalmologists in risk mitigation plans related to ANG2 Products, and the Parties shall have responsibility for education of physicians other than ophthalmologists as agreed by the Parties in accordance with the LCA.

10. Regulatory Coordination.

(a) The Parties acknowledge and agree that beginning with the First Amendment Effective Date, neither Sanofi nor its Affiliates shall have any interest or rights whatsoever in or to any (i) biologics license application (as described in FDA regulations, including all amendments and supplements to the application and any equivalent filing with a Regulatory Authority ("BLA(s)"), (ii) investigational new drug applications (as described in FDA regulations, including all amendments and supplements to the application and any equivalent filing with any Regulatory Authority outside of the United States ("IND(s)"), (iii) registration filings to the relevant Regulatory Authority of an appropriate application seeking any Approval ("Registration Filings"), and (iv) any Approvals, in each of (i) through (iv) for any Excluded Ocular ANG2 Products, except as set forth in Section 10(c) of this First Amendment. There is no Lead Regulatory Party or non-Lead Regulatory Party for the Excluded Ocular ANG2 Products. For the purposes of this Section 10, "Approvals" shall mean, with respect to the applicable ANG2 Licensed Product or Excluded Ocular ANG2 Product, as the case may be, any marketing approvals, pricing approvals, registration, license or authorization from any Regulatory Authority required for the development, manufacture or commercialization of such product in the Field or Excluded Field, as the case may be, in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, any approval, registration, license or authorization granted in connection with any Registration Filing.

(b) Regeneron and its Affiliates and licensees shall have, and Sanofi and its Affiliates hereby grant to Regeneron and its Affiliates and licensees, the right to reference the BLA(s), IND(s), and any Registration Filings and/or Approvals for any ANG2 Licensed Product requested by Regeneron to support Regeneron' s (and its Affiliates' and licensees', as applicable) IND, BLA, Registration Filings and/or Approvals for Excluded Ocular ANG2 Products anywhere in the world. Promptly upon the request of Regeneron, Sanofi or its Affiliate shall submit a letter of authorization to FDA or the applicable Regulatory Authority (and take such actions or make such other filings) in order to permit any ANG2 Licensed Product IND, BLA, Registration Filing and/or Approval to be incorporated by reference in such Excluded Ocular ANG2 Product regulatory filings.

(c) Sanofi and its Affiliates and licensees shall have, and Regeneron and its Affiliates hereby grant to Sanofi and its Affiliates and licensees, the right to reference the BLA(s), IND(s), and any Registration Filings and/or Approvals for any Excluded Ocular ANG2 Product requested by Sanofi to support Sanofi' s (and its Affiliates' and licensees', as

applicable) IND, BLA, Registration Filings and/or Approvals for ANG2 Licensed Products anywhere in the world outside of the Excluded Field. Promptly upon the request of Sanofi, Regeneron or its Affiliates shall submit a letter of authorization to FDA or the applicable Regulatory Authority (and take such actions or make such other filings) in order to permit any Excluded Ocular ANG2 Product IND, BLA, Registration Filing and/or Approval to be incorporated by reference in such ANG2 Licensed Product regulatory filings outside of the Excluded Field.

(d) Both Parties will cooperate with each other to develop and follow specific procedures to be agreed upon to coordinate the exchange of necessary safety and pharmacovigilence information from ANG2 Licensed Products Developed and Commercialized as part of the Collaboration and Excluded Ocular ANG2 Products developed and commercialized by Regeneron and its licensees to ensure prompt communication of such notifications and compliance with reporting obligations to Regulatory Authorities.

(e) Both Parties will cooperate with each other to develop and follow specific procedures to be agreed upon to coordinate the exchange of necessary regulatory information from ANG2 Licensed Products Developed and Commercialized as part of the Collaboration and Excluded Ocular ANG2 Products developed and commercialized by Regeneron and its licensees.

