

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

(Mark One)

- ☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2026
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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock - par value \$.001 per share	REGN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

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

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The number of shares outstanding of each of the registrant's classes of common stock as of October 22, 2026:

Class of Common Stock	Number of Shares
Class A Stock, \$.001 par value	1,817,146
Common Stock, \$.001 par value	101,630,713

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
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"Altibodies™," "ARCALYST®," "Evkeeza®," "EYLEA®," "EYLEA HD®," "Inmaze®," "Libtayo®," "Lynozyl®," "Ordspono™," "Otarmeni®," "Pasatru™," "Praluent®" (in the United States), "REGEN-COV®," "Regeneron®," "Regeneron Genetics Center®," "RGC®," "STEM-Fueled™," "Veloci-Bi®," "VelociGene®," "VelociHum®," "VelociMab®," "VelociImmune®," "VelociMouse®," "VelociSuite®," "VelociT®," "Veopoz®," 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)

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,659.1	\$ 3,118.1
Marketable securities	5,642.0	5,487.1
Accounts receivable, net	7,578.6	5,741.1
Inventories	2,894.6	3,200.8
Prepaid expenses and other current assets	1,020.8	474.8
Total current assets	20,795.1	18,021.9
Marketable securities	9,557.4	10,260.6
Property, plant, and equipment, net	5,727.5	5,120.4
Intangible assets, net	1,315.5	1,257.4
Deferred tax assets	4,535.6	4,077.2
Other noncurrent assets	2,474.1	1,821.2
Total assets	<u>\$ 44,405.2</u>	<u>\$ 40,558.7</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,140.3	\$ 939.0
Accrued expenses and other current liabilities	3,592.0	2,876.4
Finance lease liabilities	720.0	—
Deferred revenue	749.8	553.0
Total current liabilities	6,202.1	4,368.4
Long-term debt	1,987.0	1,985.9
Finance lease liabilities	—	720.0
Deferred revenue	220.2	208.7
Other noncurrent liabilities	2,497.4	2,018.8
Total liabilities	10,906.7	9,301.8
Stockholders' equity:		
Preferred Stock, par value \$.01 per share; 30.0 shares authorized; shares issued and outstanding - none	—	—
Class A Stock, convertible, par value \$.001 per share; 40.0 shares authorized; shares issued and outstanding - 1.8 in 2026 and 2025	—	—
Common Stock, par value \$.001 per share; 320.0 shares authorized; shares issued - 138.5 in 2026 and 137.6 in 2025	0.1	0.1
Additional paid-in capital	15,172.7	13,995.0
Retained earnings	39,471.8	35,797.1
Accumulated other comprehensive (loss) income	(197.5)	77.5
Treasury Stock, at cost; 36.9 shares in 2026 and 33.7 shares in 2025	(20,948.6)	(18,612.8)
Total stockholders' equity	33,498.5	31,256.9
Total liabilities and stockholders' equity	<u>\$ 44,405.2</u>	<u>\$ 40,558.7</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Statements of Operations				
Revenues:				
Net product sales	\$ 1,805.3	\$ 1,587.7	\$ 4,982.2	\$ 4,634.3
Collaboration revenue	3,000.5	1,968.4	7,355.2	5,360.3
Other revenue	310.0	198.2	674.5	464.0
	<u>5,115.8</u>	<u>3,754.3</u>	<u>13,011.9</u>	<u>10,458.6</u>
Expenses:				
Research and development	1,794.7	1,475.0	4,969.8	4,224.1
Acquired in-process research and development	21.5	83.1	250.4	105.4
Selling, general, and administrative	677.8	657.8	1,987.6	1,925.0
Cost of goods sold	321.7	281.0	1,055.8	822.1
Cost of collaboration and contract manufacturing	251.9	240.6	763.7	694.0
Other operating (income) expense, net	—	(10.0)	—	(10.0)
	<u>3,067.6</u>	<u>2,727.5</u>	<u>9,027.3</u>	<u>7,760.6</u>
Income from operations	2,048.2	1,026.8	3,984.6	2,698.0
Other income (expense):				
Other income (expense), net	246.5	755.8	693.0	1,520.6
Interest expense	(10.6)	(19.3)	(34.5)	(31.6)
	<u>235.9</u>	<u>736.5</u>	<u>658.5</u>	<u>1,489.0</u>
Income before income taxes	2,284.1	1,763.3	4,643.1	4,187.0
Income tax expense	<u>335.4</u>	<u>303.3</u>	<u>670.3</u>	<u>526.7</u>
Net income	<u>\$ 1,948.7</u>	<u>\$ 1,460.0</u>	<u>\$ 3,972.8</u>	<u>\$ 3,660.3</u>
Net income per share - basic	\$ 19.16	\$ 14.09	\$ 38.65	\$ 34.83
Net income per share - diluted	\$ 18.45	\$ 13.62	\$ 37.37	\$ 33.61
Weighted average shares outstanding - basic	101.7	103.6	102.8	105.1
Weighted average shares outstanding - diluted	105.6	107.2	106.3	108.9
Statements of Comprehensive Income				
Net income	\$ 1,948.7	\$ 1,460.0	\$ 3,972.8	\$ 3,660.3
Other comprehensive income (loss), net of tax:				
Unrealized (loss) gain on debt securities	(160.8)	15.7	(274.6)	75.9
(Loss) gain on foreign currency translation	(0.9)	0.8	(0.4)	1.0
Comprehensive income	<u>\$ 1,787.0</u>	<u>\$ 1,476.5</u>	<u>\$ 3,697.8</u>	<u>\$ 3,737.2</u>

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, 2025	1.8	\$ —	137.6	\$ 0.1	\$13,995.0	\$35,797.1	\$ 77.5	(33.7)	\$(18,612.8)	\$ 31,256.9
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.3	—	167.0	—	—	—	—	167.0
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(29.1)	—	—	—	—	(29.1)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	21.5	—	—	—	2.5	24.0
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.0)	(803.2)	(803.2)
Dividends declared	—	—	—	—	—	(100.5)	—	—	—	(100.5)
Stock-based compensation charges	—	—	—	—	246.9	—	—	—	—	246.9
Net income	—	—	—	—	—	727.2	—	—	—	727.2
Other comprehensive loss, net of tax	—	—	—	—	—	—	(65.6)	—	—	(65.6)
Balance, March 31, 2026	1.8	—	137.9	0.1	14,401.3	36,423.8	11.9	(34.7)	(19,413.5)	31,423.6
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.1	—	43.4	—	—	—	—	43.4
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(7.7)	—	—	—	—	(7.7)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	21.1	—	—	—	3.1	24.2
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.7)	(1,164.5)	(1,164.5)
Dividends declared	—	—	—	—	—	(99.3)	—	—	—	(99.3)
Stock-based compensation charges	—	—	—	—	242.5	—	—	—	—	242.5
Net income	—	—	—	—	—	1,296.9	—	—	—	1,296.9
Other comprehensive loss, net of tax	—	—	—	—	—	—	(47.7)	—	—	(47.7)
Balance, June 30, 2026	1.8	—	138.0	0.1	14,700.6	37,621.4	(35.8)	(36.4)	(20,574.9)	31,711.4
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.6	—	301.2	—	—	—	—	301.2
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(95.7)	—	—	—	—	(95.7)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	19.4	—	—	—	2.8	22.2
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.5)	(376.5)	(376.5)
Dividends declared	—	—	—	—	—	(98.3)	—	—	—	(98.3)
Stock-based compensation charges	—	—	—	—	247.2	—	—	—	—	247.2
Net income	—	—	—	—	—	1,948.7	—	—	—	1,948.7
Other comprehensive loss, net of tax	—	—	—	—	—	—	(161.7)	—	—	(161.7)
Balance, September 30, 2026	1.8	\$ —	138.5	\$ 0.1	\$15,172.7	\$39,471.8	\$ (197.5)	(36.9)	\$(20,948.6)	\$ 33,498.5

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

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2024	1.8	\$ —	136.0	\$ 0.1	\$12,855.9	\$31,672.9	\$ (7.9)	(28.2)	\$(15,167.4)	\$ 29,353.6
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.1	—	62.9	—	—	—	—	62.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(4.4)	—	—	—	—	(4.4)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	17.8	—	—	—	1.7	19.5
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.5)	(1,052.4)	(1,052.4)
Dividends declared	—	—	—	—	1.0	(97.2)	—	—	—	(96.2)
Stock-based compensation charges	—	—	—	—	258.9	—	—	—	—	258.9
Net income	—	—	—	—	—	808.7	—	—	—	808.7
Other comprehensive income, net of tax	—	—	—	—	—	—	37.0	—	—	37.0
Balance, March 31, 2025	1.8	—	136.1	0.1	13,192.1	32,384.4	29.1	(29.7)	(16,218.1)	29,387.6
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.1	—	28.9	—	—	—	—	28.9
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	—	—	(5.4)	—	—	—	—	(5.4)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	19.2	—	—	—	3.3	22.5
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.9)	(1,069.9)	(1,069.9)
Dividends declared	—	—	—	—	1.1	(95.8)	—	—	—	(94.7)
Stock-based compensation charges	—	—	—	—	254.9	—	—	—	—	254.9
Net income	—	—	—	—	—	1,391.6	—	—	—	1,391.6
Other comprehensive income, net of tax	—	—	—	—	—	—	23.4	—	—	23.4
Balance, June 30, 2025	1.8	—	136.2	0.1	13,490.8	33,680.2	52.5	(31.6)	(17,284.7)	29,938.9
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.1	—	39.8	—	—	—	—	39.8
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(3.0)	—	—	—	—	(3.0)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	17.7	—	—	—	3.3	21.0
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.1)	(663.0)	(663.0)
Dividends declared	—	—	—	—	1.0	(94.4)	—	—	—	(93.4)
Stock-based compensation charges	—	—	—	—	241.0	—	—	—	—	241.0
Net income	—	—	—	—	—	1,460.0	—	—	—	1,460.0
Other comprehensive income, net of tax	—	—	—	—	—	—	16.5	—	—	16.5
Balance, September 30, 2025	<u>1.8</u>	<u>\$ —</u>	<u>136.2</u>	<u>\$ 0.1</u>	<u>\$13,787.3</u>	<u>\$35,045.8</u>	<u>\$ 69.0</u>	<u>(32.7)</u>	<u>\$(17,944.4)</u>	<u>\$ 30,957.8</u>

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

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

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net income	\$ 3,972.8	\$ 3,660.3
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	367.9	398.7
Stock-based compensation expense	756.2	744.4
Gains on marketable and other securities, net	(147.2)	(967.6)
Other, net	201.6	(1.4)
Deferred income taxes	(472.7)	(552.9)
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(1,850.5)	549.3
Decrease (increase) in inventories	110.7	(277.4)
Increase in prepaid expenses and other assets	(856.7)	(458.1)
Increase (decrease) in deferred revenue	208.3	(48.6)
Increase in accounts payable, accrued expenses, and other liabilities	1,384.9	761.5
Total adjustments	(297.5)	147.9
Net cash provided by operating activities	3,675.3	3,808.2
Cash flows from investing activities:		
Purchases of marketable and other securities	(6,234.6)	(8,914.6)
Sales or maturities of marketable and other securities	6,352.1	8,991.2
Capital expenditures	(771.0)	(649.7)
Payments for intangible assets	(156.2)	(273.3)
Acquisitions, net of cash acquired	—	(3.0)
Net cash used in investing activities	(809.7)	(849.4)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	513.2	132.4
Payments in connection with Common Stock tendered for employee tax obligations	(176.5)	(12.9)
Repurchases of Common Stock	(2,363.4)	(2,766.9)
Dividends paid	(290.3)	(277.6)
Other	—	(10.3)
Net cash used in financing activities	(2,317.0)	(2,935.3)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(0.7)	0.6
Net increase in cash, cash equivalents, and restricted cash	547.9	24.1
Cash, cash equivalents, and restricted cash at beginning of period	3,123.7	2,489.0
Cash, cash equivalents, and restricted cash at end of period	\$ 3,671.6	\$ 2,513.1

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, 2025 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, 2025.