(f) Parties agree to promptly disclose to each other all relevant information related to ANG2 Licensed Products Developed and Commercialized as part of the Collaboration and Excluded Ocular ANG2 Products developed and commercialized by Regeneron and its licensees, that could have a material impact on the Manufacture, Development or Commercialization of such products. By way of example, categories of information that may have a material impact on Manufacture, Development or Commercialization of such products could include information having implications on safety, clinical, commercial, CMC or regulatory filings.

(g) With regard to ANG2 Licensed Products Developed and Commercialized outside of the Excluded Field as part of the Collaboration, Regeneron shall not respond to or initiate any communications with Regulatory Authorities or Governmental Authorities, except during the period that Regeneron is acting as the Lead Regulatory Party for the Development of ANG2 Licensed Products in the Field. Further, Regeneron shall notify Sanofi within twenty-four (24) hours of receipt by Regeneron from Regulatory Authorities, Governmental Authorities, Affiliates or licensees of any such written or verbal communications initiated by Regulatory Authorities or Governmental Authorities. With regard to Excluded Ocular ANG2 Products developed and commercialized by Regeneron and its licensees, Sanofi shall not respond to or initiate any communications with Regulatory Authorities or Governmental Authorities, and Sanofi shall notify Regeneron within twenty-four (24) hours of receipt by Regeneron from Regulatory Authorities, Governmental Authorities, Affiliates or licensees of any such verbal or written communications initiated by Regulatory Authorities or Governmental Authorities.

(h) Regeneron shall use Commercially Reasonable Efforts to support the interests of ANG2 Licensed Products Developed and Commercialized as part of the Collaboration in its communications to Regulatory

Authorities and Governmental Authorities for the Excluded Ocular ANG2 Licensed Products.

(i) Regeneron shall, [****], but in no event less than two weeks prior to the first submission to an institutional review board or ethics committee for such trial, provide Sanofi a clinical trial outline of such trial.

(j) To the extent that Regeneron determines in good faith that data from a [****], Regeneron and Sanofi shall discuss and agree [****].

(k) Regeneron shall notify Sanofi if any data regarding ANG2 Products generated under the LCA is submitted to Regulatory Authorities or Governmental Authorities in support of Excluded Ocular ANG2 Products. Should the regulatory strategy pertaining to such data have the potential to have a material impact on the regulatory strategy used to support ANG2 Licensed Product, Regeneron and Sanofi shall discuss and agree to the proposed strategy in advance of Regeneron's (or its Affiliates' or licensees') communication with Regulatory Authorities or Governmental Authorities regarding such data.

(l) Regeneron shall use Commercially Reasonable Efforts to provide to Sanofi within twenty-four (24) hours after receipt by Regeneron (or Regeneron's receipt from its' Affiliates or licensees) from any Regulatory Authorities or Governmental Authorities any such information for the Excluded Ocular ANG2 Products that it determines in good faith is materially relevant to the interests of the ANG2 Licensed Products, including but not limited to Development, regulatory communications and filings, safety, labeling, manufacturing or product quality for ANG2 Products, or any notice or results of inspections or manufacturing issues relevant to purified bulk ANG2 Product Drug Substance (to the extent that such purified bulk ANG2 Product Drug Substance is common between the ANG2 Products and Excluded Ocular ANG2 Products). Regeneron and Sanofi shall discuss and agree on the response to be communicated to Regulatory Authorities or Governmental Authorities regarding such information and Regeneron shall provide a copy of the response submitted to such Regulatory Authorities or Governmental Authorities within twenty-four (24) hours of submission by Regeneron (or Regeneron's receipt of such a submission from a licensee).