Recently Issued Accounting Standards

Standard/Description	Effective Date	Impact of Adoption on the Company's Financial Statements
ASU 2024-03: In November 2024, the FASB issued new guidance which requires disclosure of disaggregated income statement expense information about specific categories (including purchases of inventory, employee compensation, depreciation, and intangible asset amortization) in the notes to financial statements.	January 1, 2027 for annual reporting periods and January 1, 2028 for interim reporting periods	Currently evaluating impact

2. Product Sales

Net product sales consist of the following:

<i>(In millions)</i>		Three Months Ended September 30,		Nine Months Ended September 30,	
		2026	2025	2026	2025
EYLEA HD [®]	U.S.	\$ 698.8	\$ 430.6	\$ 1,763.5	\$ 1,130.6
EYLEA [®]	U.S.	399.7	680.6	1,285.0	2,170.9
Total EYLEA HD and EYLEA	U.S.	1,098.5	1,111.2	3,048.5	3,301.5
Libtayo [®]	U.S.	395.8	219.1	1,024.5	659.4
Libtayo	Rest of world	154.2	146.1	453.1	367.4
Total Libtayo	Global	550.0	365.2	1,477.6	1,026.8
Praluent [®]	U.S.	81.5	67.7	222.8	190.3
Evkeeza [®]	U.S.	55.5	42.8	154.5	114.9
Lynozym [®]	Global	19.0	0.8	46.7	0.8
Other products	Global	0.8	—	32.1	—
		<u>\$ 1,805.3</u>	<u>\$ 1,587.7</u>	<u>\$ 4,982.2</u>	<u>\$ 4,634.3</u>

As of September 30, 2026 and December 31, 2025, the Company had \$4.132 billion and \$3.458 billion, respectively, of trade accounts receivable that were recorded within Accounts receivable, net.

The Company had product sales to certain customers that each accounted for more than 10% of total gross product revenue for the three and nine months ended September 30, 2026 and 2025. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Customer A	48 %	49 %	46 %	51 %
Customer B	30 %	30 %	31 %	26 %

3. Collaboration, License, and Other Agreements

a. Sanofi

The Company is party to a global collaboration with Sanofi to research, develop, and commercialize fully human monoclonal antibodies, which, as of September 30, 2026, consisted of Dupixent® (dupilumab), Kevzara® (sarilumab), and itepekimab.

In October 2026, the parties amended the collaboration agreement to include four additional long-acting, Regeneron-invented antibodies (the "New Licensed Products"). Under the terms of the amendment, the Company received an up-front payment of \$1.0 billion from Sanofi (which will be recorded to Collaboration revenue in the fourth quarter of 2026), and the Company is entitled to receive up to an additional \$7.0 billion in the aggregate upon the achievement of certain development, regulatory, and sales-based milestones. In addition, the Company will have the option, on an asset-by-asset basis after the completion of certain ongoing clinical trials, to include additional Sanofi-developed product candidates in the collaboration. In the event the Company exercises its option for any such product, the Company will reimburse Sanofi for certain development costs related to such product.

Agreed-upon development expenses incurred by the Company and Sanofi are shared equally. Sanofi leads commercialization activities for products under the collaboration agreement, and the Company has the right to co-commercialize such products on a country-by-country basis. The Company co-commercializes Dupixent in the United States and in certain countries outside the United States. The Company also supplies certain commercial bulk product to Sanofi. For Dupixent and Kevzara, the parties equally share profits from sales within the United States, and share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (Regeneron) and ending at 55% (Sanofi)/45% (Regeneron). Global profits from sales of New Licensed Products will be shared equally between the parties.

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

(In millions)	Statement of Operations Classification	Three Months Ended September 30,		Nine Months Ended September 30,	
		2026	2025	2026	2025
Regeneron's share of profits	Collaboration revenue	\$ 2,574.9	\$ 1,455.5	\$ 6,058.3	\$ 3,755.7
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	\$ 149.1	\$ 161.5	\$ 445.1	\$ 488.1
Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses	(R&D expense)	\$ (38.4)	\$ (23.5)	\$ (74.5)	\$ (56.9)
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	\$ 196.1	\$ 182.6	\$ 569.0	\$ 535.8

As of June 30, 2026, the "development balance," which represented the Company's obligation to reimburse Sanofi for development expenses that were previously funded by Sanofi, was fully repaid.

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

(In millions)	September 30, 2026	December 31, 2025
Accounts receivable, net	\$ 2,839.9	\$ 1,610.6
Deferred revenue	\$ 710.5	\$ 442.3

b. Bayer

The Company is party to a license and collaboration agreement with Bayer for the development and commercialization of EYLEA 8 mg (aflibercept 8 mg) and EYLEA (aflibercept). Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. The Company also supplies commercial bulk product to Bayer.

Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits from such sales. Within the United States, the Company is responsible for commercialization and retains profits 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 September 30,		Nine Months Ended September 30,	
		2026	2025	2026	2025
Regeneron's share of profits	Collaboration revenue	\$ 211.5	\$ 311.9	\$ 678.8	\$ 1,012.6
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	\$ 55.3	\$ 32.9	\$ 151.5	\$ 91.1
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	\$ (0.3)	\$ (3.9)	\$ 0.1	\$ (18.9)

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

(In millions)	September 30, 2026	December 31, 2025
Accounts receivable, net	\$ 234.5	\$ 287.6
Deferred revenue	\$ 246.4	\$ 295.7

c. Other

In addition to the collaboration and license agreements discussed above, the Company has collaboration and license agreements that are not individually significant to its operating results or financial condition at this time. Pursuant to the terms of those agreements, the Company may (i) incur, and/or get reimbursed for, research and development expenses, and/or (ii) be required to pay, and/or may receive, additional amounts contingent upon the occurrence of various future events (e.g., upon the achievement of development and commercial milestones), which in the aggregate could be significant.

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

Acquired IPR&D expenses for the nine months ended September 30, 2026 included the premium on equity securities purchased and up-front, opt-in, and development milestone payments in connection with various collaboration and licensing agreements.

Acquired IPR&D expenses for the nine months ended September 30, 2025 included an \$80.0 million up-front payment in connection with the Company's license agreement with Hansoh Pharmaceuticals Group Company Limited.

4. Net Income Per Share

The calculations of basic and diluted net income per share are as follows:

<i>(In millions, except per share data)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income - basic and diluted	\$ 1,948.7	\$ 1,460.0	\$ 3,972.8	\$ 3,660.3
Weighted average shares - basic	101.7	103.6	102.8	105.1
Effect of dilutive securities:				
Stock options	2.4	1.5	2.3	1.8
Restricted stock awards and restricted stock units	1.5	2.1	1.2	2.0
Weighted average shares - diluted	105.6	107.2	106.3	108.9
Net income per share - basic	\$ 19.16	\$ 14.09	\$ 38.65	\$ 34.83
Net income per share - diluted	\$ 18.45	\$ 13.62	\$ 37.37	\$ 33.61

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

<i>(Shares in millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options	3.5	6.3	4.8	6.3
Restricted stock awards and restricted stock units	—	0.9	—	1.0

5. Marketable Securities

Marketable securities as of September 30, 2026 and December 31, 2025 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:

<i>(In millions)</i>				
As of September 30, 2026	Amortized Cost Basis	Unrealized		Fair Value
		Gains	Losses	
Corporate bonds	\$ 10,707.4	\$ 3.9	\$ (126.6)	\$ 10,584.7
U.S. government and government agency obligations	3,477.4	0.1	(38.2)	3,439.3
Commercial paper	402.7	—	(0.6)	402.1
Certificates of deposit	345.1	—	(0.4)	344.7
Asset-backed securities	159.6	—	(0.9)	158.7
Sovereign bonds	90.6	—	(1.2)	89.4
	<u>\$ 15,182.8</u>	<u>\$ 4.0</u>	<u>\$ (167.9)</u>	<u>\$ 15,018.9</u>
As of December 31, 2025				
Corporate bonds	\$ 10,141.0	\$ 80.9	\$ (2.4)	\$ 10,219.5
U.S. government and government agency obligations	4,352.2	15.2	(0.1)	4,367.3
Commercial paper	540.8	0.3	—	541.1
Certificates of deposit	265.7	0.2	—	265.9
Asset-backed securities	241.4	1.4	—	242.8
Sovereign bonds	76.3	0.5	—	76.8
	<u>\$ 15,617.4</u>	<u>\$ 98.5</u>	<u>\$ (2.5)</u>	<u>\$ 15,713.4</u>

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 September 30, 2026 mature at various dates through December 2032. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

<i>(In millions)</i>	September 30, 2026	December 31, 2025
Maturities within one year	\$ 5,642.0	\$ 5,487.1
Maturities after one year through five years	9,375.5	10,224.8
Maturities after five years	1.4	1.5
	<u>\$ 15,018.9</u>	<u>\$ 15,713.4</u>

6. Fair Value Measurements

The following fair value hierarchy is used to classify assets and liabilities, based on inputs to valuation techniques utilized to measure fair value:

- Level 1 - Quoted prices in active markets for identical assets or liabilities
- 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

The following tables summarize the Company's assets that are measured at fair value on a recurring basis:

<i>(In millions)</i> As of September 30, 2026	Fair Value	Fair Value Measurements at Reporting Date	
		Level 1	Level 2
Cash equivalents	\$ 2,644.8	\$ 678.9	\$ 1,965.9
Available-for-sale debt securities:			
Corporate bonds	10,584.7	—	10,584.7
U.S. government and government agency obligations	3,439.3	—	3,439.3
Commercial paper	402.1	—	402.1
Certificates of deposit	344.7	—	344.7
Asset-backed securities	158.7	—	158.7
Sovereign bonds	89.4	—	89.4
Equity securities ^(a)	180.5	180.5	—
	<u>\$ 17,844.2</u>	<u>\$ 859.4</u>	<u>\$ 16,984.8</u>
As of December 31, 2025			
Cash equivalents	\$ 2,121.6	\$ 1,127.7	\$ 993.9
Available-for-sale debt securities:			
Corporate bonds	10,219.5	—	10,219.5
U.S. government and government agency obligations	4,367.3	—	4,367.3
Commercial paper	541.1	—	541.1
Certificates of deposit	265.9	—	265.9
Asset-backed securities	242.8	—	242.8
Sovereign bonds	76.8	—	76.8
Equity securities	34.3	34.3	—
	<u>\$ 17,869.3</u>	<u>\$ 1,162.0</u>	<u>\$ 16,707.3</u>

^(a) Includes equity securities of \$134.5 million as of September 30, 2026 which were subject to transfer restrictions that expire in December 2026

In addition to the investments summarized in the table above, the Company recorded the following investments within Other noncurrent assets:

- As of September 30, 2026 and December 31, 2025, \$607.6 million and \$334.0 million, respectively, of equity securities that do not have a readily determinable fair value. The change in carrying value of such investments was primarily the result of additional purchases.
- As of September 30, 2026 and December 31, 2025, equity and other securities held through ownership interest in an investment fund of \$207.0 million and \$147.5 million, respectively, which are primarily measured at fair value based on Level 3 inputs. The change in carrying value was primarily the result of additional purchases by the fund.