(m) To the extent that an Excluded Ocular ANG2 Product [****], the Parties shall jointly determine the regulatory strategy for such [****]. In the event that the Parties are unable to reach consensus on such regulatory strategy, the Parties shall refer the matter to the Chief Executive Officers for resolution. Regeneron shall notify Sanofi of planned or submitted filing dates to Regulatory Authorities or Governmental Authorities regarding [****] for the Excluded Ocular ANG2 Product. In the Major Market Countries, the Parties shall jointly determine the regulatory briefing strategy for background materials or submissions related to [****] at least ten (10) days prior to submission to Regulatory Authorities or Governmental Authorities. Briefing materials conforming to the jointly agreed regulatory strategy shall be prepared by Regeneron and provided to Sanofi no later than five (5) days prior to submission to a Regulatory Authority or Governmental Authorities. Sanofi shall provide any comments to such briefing materials no later than forty-eight (48) hours following Regeneron's provision of such briefing materials, which comments shall be considered in good faith by Regeneron, and Regeneron shall provide to Sanofi a copy of the final

documents prior to submission. In the non-Major Market Countries, any materials regarding [****] submitted to a Regulatory Authority or a Governmental Authority shall be consistent with the global regulatory strategy jointly developed by the Parties for the Major Market Countries regarding such [****] and Regeneron shall notify Sanofi within seventy-two (72) hours after Regeneron's submission (or Regeneron's receipt of such a submission from a licensee). Notwithstanding the foregoing, should a Regulatory Authority or Governmental Authority request an immediate response from Regeneron regarding [****] Regeneron shall use Commercially Reasonable Efforts to consult with Sanofi in advance of a response, but will not delay a response to such request.

(n) For purposes of clarification, Regeneron and its licensees will have the sole right to determine the final content and position of any communication with Regulatory Authorities and Governmental Authorities with regard to Excluded Ocular ANG2 Products provided that Regeneron makes a good faith determination that such communication will not have a material adverse impact on the Development and Commercialization of ANG2 Licensed Products in the Field.

11. Nonproprietary Naming. To the extent not otherwise prohibited by Law, the Parties will use commercially reasonable efforts to [****].

12. Continuing Effect. Except as specifically modified by this First Amendment, all of the provisions of the LCA are hereby ratified and confirmed to be in full force and effect, and shall remain in full force and effect. The provisions of Sections 10 and 11 of this First Amendment shall apply only for so long as any ANG2 Licensed Product is being Developed and/or Commercialized under the LCA and is not an Opt-Out Product.

13. Entire Agreement; Successors and Assigns. The LCA, this First Amendment, and any written agreements executed by both Parties pertaining to the subject matter therein, constitute the entire agreement between the Parties hereto with respect to subject matter hereof and thereof. Said documents supersede all other agreements and understandings between the Parties with respect to the subject matter hereof and thereof, whether written or oral. This First Amendment shall be binding upon and shall inure to the benefit of the Parties and their respective heirs, administrators, executors, Affiliates, successors and permitted assigns.

14. Headings. The section headings contained in this First Amendment are for reference purposes only and shall not affect in any way the meaning or interpretation of the First Amendment.

15. Counterparts. This First Amendment may be executed in one or more counterparts, all of which shall be considered one and the same agreement, and shall become a binding agreement when one or more counterparts have been signed by each Party and delivered to the other Party.

16. Miscellaneous. This First Amendment shall be governed by the laws of the State of New York, without regard to its principles of conflicts of laws. Each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding arising out of or relating to this First Amendment, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this First Amendment except in such courts. This First Amendment supersedes all prior understandings and agreements, whether written or oral, among the Parties hereto relating to the essence of this First Amendment. If there is a direct conflict between the provisions of the LCA and this First

Amendment, this First Amendment shall govern. This First Amendment may be amended only by a written instrument executed by each of the Parties.

17. Public Disclosure. Regeneron shall have the right to file or register this First Amendment and a notification thereof with the United States Securities and Exchange Commission. A press release shall be issued in substantially the form attached hereto as Exhibit B. In addition to the information included in the press release attached hereto as Exhibit B, Regeneron shall have the right to publicly disclose the ANG2 Ocular Royalties described in Section 4 of this Amendment.

IN WITNESS WHEREOF, each of the Parties has caused this First Amendment to be executed as of the date hereof by a duly authorized corporate officer.