Amounts recognized in Other income (expense), net, related to the Company's investments in equity securities consist of the following:

<i>(In millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net gains recognized during the period	\$ 57.7	\$ 577.0	\$ 143.2	\$ 966.6
Less: Net gains recognized on investments sold during the period	76.6	370.9	76.6	650.4
Net unrealized (losses)/gains recognized on investments still held as of period end date	<u>\$ (18.9)</u>	<u>\$ 206.1</u>	<u>\$ 66.6</u>	<u>\$ 316.2</u>

Other Fair Value Disclosures

The fair value of the Company's long-term debt, which was determined based on Level 2 inputs, was estimated to be \$1.494 billion and \$1.576 billion as of September 30, 2026 and December 31, 2025, respectively. The carrying value was \$1.987 billion as of September 30, 2026 and \$1.986 billion as of December 31, 2025.

7. Inventories

Inventories consist of the following:

<i>(In millions)</i>	September 30, 2026	December 31, 2025
Raw materials	\$ 548.0	\$ 641.5
Work-in-process	1,345.0	1,641.6
Finished goods	101.1	190.2
Deferred costs	900.5	727.5
	<u>\$ 2,894.6</u>	<u>\$ 3,200.8</u>

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's effective tax rate was 14.7% and 17.2% for the three months ended September 30, 2026 and 2025, respectively, and 14.4% and 12.6% for the nine months ended September 30, 2026 and 2025, respectively.

The Company's effective tax rate for the three and nine months ended September 30, 2026 and 2025 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, tax benefits from cross-border tax laws and federal tax credits for research activities, partly offset by changes in unrecognized tax benefits (which, for the nine months ended September 30, 2025, included the release of liabilities upon the settlement of an IRS audit). In addition, the Company's effective tax rate for the three and nine months ended September 30, 2025 was negatively impacted by the enactment of the "One Big Beautiful Bill Act," including the re-measurement of the Company's U.S. net deferred tax assets.

9. Stockholders' Equity

a. Share Repurchase Programs

The Company's board of directors has authorized share repurchase programs, including a share repurchase program for up to \$3.0 billion of the Company's Common Stock which was authorized in April 2026. The programs have no time limit and can be discontinued at any time.

The table below summarizes the shares of the Company's Common Stock that the Company repurchased under its share repurchase programs and the cost of such shares, which were recorded as Treasury Stock.

<i>(In millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Number of shares	0.5	1.1	3.2	4.5
Total cost of shares	\$ 376.5	\$ 663.0	\$ 2,344.2	\$ 2,785.3

As of September 30, 2026, \$2.157 billion remained available for share repurchases under the Company's share repurchase program.

b. Dividends

In each of the first, second, and third quarters of 2026, the Company declared a quarterly cash dividend of \$0.94 per share on its Common Stock and Class A Stock. Each quarterly dividend was paid to the Company's shareholders in the quarter in which the dividend was declared.

Additionally, in October 2026, the Company declared a cash dividend of \$0.94 per share on its Common Stock and Class A Stock. The dividend will be payable to the Company's shareholders in December 2026.

10. Statement of Cash Flows

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

<i>(In millions)</i>	September 30,	
	2026	2025
Cash and cash equivalents	\$ 3,659.1	\$ 2,506.4
Restricted cash included in Other current assets	12.5	6.7
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statements of Cash Flows	\$ 3,671.6	\$ 2,513.1

Restricted cash consists of amounts held pursuant to contractual arrangements and for dividends payable on certain equity awards.

Supplemental disclosure of non-cash investing and financing activities

<i>(In millions)</i>	September 30, 2026	December 31, 2025	September 30, 2025	December 31, 2024
Accrued capital expenditures	\$ 224.0	\$ 178.8	\$ 176.9	\$ 151.6
Accrued contingent consideration in connection with acquisitions	\$ 70.8	\$ 58.9	\$ 52.5	\$ 62.7

11. Segment Information

The Company operates in one business segment, which includes all activities related to the discovery, development, and commercialization of medicines for serious diseases. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Chief Executive Officer, who reviews and evaluates consolidated net income for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

In addition to the significant expense categories included within consolidated net income presented on the Company's Condensed Consolidated Statements of Operations, see below for disaggregated amounts that comprise research and development expenses:

<i>(In millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Direct research and development expenses ^(a)	\$ 589.6	\$ 454.3	\$ 1,627.5	\$ 1,296.7
Indirect research and development expenses:				
Payroll and benefits	471.9	438.3	1,416.4	1,339.5
Lab supplies and other research and development costs	76.3	67.5	207.1	192.4
Occupancy and other operating costs	175.7	166.3	528.6	479.2
Total indirect research and development expenses	723.9	672.1	2,152.1	2,011.1
Clinical manufacturing costs	507.7	381.4	1,276.6	1,028.8
Reimbursement of research and development expenses by collaborators	(26.5)	(32.8)	(86.4)	(112.5)
Total research and development expenses	<u>\$ 1,794.7</u>	<u>\$ 1,475.0</u>	<u>\$ 4,969.8</u>	<u>\$ 4,224.1</u>

^(a) Direct research and development expenses are comprised primarily of costs paid to third parties for clinical development activities, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse

12. Legal Matters

The Company is a party to legal proceedings that arise in the ordinary course of its business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company is unable to prevail in one or more of such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially adversely impacted.

The Company recognizes gain contingencies associated with such proceedings when the award or recovery is realized or realizable and loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of September 30, 2026 and December 31, 2025, 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. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

a. Proceedings Relating to EYLEA (afibercept) Injection

(1) United States

In addition to the patent infringement proceedings in the United States alleging infringement of certain Company patents pertaining to EYLEA discussed below, certain of these patents have also been subject to post-grant proceedings before the United States Patent and Trademark Office (the "USPTO").

On January 10, 2024, the Company filed a patent infringement lawsuit (as amended on January 7, 2026) against Amgen Inc. ("Amgen") in the United States District Court for the Central District of California (subsequently transferred to the United States District Court for the Northern District of West Virginia) alleging that Amgen's filing for U.S. Food and Drug Administration ("FDA") approval of an aflibercept 2 mg biosimilar infringed certain Company patents (as amended, the "2024 lawsuit"). On September 23, 2024, the court denied the Company's motion for a preliminary injunction, which decision was affirmed by the Federal Circuit on March 14, 2025. On June 17, 2025, the Company filed an additional patent infringement lawsuit against Amgen in the United States District Court for the Central District of California (subsequently transferred to the United States District Court for the Northern District of West Virginia) alleging that Amgen's continued commercialization of its aflibercept 2 mg biosimilar infringes the Company's U.S. Patent No. 12,331,099 (the "2025 lawsuit"). On September 12, 2025, Amgen filed its answer and counterclaims in the 2025 lawsuit alleging, among other things, that the Company obtained numerous patents fraudulently, rendering them unenforceable, and that obtaining and enforcing certain Company patents violated Section 2 of the Sherman Antitrust Act of 1890, as amended (the "Sherman Antitrust Act"). On March 9, 2026, Amgen filed its answer and counterclaims in the 2024 lawsuit; and, on April 20, 2026, the Company filed a motion to dismiss certain of Amgen's affirmative defenses and counterclaims in the 2024 lawsuit. On July 7, 2026, the court granted the Company's motion to dismiss Amgen's affirmative defenses and counterclaims challenged in the 2025 lawsuit with the exception of Amgen's prosecution delay affirmative defense and counterclaim. A claim construction hearing has been scheduled for December 1, 2026.

(2) Outside the United States

As described in greater detail below, the Company has filed patent infringement lawsuits against various parties in several jurisdictions outside the United States alleging infringement of certain Company patents pertaining to EYLEA, and certain of these patents have also been subject to post-grant proceedings before the European Patent Office (the "EPO") and/or other comparable foreign authorities.

(i) Multijurisdictional Settlements

Sam Chun Dang. On August 12, 2026, the Company and Bayer Consumer Care AG ("Bayer") entered into a settlement agreement with Sam Chun Dang Pharm. Co., Ltd ("Sam Chun Dang") in respect of Europe, South Korea, and certain other markets in the Asia-Pacific region. Pursuant to the settlement agreement, all pending judicial and administrative proceedings related to Sam Chun Dang's aflibercept 2 mg biosimilar product have been dismissed.

Sandoz. On October 9, 2026, the Company and Bayer entered into a settlement agreement with Sandoz AG and its affiliated entities (collectively, "Sandoz") in respect of all jurisdictions other than the United States, Australia, and Canada (each of which was separately settled in 2025, as previously disclosed). Pursuant to the settlement agreement, all remaining pending judicial and administrative proceedings related to Sandoz's aflibercept 2 mg biosimilar product, including the previously disclosed litigation in Germany, have been or will be dismissed.

(ii) Europe – EPO Post-Grant Proceedings

The Company's European Patent Nos. 2,944,306 (the "'306 Patent'"), 3,716,992 (the "'992 Patent'"), and 3,384,049 (the "'049 Patent'") have been subject to post-grant proceedings before the Opposition Division ("OD") of the EPO:

- On November 26, 2024, following an oral hearing, the OD announced its decision to revoke the '306 Patent, which decision has been appealed by Regeneron.
- On October 22, 2025, following an oral hearing, the OD upheld the validity of the '992 Patent's claims in amended form, which decision has been appealed by Amgen.
- On April 21, 2026, following an oral hearing, the OD invalidated the '049 Patent. The Company did not appeal the OD's decision and, as a result, the '049 Patent has been revoked.

b. Proceedings Relating to EYLEA HD (aflibercept 8 mg) Injection

As described in greater detail below, certain of the Company's patents pertaining to EYLEA HD are subject to post-grant proceedings before the USPTO and the EPO as well as patent proceedings in certain jurisdictions outside the United States.

(1) United States – USPTO Post-Grant Proceedings

On September 18, 2025, Alvotech USA Inc. and Alvotech hf. (collectively, "Alvotech") petitioned the USPTO's Patent Trial and Appeal Board ("PTAB") for post-grant review ("PGR") of the Company's U.S. Patent No. 12,168,036 (the "'036 Patent'"), alleging that such patent is invalid. On March 3, 2026, the PTAB instituted a PGR of the '036 Patent. Oral argument before the PTAB is scheduled for December 4, 2026.

(2) Outside the United States

(i) EPO Post-Grant Proceedings

Various parties, including Advanz Pharma Services UK Limited ("Advanz UK"), Alvotech hf., Amgen Inc., Intas Pharmaceuticals Ltd., Sandoz AG, and other, anonymous parties, are seeking revocation of the Company's European Patent Nos. 4,185,318 (the "'318 Patent") and 4,364,724 (the "'724 Patent") before the OD of the EPO.