AVENTIS PHARMACEUTICALS INC.

By: /s/ Robert Deberardine

Name: Robert Deberardine

Title: Vice President, General Counsel & Secretary

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard S. Schleifer

Name: Leonard S. Schleifer, M.D., P.h.D.

Title: President & CEO

EXHIBIT A

(Example calculations of Regeneron Reimbursement Amount and certain Development Costs)

(USD MM)

Example Scenario: Regeneron and Sanofi develop a plan and budget for the Ang-2 Oncology Development program that totals $50MM for a given year.
Included in this plan and budget is $3MM (A) for [****]. The Parties agree (based on definitions in this amendment) that such [****] is a "**Shared ANG2 Product Development Cost**". In addition, Regeneron is working on [****] in that same year for its ANG2 ophthalmology program that it believes will cost $1MM (B) and benefit the ANG2 oncology program. The Parties agree via the Joint Steering Committee agree that the formulation work is a "**Shared Excluded Ocular ANG2 Product Development Cost".** The **Regeneron Reimbursement Amount** for all antibody programs under the LCA for this same period is $75MM (C) before taking into consideration any of these ANG2 related adjustments

Financial Calculations

	Costs Year X	**Comments**
ANG2 Development Activities (Oncology Program):		
[****] (Shared ANG2 Product Development Costs)	3.0	**(A)**
Other Development Costs	47.0	
Total ANG2 Development Costs	50.0	**(D)**
Less: Regeneron Shared ANG2 Product Development Costs	(1.5)	**(E) = 50% * (A)**
Plus: Collaboration Shared Excluded Ocular ANG2 Product Development Costs	0.5	**(F) = 50% * (B)**
Adjusted ANG2 Development Costs	49.0	**This adjusted amount is what will be used to calculate the Development Balance**
Calculation of the Regeneron Reimbursement Amount:		
Base Regeneron Reimbursement Amount	75.0	**(C)**
Less: Regeneron Shared ANG2 Product Development Costs	(1.5)	**(E)**
Plus: Collaboration Shared Excluded Ocular ANG2 Product Development Costs	0.5	**(F)**
Adjusted Regeneron Reimbursement Amount	74.0	**This adjusted amount will be the Regeneron Reimbursement Amount**

EXHIBIT B

(Draft press release)

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [**], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(b)(10)(iv). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 1
to the Master Agreement

This Amendment No. 1 ("**Amendment No. 1**") to the Master Agreement is entered into and effective as of April 10, 2023 ("**Amendment No. 1 Effective Date**") by and between Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York ("**Regeneron**"), and Alnylam Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("**Alnylam**"). All capitalized terms not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

Recitals

WHEREAS, Regeneron and Alnylam are parties to that Master Agreement dated April 8, 2019 (the "**Agreement**");

WHEREAS, Regeneron and Alnylam find it in their respective interests to amend the Agreement to clarify certain terms;

NOW THEREFORE, in consideration of the foregoing and the agreements below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Defined Terms.** The following defined terms in Article 1 of the Agreement are hereby restated and amended, effective as of the Effective Date of the Agreement:

1.12 "**Alnylam Background Technology**" means (a) on a Program-by-Program basis, (i) Information that is necessary or reasonably useful to Exploit any Collaboration Product under such Program and (ii) Patent Rights that Cover any Collaboration Product under such Program or the Exploitation of any Collaboration Product under such Program, and (b) Information or Patent Rights that are necessary or reasonably useful to perform any Technology Development Activities, in each case, ((a) and (b)), that are Controlled by Alnylam or its Affiliates as of the Execution Date or at any time thereafter until the end of the Term, but excluding Alnylam Collaboration IP and Alnylam's interest in the Joint Collaboration IP.