(ii) Country-Specific Proceedings in Europe

In July and August 2026, Advanz Pharma Italia S.r.l. and Advanz UK (collectively, "Advanz") commenced actions against the Company and Bayer in Italy and the United Kingdom, respectively, seeking declarations that the Italian designations (in the Italian proceedings) and United Kingdom designations (in the U.K. proceedings) of the '318 Patent, the '724 Patent, and the Company's European Patent No. 3,790,532 are invalid as well as a declaration that Advanz's aflibercept 8 mg biosimilar does not infringe one or more of these patents.

c. Proceedings Relating to EYLEA (aflibercept) Injection Pre-filled Syringe

On July 17, 2020, the Company filed an antitrust lawsuit (as amended on January 25, 2021) against Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") and Vetter Pharma International GmbH in the United States District Court for the Southern District of New York (the "SDNY") seeking a judgment that the defendants' conduct relating to Novartis's attempt to assert its U.S. Patent No. 9,220,631 against Regeneron in 2020 violated Sections 1 and 2 of the Sherman Antitrust Act, and constituted tortious interference with contract. The Company is also seeking injunctive relief and treble damages. On September 21, 2021, this lawsuit was transferred to the Northern District of New York. 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 (the "Second Circuit"). On March 18, 2024, the Second Circuit reversed the District Court's decision to dismiss the amended complaint and remanded the lawsuit to the District Court for further proceedings consistent with the Second Circuit's opinion. On November 19, 2024, the Company moved to transfer the lawsuit back to the SDNY, which motion was granted on December 5, 2024.

d. Proceedings Relating to Praluent (alirocumab) Injection

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. A trial was held in May 2025. On May 15, 2025, the jury reached a verdict in Regeneron's favor on nine of the ten counts submitted to it and awarded Regeneron \$135.6 million in compensatory damages and \$271.2 million in punitive damages. On June 20, 2025, Amgen filed a post-trial motion for judgment as a matter of law or, in the alternative, for a new trial. Also on June 20, 2025, the Company filed a post-trial motion for (i) permanent injunctive relief, (ii) a constructive trust, and (iii) prejudgment interest. An oral hearing on Amgen's and Regeneron's respective post-trial motions was held on August 27, 2025.

e. Department of Justice Matters

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 (the "June 2020 Civil Complaint") relating to the Company's support of 501(c)(3) organizations that provide financial assistance to patients. On September 27, 2023, the court (i) denied in part and granted in part the Company's motion for summary judgment and (ii) denied in its entirety the motion for partial summary judgment filed by the U.S. Attorney's Office for the District of Massachusetts. On October 25, 2023, the court certified for interlocutory appeal a portion of the court's September 27, 2023 order that addressed the causation standard applicable to the alleged violations of the federal Anti-Kickback Statute and federal False Claims Act. On February 18, 2025, the U.S. Court of Appeals for the First Circuit affirmed the portion of the court's September 27, 2023 order that had been certified for interlocutory appeal. On October 1, 2025, the U.S. Attorney's Office for the District of Massachusetts filed a second motion for partial summary judgment.

On June 3, 2021, the United States District Court for the Central District of California unsealed a qui tam complaint (as amended on October 29, 2021) 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"). The amended complaint alleges violations of the federal Anti-Kickback Statute and asserts causes of action under the federal False Claims Act and state law relating to allegedly unlawful remuneration and assistance provided to prescribers. 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 January 14, 2022, the Company filed a motion to dismiss the amended complaint in its entirety. On July 25, 2023, the

court granted in part and denied in part the Company's motion to dismiss. On September 1, 2023, the Company filed a second motion to dismiss the amended complaint or, in the alternative, a motion for judgment on the pleadings. On July 31, 2024 and August 15, 2024, respectively, the District Court granted the Company's second motion to dismiss the amended complaint with respect to the remaining causes of action under federal law and declined to exercise supplemental jurisdiction over the remaining causes of action under state law. On August 26, 2024, the qui tam plaintiffs filed a notice of appeal. Oral argument on the appeal was held on November 18, 2025. On August 19, 2026, the U.S. Court of Appeals for the Ninth Circuit (the "Ninth Circuit") reversed the District Court's decision to dismiss the amended complaint with respect to Regeneron in part, affirmed the decision in part, and remanded the lawsuit to the District Court for further proceedings.

In June 2021, the Company received a civil investigative demand ("CID") from the U.S. Department of Justice pursuant to the federal False Claims Act relating to, among other things, alleged 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. On March 28, 2024, the U.S. District Court for the District of Massachusetts unsealed a qui tam complaint against the Company and others by two qui tam plaintiffs, purportedly on behalf of the United States and various states and municipalities, asserting causes of action under the federal False Claims Act and state and local laws, and alleging violations of the federal Anti-Kickback statute related to, among other things, the alleged conduct described above. Also on March 28, 2024, the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint in partial intervention (the "March 2024 Civil Complaint") of the qui tam action, in the same court, asserting causes of action under the federal False Claims Act and a claim for unjust enrichment related to the alleged conduct described above. On June 25, 2024, the States of Colorado, Georgia, Michigan, North Carolina, Texas, and Washington filed a civil complaint in partial intervention (the "June 2024 Civil Complaint") in the same court asserting causes of action under various state laws related to the same alleged conduct. On April 29, 2025, the court denied the Company's motion to dismiss the March 2024 Civil Complaint and the June 2024 Civil Complaint. On June 18, 2025, the States of Maine, Nebraska, Ohio, Oregon, and Wyoming intervened in the action and filed a consolidated complaint asserting causes of action under their respective state laws.

On January 20, 2026, a qui tam plaintiff filed a complaint under seal against the Company and other pharmaceutical companies purportedly on behalf of the United States and various states. The complaint alleges violations of the federal Anti-Kickback Statute and other laws and asserts causes of action under the federal False Claims Act and various state laws relating to allegedly unlawful remuneration and assistance provided to prescribers. On May 22, 2026 and June 17, 2026, respectively, the United States and the applicable states notified the court of their decisions to decline to intervene in the case. On June 18, 2026, the United States District Court for the Central District of California unsealed the qui tam complaint. On July 20, 2026, the plaintiff filed an amended complaint. On August 19, 2026, the court dismissed the amended complaint; and, on September 9, 2026, the plaintiff filed a second amended complaint. On October 19, 2026, the court dismissed the action as to all defendants without prejudice for failure to timely serve the complaint and ordered the case closed.

f. Proceedings Initiated by Other Payors

The Company is party to several lawsuits relating to the conduct alleged in the June 2020 Civil Complaint discussed under "e. 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 SDNY 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 ("RICO") 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 SDNY pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts concerning the allegations in the June 2020 Civil Complaint. 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 concerning the allegations in the June 2020 Civil Complaint; and, in light of these stays, the parties to the Local 464A action have also agreed to stay that matter.

On June 24, 2024, a group of plaintiffs purporting to be assignees of claims by various Medicare Advantage plans and related entities filed a putative class action complaint in the U.S. District Court for the District of Columbia on behalf of Medicare Advantage plans and other payors. The lawsuit relates to the conduct alleged in the June 2020 Civil Complaint, March 2024 Civil Complaint, and June 2024 Civil Complaint discussed under "e. Department of Justice Matters" above. The lawsuit alleges causes of action under state law and RICO and seeks monetary damages and equitable relief. On October 22, 2024, the Company filed a motion to transfer the proceedings to the U.S. District Court for the District of Massachusetts or, in the alternative, to stay the proceedings or dismiss the proceedings. On January 28, 2025, pursuant to a stipulation among the

parties, the proceedings were transferred to the U.S. District Court for the District of Massachusetts. On February 1, 2025, the parties jointly filed a stipulation to stay the action pending resolution of the proceedings before the same court concerning the allegations in the June 2020 Civil Complaint.

g. Shareholder Derivative Complaint – Department of Justice June 2020 Civil Complaint Matters

On June 29, 2021, an alleged shareholder filed a shareholder derivative complaint in the Supreme Court of the State of New York (the "NY Supreme Court"), naming the then-current and certain former members of the Company's board of directors and certain then-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 June 2020 Civil Complaint discussed under "e. 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 NY Supreme Court to the SDNY. On September 23, 2021, the plaintiff moved to remand the case to the NY Supreme Court. Also on September 23, 2021, the individual defendants moved to dismiss the complaint in its entirety. On December 19, 2022, the SDNY 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 concerning the allegations in the June 2020 Civil Complaint. 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.

h. Shareholder Derivative Complaints – Department of Justice March 2024 Civil Complaint Matters

In 2025, various purported shareholders of the Company filed several shareholder derivative complaints in the SDNY or the NY Supreme Court against 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 complaints allege that the individual defendants, among other things, breached their fiduciary duties to the Company by failing to properly manage and oversee the Company in connection with the conduct alleged in the March 2024 Civil Complaint discussed under "e. Department of Justice Matters" above, and one lawsuit also alleges a breach of fiduciary duty relating to the conduct alleged in the January 2025 Class Action Complaint discussed under "k. Class Action Civil Complaints" below. The complaints also allege that the individual defendants breached the federal securities laws, wasted corporate assets, and unjustly enriched themselves at the expense of the Company. The complaints seek, among other things, an award of damages allegedly sustained by the Company as a result of the alleged misconduct of the individual defendants; an order requiring the individual defendants to take all necessary actions to reform and improve the Company's corporate governance and internal procedures; and costs and disbursements of the applicable action, including attorneys' fees. The cases filed in the SDNY were consolidated and stayed pending resolution of the motion to dismiss, including any appeal of the decision on the motion to dismiss, filed in the January 2025 Class Action Complaint discussed under "k. Class Action Civil Complaints" below. The shareholder derivative complaints filed in the NY Supreme Court were removed to the SDNY, and the purported shareholders filed motions to remand. On March 16, 2026, the SDNY denied the motions to remand and consolidated the cases with the other shareholder derivative lawsuits pending in the SDNY (which, as noted above, are subject to a stay).

i. Shareholder Derivative Complaint – July 2026 Securities Class Action

On September 23, 2026, an alleged shareholder filed a shareholder derivative complaint in the SDNY, naming members of the Company's board of directors and certain executive officers and employees of the Company as defendants and Regeneron as a nominal defendant. The complaint alleges, among other things, that the individual defendants violated securities laws, breached their fiduciary duties, and wasted corporate assets by failing to properly manage and oversee the Company in connection with the conduct alleged in the July 2026 Class Action Complaint discussed under "k. Class Action Civil Complaints" below.

j. Shareholder Derivative Complaint – Director Compensation

On July 22, 2025, an alleged shareholder filed a shareholder derivative complaint in the NY Supreme Court, naming the current non-employee members of the Company's board of directors, and the co-Chairs of the Company's board of directors (who also serve as Regeneron's President and Chief Executive Officer and Regeneron's President and Chief Scientific Officer, respectively) as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and/or were unjustly enriched when they approved and/or received allegedly excessive non-employee director compensation in 2024 and 2025, and that this allegedly excessive compensation was a waste of corporate assets. The complaint seeks damages in favor of Regeneron for the alleged breaches of fiduciary duties, unjust enrichment, and waste of corporate assets; improvements to Regeneron's corporate governance and internal procedures; equitable relief, including restitution from the individual defendants; and award of the costs of the action, including attorneys' fees. An oral

hearing on the Company's motion to dismiss the complaint was held on April 17, 2026. On June 22, 2026, plaintiff's counsel filed a motion to substitute the named plaintiff. On October 9, 2026, the court denied the Company's motion to dismiss as to the plaintiff's breach of fiduciary duty claim, but granted it as to the unjust enrichment and corporate waste claims. The court also granted the plaintiff's motion to substitute the named plaintiff.

k. Class Action Civil Complaints

On January 7, 2025 (as amended on September 8, 2025 and October 30, 2025), a purported shareholder filed a putative class action civil complaint (the "January 2025 Class Action Complaint"), on behalf of himself and all others similarly situated, in the SDNY against the Company and certain current and former executive officers of the Company. The second amended complaint asserts violations of federal securities laws in connection with statements or disclosures purportedly related to the conduct alleged in the March 2024 Civil Complaint discussed under "e. Department of Justice Matters" above as well as allegations relating to the launch of EYLEA HD. On July 10, 2025, the court appointed a lead plaintiff and lead counsel for the action. On November 17, 2025, the Company filed a motion to dismiss the second amended complaint. An oral hearing on the Company's motion to dismiss was held on June 25, 2026. On September 18, 2026, the court granted the Company's motion to dismiss; and, on October 15, 2026, the purported shareholder filed a notice of appeal.