1.218 "**Regeneron Background Technology**" means (a) on a Program-by-Program basis, (i) Information that is necessary or reasonably useful to Exploit any Collaboration Product under such Program and (ii) Patent Rights that Cover any Collaboration Product under such Program or the Exploitation of any Collaboration Product under such Program; and (b) Information or Patent Rights that are necessary or reasonably useful to perform any Technology Development Activities, in each case, ((a) and (b)), that are Controlled by Regeneron or its Affiliates as of the Execution Date or at any time thereafter until the end of the Term, but excluding Regeneron Collaboration IP and Regeneron's interest in the Joint Collaboration IP. Notwithstanding the foregoing, Regeneron Background Technology shall exclude (i) any Information related to any Unlicensed Component and (ii) any Patent Rights that Cover the composition or use or manufacture of any Unlicensed Component (alone or in combination).

2. The following new defined terms are hereby added to Article 1 of the Agreement, effective as of the Effective Date of the Agreement:

1.275 "**[**] Research Plan**" has the meaning set forth in Section 3.2.3(f)(ii).

1.276 "**Technology Development Activities**" has the meaning set forth in Section 3.2.3(f)(iii).

1.277 "**[**] Research Plan**" has the meaning set forth in Section 3.2.3(f)(i).

3. The following new sections are hereby added to the Agreement, effective as of the Effective Date of the Agreement:

Add as new 3.2.3(f):

3.2.3 Selection of New Collaboration Targets; Technology Development Activities.

(f) Technology Development Activities.

(i) The Parties agree to conduct certain technology development activities related to the generation and evaluation of [**], in accordance with the mutually agreed research plan attached hereto as Schedule 1.277 (the "**[**] Research Plan**"). Under the [**] Research Plan**,** Regeneron will provide [**] antibody ligands and Alnylam will provide siRNAs for the activities under the workplan.

(ii) The Parties agree to conduct certain technology development activities related to formulation and the evaluation [**] in accordance with the mutually agreed research plan attached hereto as Schedule 1.275 (the "**[**] Research Plan**"). Under the [**] Research Plan, Alnylam will provide the siRNAs for the activities under the workplan.

(iii) The technology development activities described in clauses (i) and (ii) above may be referred to herein as the "**Technology Development Activities**." All costs associated with Technology Development Activities shall be borne by the Party performing such activities and shall not be creditable against any payments hereunder. The Parties shall conduct all Technology Development Activities in good faith. For clarity, any Materials provided by one Party to the other Party in connection with the Technology Development Activities shall be governed by Section 3.8 and, in particular, shall be used by the recipient Party solely for the intended Technology Development Activities. At least once each Calendar Quarter or upon the other Party's reasonable request, each Party will provide the other Party information in its Control generated through the Technology Development Activities.

(iv) Notwithstanding anything to the contrary (including Section 7.1.1), with respect to the Technology Development Activities, (A) any improvement, discovery or Information, patentable or otherwise, that are conceived or reduced to practice (in whole or in part) or otherwise identified, discovered, made or developed, as applicable, solely by Alnylam, its employees, agents or consultants, solely by Regeneron, its employees, agents or consultants or jointly by individuals who are employees, agents or consultants of Alnylam or its Affiliates or its or their Sublicensees, on the one hand, and individuals who are employees, agents or consultants of Regeneron or its Affiliates or its or their Sublicensees, on the other hand, under or in the course of such Technology Development Activities, and (B) any Patent Rights that Cover such improvements, discoveries or Information described in clause (A), will be classified as Joint Collaboration IP, and the Patent Rights in clause (B) will be classified as Joint Collaboration Patents.