On July 16, 2026, a purported shareholder filed a putative class action civil complaint (the "July 2026 Class Action Complaint"), on behalf of herself and all others similarly situated, in the SDNY against the Company and certain employees of the Company. The complaint asserts violations of federal securities laws in connection with statements or disclosures purportedly related to the Company's fianlimab clinical development program.

l. Sanofi Litigation

On November 18, 2024, the Company filed a lawsuit (as amended on December 20, 2024) in the SDNY against Sanofi and certain of its affiliated entities (collectively, "Sanofi"). The lawsuit alleged that the defendants breached certain provisions of the parties' Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009 (as amended, the "Collaboration Agreement"), concerning Sanofi's obligation to provide Regeneron with full access to material information relating to the commercialization of Dupixent or other products commercialized pursuant to the Collaboration Agreement and Regeneron's audit rights under the Collaboration Agreement. The lawsuit sought a declaratory judgment, injunctive relief, damages, and other relief. On March 17, 2026, the court denied Sanofi's motion to dismiss the complaint. On October 1, 2026, the parties entered into a settlement agreement, pursuant to which this lawsuit has been dismissed.

m. Dupixent Product Liability Litigation

Since 2025, a number of product liability lawsuits have been filed in various U.S. district and state courts against the Company and certain of Sanofi's affiliated entities claiming that Dupixent either caused or exacerbated the patients' T-cell lymphoma, and asserting causes of action under various state laws. On February 13, 2026, several of the plaintiffs filed a motion with the United States Judicial Panel on Multidistrict Litigation (the "JPML") seeking to consolidate the federal lawsuits for coordinated pretrial proceedings. On June 4, 2026, the JPML issued an order transferring the federal lawsuits to the District of New Jersey for coordinated pretrial proceedings. On September 15, 2026, the parties filed a joint request seeking to consolidate the state lawsuits in New Jersey for coordinated pretrial proceedings.

On July 17, 2026, two plaintiffs filed a putative class action lawsuit in the United States District Court for the District of Maryland, alleging that the Company failed to warn that Dupixent allegedly causes or is linked to the development of cutaneous T-cell lymphoma. The complaint asserts causes of action under various state laws and seeks damages and equitable relief, including the creation of a fund to finance Dupixent medical monitoring and treatment services. On August 25, 2026, this action was transferred to the federal multidistrict litigation pending in the District of New Jersey.

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:

- competing products and product candidates (including biosimilar products) that may be superior to, or more cost effective than, 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");*
- 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 or other factors beyond Regeneron's control on the commercial success of Regeneron's Products and Regeneron's Product Candidates;*
- the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's Product Candidates and research and clinical programs now underway or planned, including without limitation those discussed or referenced in this report, 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 Regeneron's Product Candidates and new indications for Regeneron's Products, including without limitation those discussed or referenced in this report;*
- 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;*
- our ability to manufacture and manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions;*
- 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, 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 other third parties and new policies and procedures adopted by such payors and other third parties;*
- changes to drug pricing regulations and requirements and our drug pricing strategy, including in connection with our April 2026 agreements with the U.S. government discussed in this report;*
- other changes in laws, regulations, and policies affecting the healthcare industry;*
- the costs of developing, producing, and selling products or unanticipated expenses;*
- our ability to meet any of our financial projections or guidance 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 on our business; and*
- risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 12 to our Condensed Consolidated Financial Statements included in this report), risks associated with intellectual property of the Company or other parties and pending or future litigation or patent office proceedings relating thereto (including without limitation the patent litigation and other related proceedings described further in Note 12 to our Condensed Consolidated Financial*

Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition.

These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update (publicly 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Our core business strategy is to maintain a strong foundation in scientific research and drug development using our proprietary 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:

(In millions, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenues	\$ 5,115.8	\$ 3,754.3	\$ 13,011.9	\$ 10,458.6
Net income	\$ 1,948.7	\$ 1,460.0	\$ 3,972.8	\$ 3,660.3
Net income per share - diluted	\$ 18.45	\$ 13.62	\$ 37.37	\$ 33.61

For purposes of this report, references to our products encompass products 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. Certain products have also received marketing approval in countries outside the United States, European Union ("EU"), or Japan.

Product	Disease	Territory		
		U.S.	EU	Japan
EYLEA HD [®] (aflibercept) Injection 8 mg ^(a)	Wet age-related macular degeneration ("wAMD")	✓	✓	✓
	Diabetic macular edema ("DME")	✓	✓	✓
	Diabetic retinopathy ("DR")	✓		
	Macular edema following retinal vein occlusion ("RVO")	✓	✓	✓
EYLEA [®] (aflibercept) Injection ^(a)	wAMD	✓	✓	✓
	DME	✓	✓	✓
	DR	✓		
	RVO	✓	✓	✓
	Myopic choroidal neovascularization ("mCNV")		✓	✓
	Neovascular glaucoma ("NVG")			✓
	Retinopathy of prematurity ("ROP")	✓	✓	✓

Product (<i>continued</i>)	Disease	Territory		
		U.S.	EU	Japan
Dupixent® (dupilumab) Injection ^(b)	Atopic dermatitis (in patients aged 6 months and older)	✓	✓	✓
	Asthma (in patients aged 6 years and older)	✓	✓	✓
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP") (in adults)	✓	✓	✓
	CRSwNP (in adolescents)	✓		
	Chronic obstructive pulmonary disease ("COPD")	✓	✓	✓
	Eosinophilic esophagitis ("EoE") (in patients aged 1 year and older)	✓	✓	
	Prurigo nodularis	✓	✓	✓
	Chronic spontaneous urticaria ("CSU") (in adults and adolescents)	✓	✓	✓
	CSU (in pediatrics 2–11 years of age)	✓	✓	
	Bullous pemphigoid	✓		✓
	Allergic fungal rhinosinusitis ("AFRS") (in patients aged 6 years and older)	✓		
Libtayo® (cemiplimab) Injection	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC"), monotherapy and in combination with chemotherapy	✓	✓	✓
	Metastatic or locally advanced basal cell carcinoma ("BCC")	✓	✓	
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✓	✓	✓
	Adjuvant CSCC	✓	✓	✓
	Metastatic or recurrent second-line cervical cancer		✓	✓
Praluent® (alirocumab) Injection ^(c)	Cardiovascular risk reduction in patients at increased risk of cardiovascular events	✓	✓	
	Hypercholesterolemia	✓	✓	
	Heterozygous familial hypercholesterolemia ("HeFH") (in patients aged 8 years and older)	✓	✓	
	Homozygous familial hypercholesterolemia ("HoFH")	✓		
Kevzara® (sarilumab) Injection ^(b)	Rheumatoid arthritis ("RA")	✓	✓	✓
	Polymyalgia rheumatica ("PMR")	✓	✓	
	Polyarticular juvenile idiopathic arthritis ("pJIA")	✓	✓	
Evkeeza® (evinacumab) Injection ^(d)	HoFH (in adults, adolescents, and pediatrics)	✓	✓	✓
Ordspono™ (odronextamab)	Follicular lymphoma ("FL")		✓	
	Diffuse large B-cell lymphoma ("DLBCL")		✓	
Lynozyfic® (linvoseltamab)	Relapsed/refractory multiple myeloma	✓	✓	
Inmaze® (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by <i>Zaire ebolavirus</i>	✓		
Pasatru™ (garetosmab)	Fibrodysplasia ossificans progressiva ("FOP")	✓		

Product (continued)	Disease	Territory		
		U.S.	EU	Japan
Veopoz® (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in patients aged 1 year and older)	✓		
Otarmeni® (lunsotogene parvec)	Hearing loss associated with variants in the <i>OTOF</i> gene (in adults, adolescents, and pediatrics)	✓		
ARCALYST® (rilonacept) Injection ^(e)	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, adolescents, and pediatrics)	✓		
	Recurrent pericarditis (in adults and adolescents)	✓		
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion ^(f)	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. Aflibercept 8 mg is known as EYLEA HD in the United States and EYLEA 8 mg in other countries.

^(b) In collaboration with Sanofi

^(c) The Company is responsible for the development and commercialization of Praluent in the United States and Sanofi is responsible for the development and commercialization of Praluent outside the United States

^(d) The Company is responsible for the development and commercialization of Evkeeza in the United States and Ultragenyx is responsible for the development and commercialization of Evkeeza outside the United States

^(e) Kiniksa is responsible for the development and commercialization of ARCALYST

^(f) Sanofi is responsible for the development and commercialization of ZALTRAP

The table below includes net product sales of Regeneron-discovered products. Such net product sales are recorded by us or others, as further described in the footnotes to the table. We believe the information in the table is useful to investors as it demonstrates our pipeline productivity and our ability to innovate, discover, and develop new products, and bring those products to market either alone or based on contractual arrangements with other parties, which has a direct impact on our results of operations and financial condition. The table also shows the degree to which we, a collaborator, and/or a licensee is currently commercializing the products discovered by Regeneron. In addition, this information allows management and investors to assess the commercial trends and developments impacting Regeneron-discovered products. In arrangements where our collaborator or licensee is currently commercializing such products and is recording net product sales as a result, the net product sales shown in the table also are an important metric for management's review and assessment of (i) the revenues we record for our share of profits and/or royalties from such sales and (ii) the impact of our obligation to supply commercial product to certain of these collaborators or licensees.

	Three Months Ended September 30,						
	2026			2025			% Change
(In millions)	U.S.	ROW ^(f)	Total	U.S.	ROW	Total	(Total Sales)
Dupixent ^(a)	\$ 5,064.1	\$ 1,476.4	\$ 6,540.5	\$ 3,618.8	\$ 1,238.2	\$ 4,857.0	35%
EYLEA HD ^(b)	\$ 698.8	\$ 384.0	\$ 1,082.8	\$ 430.6	\$ 232.4	\$ 663.0	63%
EYLEA ^(b)	\$ 399.7	\$ 258.7	\$ 658.4	\$ 680.6	\$ 621.4	\$ 1,302.0	(49%)
Total EYLEA HD and EYLEA	\$ 1,098.5	\$ 642.7	\$ 1,741.2	\$ 1,111.2	\$ 853.8	\$ 1,965.0	(11%)
Libtayo ^(c)	\$ 395.8	\$ 154.2	\$ 550.0	\$ 219.1	\$ 146.1	\$ 365.2	51%
Praluent ^(d)	\$ 81.5	\$ 179.4	\$ 260.9	\$ 67.7	\$ 148.0	\$ 215.7	21%
Kevzara ^(a)	\$ 192.7	\$ 62.9	\$ 255.6	\$ 102.9	\$ 51.1	\$ 154.0	66%
Lynozyfic	\$ 18.6	\$ 0.4	\$ 19.0	\$ 0.8	\$ —	\$ 0.8	*
Other products ^(e)	\$ 56.2	\$ 35.1	\$ 91.3	\$ 43.1	\$ 28.0	\$ 71.1	28%

	Nine Months Ended September 30,						
	2026			2025			% Change
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
Dupixent ^(a)	\$ 13,183.6	\$ 4,235.2	\$ 17,418.8	\$ 9,453.2	\$ 3,414.0	\$ 12,867.2	35%
EYLEA HD ^(b)	\$ 1,763.5	\$ 1,082.8	\$ 2,846.3	\$ 1,130.6	\$ 620.5	\$ 1,751.1	63%
EYLEA ^(b)	\$ 1,285.0	\$ 955.1	\$ 2,240.1	\$ 2,170.9	\$ 2,068.8	\$ 4,239.7	(47%)
Total EYLEA HD and EYLEA	\$ 3,048.5	\$ 2,037.9	\$ 5,086.4	\$ 3,301.5	\$ 2,689.3	\$ 5,990.8	(15%)
Libtayo ^(c)	\$ 1,024.5	\$ 453.1	\$ 1,477.6	\$ 659.4	\$ 367.4	\$ 1,026.8	44%
Praluent ^(d)	\$ 222.8	\$ 549.4	\$ 772.2	\$ 190.3	\$ 440.7	\$ 631.0	22%
Kevzara ^(a)	\$ 436.6	\$ 169.7	\$ 606.3	\$ 271.4	\$ 151.2	\$ 422.6	43%
Lynozyfic	\$ 45.5	\$ 1.2	\$ 46.7	\$ 0.8	\$ —	\$ 0.8	*
Other products ^(e)	\$ 187.3	\$ 95.0	\$ 282.3	\$ 116.3	\$ 81.5	\$ 197.8	43%

* Percentage not meaningful or greater than 100%

^(a) Sanofi records global net product sales of Dupixent and Kevzara, and we record our share of profits in connection with global sales of such products within Collaboration revenue. Refer to "Results of Operations - Revenues - Sanofi Collaboration Revenue" below for such amounts.

^(b) We record net product sales of EYLEA HD and EYLEA in the United States, and Bayer records net product sales outside the United States. We record our share of profits in connection with sales outside the United States within Collaboration revenue; refer to "Results of Operations - Revenues - Bayer Collaboration Revenue" below for such amounts.

^(c) We record global net product sales of Libtayo and pay Sanofi a royalty on such sales

^(d) We record net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays us a royalty on such sales, which is recorded within Other revenue.

^(e) Included in this line item are products which are sold by us and others. Refer to "Results of Operations - Revenues" below for a listing of net product sales recorded by us. Not included in this line item are net product sales of ARCALYST, which are recorded by Kiniksa.

^(f) Rest of world ("ROW")

Programs in Clinical Development

Product candidates in Phase 2 and Phase 3 clinical development that are being developed by us and/or our collaborators are summarized in the table below. A program is classified in Phase 2 or 3 clinical development after enrollment for the corresponding study or studies has commenced.

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 2	Phase 3	Regulatory Review ^(h)	2026 Events to Date	Select Upcoming Milestones
Ophthalmology					
EYLEA HD (aflibercept) 8 mg^(a)			–Pre-filled syringe (U.S.)	–Approved by European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") for RVO –Approved by U.S. Food and Drug Administration ("FDA") for extension of dosing intervals up to 20 weeks in wAMD and DME	–FDA decision for pre-filled syringe
Cemdisiran^(k) (RNAi therapeutic targeting C5) ± pozelimab⁽ⁿ⁾ (antibody to C5)		–Geographic atrophy			–Report initial results from lead-in cohort of Phase 3 study in geographic atrophy (combination and cemdisiran monotherapy) (first quarter 2027)
Immunology & Inflammation					
Dupixent (dupilumab)^(b) <i>Antibody to IL-4R alpha subunit</i>		–Asthma in pediatrics (2–5 years of age) –Chronic pruritus of unknown origin ("CPUO")	–CSU in pediatrics (2–11 years of age) (Japan) –AFRS (Japan)	–Approved by FDA for AFRS –Approved by FDA and EC for CSU in pediatrics –Approved by MHLW for bullous pemphigoid –Withdrew regulatory application in EU for bullous pemphigoid –Phase 3 studies in lichen simplex chronicus did not meet primary endpoints	
Kevzara (sarilumab)^(b) <i>Antibody to IL-6R</i>	–Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)				
Freneslerbart-mevonlerbart⁽ⁿ⁾ (REGN1908-1909) <i>Multi-antibody therapy to Fel d 1</i>		–Cat allergy		–Initiated second Phase 3 trial in cat allergy	

Clinical Program (continued)	Phase 2	Phase 3	Regulatory Review ^(h)	2026 Events to Date	Select Upcoming Milestones
Solid Tumor Oncology					
Libtayo (cemiplimab)^{(f)(g)} <i>Antibody to PD-1</i>	<ul style="list-style-type: none"> –Neoadjuvant CSCC –First-line NSCLC, BNT116⁽ⁱ⁾ combination –Neoadjuvant NSCLC –Neoadjuvant hepatocellular carcinoma ("HCC") 	<ul style="list-style-type: none"> –Early-stage CSCC (intralesional) 	<ul style="list-style-type: none"> –Every 6-week dosing regimen for approved indications (U.S. and EU) 	<ul style="list-style-type: none"> –Approved by MHLW for adjuvant and advanced CSCC –European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") adopted positive opinion for every 6-week dosing regimen for approved indications –Presented longer-term data from Phase 3 study in adjuvant CSCC at European Society for Medical Oncology ("ESMO") 2026 Meeting 	<ul style="list-style-type: none"> –FDA decision on supplemental Biologics License Application ("sBLA") (March 2027) and EC decision on regulatory submission (fourth quarter 2026) for every 6-week dosing regimen for approved indications
Fianlimab^(f) (REGN3767) <i>(antibody to LAG-3) + Libtayo (cemiplimab)^(f)</i>	<ul style="list-style-type: none"> –Perioperative NSCLC –Perioperative melanoma –First-line metastatic head and neck squamous cell carcinoma 	<ul style="list-style-type: none"> –First-line metastatic melanoma^(e) –Adjuvant melanoma 		<ul style="list-style-type: none"> –Reported that Phase 3 study versus pembrolizumab in first-line metastatic melanoma did not reach statistical significance for primary endpoint –Phase 3 adjuvant melanoma study passed both pre-planned interim analyses conducted by Independent Data Monitoring Committee; study will continue to final analysis –Phase 2 data in first-line advanced NSCLC did not support advancement to Phase 3 	<ul style="list-style-type: none"> –Report results from Phase 3 study versus pembrolizumab in adjuvant melanoma (first half 2027)
Vidutolimod <i>Immune activator targeting TLR9</i>					

Clinical Program (continued)	Phase 2	Phase 3	Regulatory Review ^(h)	2026 Events to Date	Select Upcoming Milestones
Ubamatamab⁽ⁿ⁾ (REGN4018) <i>Bispecific antibody targeting MUC16 and CD3</i>	–High-grade serous ovarian cancer –Low-grade serous ovarian cancer (potentially pivotal study) –Advanced NSCLC ^(l)			–Reported data from Phase 1/2 trial in patients with low-grade serous ovarian cancer	
REGN5668^(p) <i>Bispecific antibody targeting MUC16 and CD28</i>	–Ovarian cancer				
Nezastomig (REGN5678) <i>Bispecific antibody targeting PSMA and CD28</i>	–Prostate cancer				
Marlotamig (REGN7075) <i>Bispecific antibody targeting EGFR and CD28</i>	–Solid tumors				
REGN10597 <i>Antibody-targeted cytokine PD1-IL2Rα-IL2</i>	–Solid tumors				
Davutamig (REGN5093) <i>Bispecific antibody targeting two distinct MET epitopes</i>	–MET-altered advanced NSCLC				
Hematology-Oncology					
Ordspono (odronextamab) <i>Bispecific antibody targeting CD20 and CD3</i>	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–Lymphoma ^{(c)(e)} (multiple lines and settings)	– Relapsed/refractory DLBCL (U.S.)		–FDA decision on BLA for relapsed/refractory DLBCL (February 2027) –Report potentially pivotal data in low-grade lymphoma (fourth quarter 2026)
Lynozyfic (linvoseltamab)^(r) <i>Bispecific antibody targeting BCMA and CD3</i>	–Multiple myeloma precursor and related conditions	–Multiple myeloma ^(c) ^(e) (multiple lines and settings)		–Reported positive data from Phase 1/2 trial in amyloid light chain amyloidosis; results presented at American Society of Clinical Oncology ("ASCO") 2026 Annual Meeting	

Clinical Program (continued)	Phase 2	Phase 3	Regulatory Review ^(h)	2026 Events to Date	Select Upcoming Milestones
Cardiometabolic/Internal Medicine					
Cenvacibart (REGN7508) <i>Antibody to Factor XI (catalytic domain)</i>	–Thrombosis	–Venous thromboembolism ("VTE") after total knee replacement surgery –Cancer-associated VTE –Stroke prevention in atrial fibrillation ("SPAF") –Peripheral artery disease ("PAD") –Peripherally inserted central catheter ("PICC")-associated thrombosis			–Initiate additional Phase 3 study in anticoagulation (fourth quarter 2026)
Amrecibart (REGN9933) <i>Antibody to Factor XI (A2 domain)</i>	–Thrombosis	–SPAF –PAD –PICC-associated thrombosis			
Mibavademab^{(f)(6)} (REGN4461) <i>Agonist antibody to leptin receptor ("LEPR")</i>	–Functional hypothalamic amenorrhea				
Trevogrumab^(f) (REGN1033) <i>Antibody to myostatin (GDF8)</i>	–Obesity ⁽ⁿ⁾			–Presented additional data from Phase 2 study in obesity at European Association for the Study of Diabetes ("EASD") Annual Meeting	
Olatorepatide^(q) (HS-20094) <i>GLP-1/GIP receptor agonist</i>	–Obesity				–Initiate Phase 3 program in obesity in patients without Type 2 diabetes (fourth quarter 2026) and with Type 2 diabetes (first half 2027)

Clinical Program (continued)	Phase 2	Phase 3	Regulatory Review ^(h)	2026 Events to Date	Select Upcoming Milestones
Baluncibart (REGN7544) <i>Antagonist antibody to NPR1</i>	–Postural orthostatic tachycardia syndrome ("POTS")			–Phase 2 study in sepsis- induced hypotension did not meet primary endpoint	–Report results from Phase 2 study in POTS (fourth quarter 2026)
Rapirosiran (ALN-HSD)^(k) <i>RNAi therapeutic targeting HSD17B13</i>	–Metabolic dysfunction- associated steatohepatitis ("MASH")				
ALN-CIDEB^(k) <i>RNAi therapeutic targeting CIDEB</i>	–MASH ^(e)				–Present results from Phase 1/2 study (fourth quarter 2026) –Initiate Phase 3 study in MASH/metabolic dysfunction-associated steatotic liver disease ("MASLD") (fourth quarter 2026)
Pivicasiran (ALN-PNP)^(k) <i>RNAi therapeutic targeting PNPLA3</i>	–MASH				
ALN-ANG3^(k) <i>RNAi therapeutic targeting ANGPTL3</i>	–Diabetic kidney disease				
REGN13335 <i>Antagonist antibody to PDGF-B</i>	–Pulmonary arterial hypertension ("PAH") ^(c)				
Neurology/Rare Diseases					
Pasatru (garetozmab)^(f) <i>Antibody to Activin A</i>			–FOP (EU)	–Approved by FDA for FOP –Reported positive 84- week data from Phase 3 study in FOP	–EC decision on Marketing Authorization Application ("MAA") for FOP (first half 2027)
Cemdisiran^(k) <i>RNAi therapeutic targeting C5</i>		–Generalized myasthenia gravis ("gMG") ^(c)	–gMG (U.S. and EU)		–FDA decision on New Drug Application ("NDA") (November 2026) and EC decision on MAA (second half 2027) for gMG
Cemdisiran^(k) (RNAi therapeutic targeting C5) + pozelimab^(f) (antibody to C5)		–Paroxysmal nocturnal hemoglobinuria ("PNH") ^(c)			–Report results from Phase 3 study in PNH (fourth quarter 2026)