Add as new 5.1.5:

5.1.5 during the Research Term, a non-exclusive, non-transferable (except as permitted by Section 12.2), worldwide license (or sublicense), without any right to grant sublicenses (other than to subcontractors permitted under Section 3.4.5), under any Alnylam Technology that is relevant to the Technology Development Activities assigned to Regeneron under the [**] Research Plan or the [**] Research Plan, to perform such Technology Development Activities, which license shall be fully paid-up;

Add as new 5.2.3:

5.2.3 during the Research Term, a non-exclusive, non-transferable (except as permitted by Section 12.2), worldwide license (or sublicense), without any right to grant sublicenses (other than to subcontractors permitted under Section 3.4.5), under any Regeneron Technology that is relevant to the Technology Development Activities assigned to Alnylam under the [**] Research Plan or the [**] Research Plan, to perform such Technology Development Activities, which license shall be fully paid-up;

4. Except as specifically amended herein, all other terms of the Agreement shall remain in full force and effect. The Parties may execute this Amendment No. 1 in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement. The Amendment No. 1 may be executed or delivered electronically or by facsimile transmission, and the Parties hereby agree that any electronic or facsimile signatures hereto are legal, valid and enforceable as originals.

[*signatures follow*]

THIS AMENDMENT NO. 1 IS EXECUTED by the authorized representatives of the Parties as of the Amendment No. 1 Effective Date.

ALNYLAM PHARMACEUTICALS, INC.	**REGENERON PHARMACEUTICALS, INC.**
By: /s/ Jeff Poulton	By: /s/ Kerry Reinertsen
Name: Jeff Poulton	Name: Kerry Reinertsen
Title: Chief Financial Officer	Title: SVP Strategic Alliances

Schedule 1.275
[**] Research Plan

[**]

Schedule 1.277
[**] Research Plan

[**]

CONFIDENTIAL

April 14, 2023

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6707

Attention: Arthur F. Ryan, Chair of the Corporate Governance and Compliance Committee, Member of the Board of Directors and Presiding Director Christine A. Poon, Chair of the Compensation Committee of the Board of Directors Joseph J. LaRosa, Executive Vice President, General Counsel and Secretary

Re: Waiver and Consent

Reference is hereby made to the Amended and Restated Employment Agreement, dated as of November 14, 2008 (the "Agreement"), between Regeneron Pharmaceuticals, Inc. (the "Company") and Leonard S. Schleifer, M.D., Ph.D. (the "Executive"). Pursuant to Sections 1(a) and 6(c)(ii) of the Agreement, the Company shall, during the Executive's Employment Term (as defined in the Agreement) recommend and propose the Executive as Chairman of the Board of Directors of the Company (the "Board") if the Chairman of the Board as of the date of the Agreement at any time ceases to serve as such; and the failure to elect the Executive as Chairman of the Board if the current Chairman of the Board ceases to serve as such would constitute a "Good Reason" for the Executive's resignation from employment with the Company.

On the date hereof, P. Roy Vagelos, M.D., the current Chairman of the Board (the "Current Chairman"), has notified the Company of his decision not to stand for re-election as a member of the Board when his current term expires and to retire as Chairman effective as of the conclusion of the 2023 annual meeting of shareholders of the Company. Effective upon the expiration of the Current Chairman's term, the Board plans to elect the Executive and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of the Company, as Co-Chairs of the Board.

The undersigned Executive hereby irrevocably waives any rights he may have under the Agreement (or any equity award agreement in which such definition is utilized) to assert the existence of "Good Reason" under the Agreement (or any such equity award agreement) as a result of the election of George D. Yancopoulos, M.D., Ph.D. as Co-Chair of the Board. Except as modified pursuant to this Waiver and Consent, the Agreement shall continue in full force and effect.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows.*]

IN WITNESS WHEREOF, the Executive has executed this Waiver and Consent as of the date first above written:

EXECUTIVE:

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.

AGREED AND ACKNOWLEDGED as of the date first above written:

COMPANY:

By: /s/ Christine A. Poon
Name: Christine A. Poon
Title: Chair of the Compensation Committee of the Board of Directors

Exhibit 31.1

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

I, Leonard S. Schleifer, certify that:

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

Date: August 3, 2023

/s/ Leonard S. Schleifer

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

Exhibit 31.2

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

I, Robert E. Landry, certify that:

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

Date: August 3, 2023

/s/ Robert E. Landry

Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

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

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

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
August 3, 2023

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
August 3, 2023