Clinical Program (continued)	Phase 2	Phase 3	Regulatory Review ^(h)	2026 Events to Date	Select Upcoming Milestones
Mibavademab^(f) (REGN4461) <i>Agonist antibody to leptin receptor ("LEPR")</i>		–Generalized lipodystrophy ^{(c)(d)(e)} –Monogenic obesity			
Nexiguran ziclumeran (nex-z)^(f) <i>TTR gene knockout using CRISPR/Cas9</i>		–Transthyretin amyloidosis with cardiomyopathy ("ATTR-CM") ^{(c)(m)} –Hereditary transthyretin amyloidosis with polyneuropathy ("ATTRv-PN") ^{(c)(m)}		–FDA removed clinical hold on Phase 3 trials in ATTR-CM and ATTRv- PN	
Otarmeni (lunsotogene parvec, formerly known as DB-OTO) <i>AAV-based gene therapy</i>	–Hearing loss due to variants of otoferlin ("OTOF") gene ^(c) (pivotal study)		–Hearing loss associated with variants in <i>OTOF</i> gene (EU and Japan)	–Approved by FDA for hearing loss associated with variants in <i>OTOF</i> gene	–EC decision on MAA for hearing loss associated with variants in <i>OTOF</i> gene (first half 2027)
ALN-SOD^(r) <i>RNAi therapeutic targeting SOD1</i>	–Amyotrophic lateral sclerosis (ALS)				

Note: During 2026, we and Sanofi discontinued further clinical development of itepekimab, an antibody to IL-33, in COPD, CRSwNP, and chronic rhinosinusitis without nasal polyposis ("CRSsNP"). In addition, we discontinued further clinical development of brexmalizumab-atrisnolizumab (REGN5713-5715), a multi-antibody therapy to Bet v 1, in birch allergy and REGN7999, an antibody to TMPRSS6, in iron overload in beta-thalassemia.

- ^(a) In collaboration with Bayer outside the United States
- ^(b) In collaboration with Sanofi
- ^(c) FDA granted Orphan Drug designation for one or more indications
- ^(d) FDA granted Breakthrough Therapy designation for one or more indications
- ^(e) FDA granted Fast Track designation for one or more indications
- ^(f) Sanofi is entitled to receive royalties on sales of the product
- ^(g) Studied as monotherapy and in combination with other antibodies and treatments
- ^(h) Information in this column captures submissions to U.S., EU, and/or Japan regulatory authorities
- ⁽ⁱ⁾ BioNTech's BNT116 is an mRNA cancer vaccine
- ^(j) In collaboration with Intellia
- ^(k) In-licensed from Alnylam
- ^(l) Also studied in combination with marlotamig
- ^(m) FDA granted Regenerative Medicine Advanced Therapy ("RMAT") designation for one or more indications
- ⁽ⁿ⁾ Studied in combination with semaglutide with and without Pasatru (garetosmab)
- ^(o) A Phase 2 study, sponsored by Eli Lilly, is also ongoing and testing the combination of tirzepatide and mibavademab compared with tirzepatide alone in patients with obesity
- ^(p) Studied in combination with ubamatamab or fianlimab
- ^(q) In-licensed from Hansoh
- ^(r) In collaboration with Alnylam

Additional Information - Clinical Development Programs

EYLEA HD

The Company is working with the FDA and multiple third-party filling manufacturers to potentially achieve regulatory approval for the pre-filled syringe by the end of 2026.

Select Early-Stage Clinical Development Updates

In 2026, a Phase 1 study for REGN20423, a long-acting IL-13 antibody, in healthy volunteers and patients with atopic dermatitis was initiated.

U.S. Government Agreements

In April 2026, we announced agreements with the U.S. government (the "U.S. Government Agreements") pursuant to which we have agreed, among other matters, to provide certain of our products that we wholly own in the United States to the Medicaid program at prices no greater than prices determined based on benchmarking against a defined group of other developed countries ("Most-Favored-Nation Pricing"). We have also agreed to price certain future medicines in the United States at prices no greater than Most-Favored-Nation Pricing; to participate in a direct purchasing platform, TrumpRx.gov, that will allow eligible patients to purchase Praluent directly; and to provide our recently FDA-approved gene therapy Otarmeni for free in the United States. The U.S. Government Agreements further provide that Regeneron's products will not face tariffs as a result of the U.S. Department of Commerce's recent investigation under Section 232 of the Trade Expansion Act of 1962, as amended, through January 2029 so long as the Company continues its commitments to invest in manufacturing and research and development infrastructure in the United States.

Collaboration, License, and Other Agreements

Sanofi

We are party to a global collaboration with Sanofi to research, develop, and commercialize fully human monoclonal antibodies, which, as of September 30, 2026, consisted of Dupixent, Kevzara, and itepekimab. As described above, during 2026 we and Sanofi discontinued further clinical development of itepekimab.

In October 2026, the parties amended the collaboration agreement to include four additional long-acting, Regeneron-invented antibodies: (i) an antibody targeting IL-13, (ii) an antibody targeting IL-4, (iii) an antibody targeting IL-4 receptor alpha, and (iv) a bispecific antibody targeting IL-4xIL-13 (collectively, the "New Licensed Products"). As described above, REGN20423, an antibody targeting IL-13, is currently in Phase 1 clinical development, and the other three product candidates are expected to enter clinical studies in 2027. We will also have the option, on an asset-by-asset basis after completion of certain ongoing clinical trials, to include in the collaboration Sanofi's Phase 2/3 asset lunsekimig, an investigational bispecific Nanobody® VHH therapy targeting thymic stromal lymphopoietin ("TSLP") and IL-13, and another Sanofi early development product candidate. In the event we exercise our option for any such product, we will reimburse Sanofi for certain development costs related to such product.

Under the terms of the amendment, we received an up-front payment of \$1.0 billion from Sanofi, and we are entitled to receive up to an additional \$7.0 billion in the aggregate upon the achievement of certain development, regulatory, and sales-based milestones.

Agreed-upon development expenses incurred by the parties are shared equally. Sanofi leads commercialization activities for products under the collaboration agreement, and we have 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 also supply certain commercial bulk product to Sanofi. For Dupixent and Kevzara, we and Sanofi equally share profits from sales within the United States, and 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). Global profits from sales of New Licensed Products will be shared equally between the parties.

Bayer

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

We are obligated to reimburse Bayer for 50% of the development expenses 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

We and Alnylam Pharmaceuticals, Inc. are parties to a 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.

For each target nominated, we provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation. Under the terms of the collaboration, the parties 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 and co-commercialization collaboration agreement ("Co-Co Collaboration Agreement") or a license agreement. The target nomination period of the collaboration agreement ended in May 2026.

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 share profits and costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions.

We have also entered into various license agreements with Alnylam, with us as the licensee, including for cemdisiran as a monotherapy and for a combination consisting of cemdisiran and pozelimab. Under a license agreement, the lead party is designated as the licensee and has the right to develop and commercialize the product under such program. The licensee will be responsible for its own expenses incurred. The licensee will pay to the licensor certain development and/or commercialization milestone payments, as well as tiered royalty payments to the licensor based on the aggregate annual sales of the product.

Intellia

We and Intellia Therapeutics, Inc. are parties to a license and collaboration agreement to advance CRISPR/Cas9 gene-editing technology for in vivo therapeutic development, including therapies focused on neurological and muscular diseases. We had the right to select targets under the license and collaboration agreement until April 2026.

Intellia leads the design of the editing methodology, we lead the design of the targeted viral vector delivery approach, and the parties share costs. Each company has the opportunity to lead potential development and commercialization of product candidates for a target, and the company that is not leading development and commercialization will have the option to enter into a co-development and co-commercialization agreement for the target.

Nex-z, which is in clinical development, is subject to a co-development and co-commercialization arrangement pursuant to which Intellia leads development activities and the parties share development expenses 75% (Intellia)/25% (us). If nex-z is commercialized, Intellia will lead commercialization activities and we will share in 25% of any profits or losses.

Hansoh

We have licensed from Hansoh Pharmaceuticals Group Company Limited the development and commercial rights for olatorepatide (a dual GLP-1/GIP receptor agonist) outside of mainland China, Hong Kong, and Macau. Under the terms of the agreement, we made an \$80.0 million up-front payment in July 2025. In addition, we are obligated to make additional payments upon achievement of development, regulatory, and sales milestones, as well as pay a low double-digit royalty on sales.

Tessera

In January 2026, our collaboration agreement with Tessera Therapeutics, Inc. to develop and commercialize TSRA-196 (Tessera's investigational program for the treatment of alpha-1 antitrypsin deficiency ("AATD")) became effective. Tessera will lead the initial first-in-human trial, while we will lead subsequent global development and commercialization. The parties will share global development expenses and, if commercialized, any future profits or losses equally. Under the terms of the agreement, the Company made aggregate payments of \$150.0 million in the first quarter of 2026, consisting of an up-front payment and the purchase of Tessera preferred stock. In addition, we are obligated to make additional payments upon achievement of certain development milestones.

Parabilis

In May 2026, we entered into a collaboration agreement with Parabilis Medicines to discover and develop multiple therapeutic candidates based on Parabilis' Helicon™ peptide platform. Under the terms of the agreement, we made a \$50.0 million up-front payment and purchased \$75.0 million of Parabilis common stock. We will lead development and commercialization, and Parabilis will be entitled to receive milestone payments for development, regulatory, and sales milestones, as well as tiered royalties up to low double-digits on sales. Under the terms of the agreement, additional targets may be pursued upon additional option payments made by us.

General

Our ability to generate profits and to generate positive cash flow from operations over the next several years depends significantly on the success in commercializing our products, including EYLEA HD and Dupixent. We expect to continue to incur substantial expenses related to our research and development activities, and our research and development activities and related costs 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 in each of the countries in which we operate. There is uncertainty surrounding 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 products and whether or when they may become profitable.

Results of Operations

Net Income

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
<i>(In millions, except per share data)</i>				
Revenues	\$ 5,115.8	\$ 3,754.3	\$ 13,011.9	\$ 10,458.6
Operating expenses	3,067.6	2,727.5	9,027.3	7,760.6
Income from operations	2,048.2	1,026.8	3,984.6	2,698.0
Other income (expense)	235.9	736.5	658.5	1,489.0
Income before income taxes	2,284.1	1,763.3	4,643.1	4,187.0
Income tax expense	335.4	303.3	670.3	526.7
Net income	\$ 1,948.7	\$ 1,460.0	\$ 3,972.8	\$ 3,660.3
Net income per share - diluted	\$ 18.45	\$ 13.62	\$ 37.37	\$ 33.61

Revenues

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	\$ Change	2026	2025	\$ Change
Net product sales:						
EYLEA HD - U.S.	\$ 698.8	\$ 430.6	\$ 268.2	\$ 1,763.5	\$ 1,130.6	\$ 632.9
EYLEA - U.S.	399.7	680.6	(280.9)	1,285.0	2,170.9	(885.9)
Total EYLEA HD and EYLEA - U.S.	1,098.5	1,111.2	(12.7)	3,048.5	3,301.5	(253.0)
Libtayo - U.S.	395.8	219.1	176.7	1,024.5	659.4	365.1
Libtayo - ROW	154.2	146.1	8.1	453.1	367.4	85.7
Total Libtayo - Global	550.0	365.2	184.8	1,477.6	1,026.8	450.8
Praluent - U.S.	81.5	67.7	13.8	222.8	190.3	32.5
Evkeeza - U.S.	55.5	42.8	12.7	154.5	114.9	39.6
Lynozytic - Global	19.0	0.8	18.2	46.7	0.8	45.9
Other products - Global	0.8	—	0.8	32.1	—	32.1
Total net product sales	\$ 1,805.3	\$ 1,587.7	\$ 217.6	\$ 4,982.2	\$ 4,634.3	\$ 347.9
Collaboration revenue:						
Sanofi	\$ 2,724.0	\$ 1,617.0	\$ 1,107.0	\$ 6,503.4	\$ 4,243.8	\$ 2,259.6
Bayer	266.8	344.8	(78.0)	830.3	1,103.7	(273.4)
Other	9.7	6.6	3.1	21.5	12.8	8.7
Other revenue	310.0	198.2	111.8	674.5	464.0	210.5
Total revenues	\$ 5,115.8	\$ 3,754.3	\$ 1,361.5	\$ 13,011.9	\$ 10,458.6	\$ 2,553.3

Net Product Sales

EYLEA HD U.S. net product sales increased for the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily due to higher sales volumes, partly offset by a lower net selling price.

EYLEA U.S. net product sales decreased for the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily due to lower sales volumes as a result of continued competitive pressures (as described below) and the continued transition of patients to EYLEA HD.

EYLEA net product sales have been, and are likely to continue to be, negatively impacted by increased competition from other anti-VEGF products, including biosimilars, as well as the transition of patients from EYLEA to EYLEA HD. The magnitude and duration of such impact is presently unknown. For more information, see Part II, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *We are substantially dependent on revenues derived from net product sales of EYLEA HD, EYLEA, and Dupixent*" and "*The commercial success of our products and product candidates is subject to significant competition - Marketed Products.*"

Libtayo U.S. net product sales increased for the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily due to higher sales volumes.

Collaboration Revenue

Sanofi Collaboration Revenue

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Regeneron's share of profits	\$ 2,574.9	\$ 1,455.5	\$ 6,058.3	\$ 3,755.7
Reimbursement for manufacturing of commercial supplies ^(a)	149.1	161.5	445.1	488.1
Total Sanofi collaboration revenue	\$ 2,724.0	\$ 1,617.0	\$ 6,503.4	\$ 4,243.8

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

Global net product sales of Dupixent and Kevzara are recorded by Sanofi, and we and Sanofi share profits on such sales.

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

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Dupixent and Kevzara net product sales	\$ 6,796.1	\$ 5,011.0	\$ 18,025.1	\$ 13,289.8
Regeneron's share of collaboration profits in connection with commercialization of antibodies	\$ 2,574.9	\$ 1,723.6	\$ 6,588.3	\$ 4,400.5
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation ^(a)	—	(268.1)	(530.0)	(644.8)
Regeneron's share of profits	\$ 2,574.9	\$ 1,455.5	\$ 6,058.3	\$ 3,755.7
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales	38%	29%	34%	28%

^(a) The Sanofi development balance, which represented our obligation to reimburse Sanofi for development expenses that were previously funded by Sanofi, was fully repaid as of June 30, 2026

The increase in our share of profits for the three and nine months ended September 30, 2026, compared to the same periods in 2025, was driven by higher profits primarily associated with an increase in Dupixent net product sales, as well as higher Sanofi collaboration revenue resulting from the full repayment of the Sanofi development balance as of the second quarter of 2026.

As described in the "Collaboration, License, and Other Agreements – Sanofi" section above, in October 2026, the parties amended the collaboration agreement. Under the terms of the agreement, we received an up-front payment of \$1.0 billion from Sanofi, which will be recorded to Collaboration revenue in the fourth quarter of 2026.

Bayer Collaboration Revenue

<i>(In millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Regeneron's share of profits	\$ 211.5	\$ 311.9	\$ 678.8	\$ 1,012.6
Reimbursement for manufacturing of commercial supplies ^(a)	55.3	32.9	151.5	91.1
Total Bayer collaboration revenue	<u>\$ 266.8</u>	<u>\$ 344.8</u>	<u>\$ 830.3</u>	<u>\$ 1,103.7</u>

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

Bayer records net product sales of EYLEA 8 mg and EYLEA outside the United States, and we and Bayer share profits on such sales.

Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States is summarized below:

<i>(In millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
EYLEA 8 mg and EYLEA net product sales outside the United States	\$ 642.7	\$ 853.8	\$ 2,037.9	\$ 2,689.3
Regeneron's share of collaboration profit from sales outside the United States	\$ 226.3	\$ 328.0	\$ 724.1	\$ 1,061.5
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation ^(a)	(14.8)	(16.1)	(45.3)	(48.9)
Regeneron's share of profits	<u>\$ 211.5</u>	<u>\$ 311.9</u>	<u>\$ 678.8</u>	<u>\$ 1,012.6</u>
Regeneron's share of profits as a percentage of EYLEA 8 mg and EYLEA net product sales outside the United States	33%	37%	33%	38%

^(a) See "Collaboration, License, and Other Agreements - Bayer" above for additional details on our contingent reimbursement obligation

The decrease in our share of profits for the three and nine months ended September 30, 2026, compared to the same periods in 2025, was driven by lower profits primarily associated with a decrease in EYLEA sales outside the United States.

Other Revenue

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Share of profits and royalties in connection with license and other agreements ^(a)	\$ 253.2	\$ 154.7	\$ 510.5	\$ 326.7
Other ^(b)	56.8	43.5	164.0	137.3
Total other revenue	<u>\$ 310.0</u>	<u>\$ 198.2</u>	<u>\$ 674.5</u>	<u>\$ 464.0</u>

^(a) Includes royalties on sales of Novartis' Ilaris® (canakinumab) and our share of profits from Kiniksa's sales of ARCALYST

^(b) Includes amounts earned in connection with manufacturing product for others; corresponding costs incurred by the Company in connection with such manufacturing is recorded within Cost of collaboration and contract manufacturing

Operating Expenses

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	\$ Change	2026	2025	\$ Change
Research and development ^(a)	\$ 1,794.7	\$ 1,475.0	\$ 319.7	\$ 4,969.8	\$ 4,224.1	\$ 745.7
Acquired in-process research and development	21.5	83.1	(61.6)	250.4	105.4	145.0
Selling, general, and administrative ^(a)	677.8	657.8	20.0	1,987.6	1,925.0	62.6
Cost of goods sold	321.7	281.0	40.7	1,055.8	822.1	233.7
Cost of collaboration and contract manufacturing ^(b)	251.9	240.6	11.3	763.7	694.0	69.7
Other operating (income) expense, net	—	(10.0)	10.0	—	(10.0)	10.0
Total operating expenses	<u>\$ 3,067.6</u>	<u>\$ 2,727.5</u>	<u>\$ 340.1</u>	<u>\$ 9,027.3</u>	<u>\$ 7,760.6</u>	<u>\$ 1,266.7</u>

^(a) Includes costs incurred net of any cost reimbursements from collaborators

^(b) Includes costs incurred in connection with manufacturing drug supplies for collaborators and others

Operating expenses included stock-based compensation expense of \$255.8 million and \$237.0 million for the three months ended September 30, 2026 and 2025, respectively, and \$756.2 million and \$744.4 million for the nine months ended September 30, 2026 and 2025, respectively.

Research and Development Expenses

The following table summarizes our 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 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 include pre-launch commercial supplies which did not meet the criteria to be capitalized as inventory. The table below also includes reimbursements of research and development expenses by collaborators, as when we are entitled to reimbursement of all or a portion of such expenses that we incur under a collaboration, we record those reimbursable amounts in the period in which such costs are incurred.

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025*	\$ Change	2026	2025*	\$ Change
Direct research and development expenses:						
Lynozytic (linvoseltamab)	\$ 64.2	\$ 32.8	\$ 31.4	\$ 202.0	\$ 118.1	\$ 83.9
Cenvacibart & amrecibart	62.2	11.7	50.5	140.3	31.9	108.4
Ordspiono (odronextamab)	57.9	50.1	7.8	155.9	119.1	36.8
Fianlimab	44.9	55.8	(10.9)	159.8	155.3	4.5
Itepekimab	33.8	28.1	5.7	79.2	90.9	(11.7)
Dupixent (dupilumab)	28.8	27.6	1.2	82.4	81.1	1.3
Pozelimab/cemdisiran	21.4	16.5	4.9	62.5	45.6	16.9
Libtayo (cemiplimab)	13.4	18.0	(4.6)	48.7	57.3	(8.6)
Other product candidates in clinical development and other research programs	263.0	213.7	49.3	696.7	597.4	99.3
Total direct research and development expenses	589.6	454.3	135.3	1,627.5	1,296.7	330.8
Indirect research and development expenses:						
Payroll and benefits	471.9	438.3	33.6	1,416.4	1,339.5	76.9
Lab supplies and other research and development costs	76.3	67.5	8.8	207.1	192.4	14.7
Occupancy and other operating costs	175.7	166.3	9.4	528.6	479.2	49.4
Total indirect research and development expenses	723.9	672.1	51.8	2,152.1	2,011.1	141.0
Clinical manufacturing costs	507.7	381.4	126.3	1,276.6	1,028.8	247.8
Reimbursement of research and development expenses by collaborators	(26.5)	(32.8)	6.3	(86.4)	(112.5)	26.1
Total research and development expenses	\$ 1,794.7	\$ 1,475.0	\$ 319.7	\$ 4,969.8	\$ 4,224.1	\$ 745.7

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

Research and development expenses included stock-based compensation expense of \$140.3 million and \$125.1 million for the three months ended September 30, 2026 and 2025, respectively, and \$406.2 million and \$405.1 million for the nine months ended September 30, 2026 and 2025, 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 product candidate, 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") Expenses

Acquired IPR&D expenses for the nine months ended September 30, 2026 included the premium on equity securities purchased and up-front, opt-in, and development milestone payments in connection with various collaboration and licensing agreements.

Acquired IPR&D expenses for the nine months ended September 30, 2025 included an \$80.0 million up-front payment in connection with our license agreement with Hansoh Pharmaceuticals Group Company Limited.

Cost of Goods Sold

(In millions, except gross margin on net product sales)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of goods sold	\$ 321.7	\$ 281.0	\$ 1,055.8	\$ 822.1
Gross margin on net product sales ^(a)	82%	82%	79%	82%

^(a) Gross margin on net product sales represents gross profit expressed as a percentage of total net product sales recorded by the Company. Gross profit is calculated as net product sales (see "Net Product Sales" section above) less cost of goods sold.

Gross margin on net product sales decreased for the nine months ended September 30, 2026, compared to the same period in 2025, primarily due to unabsorbed manufacturing costs as a result of a temporary interruption of bulk manufacturing production at our facility in Limerick, Ireland, due to unanticipated facility repairs that commenced during the first quarter of 2026. The interruption did not impact the availability of any of our products; and, as of June 30, 2026, bulk manufacturing production had returned to normal levels.

Other Income (Expense)

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Gains on marketable and other securities, net	\$ 60.3	\$ 577.7	\$ 147.2	\$ 967.6
Interest income	181.8	175.1	548.6	523.5
Other	4.4	3.0	(2.8)	29.5
Other income (expense), net	246.5	755.8	693.0	1,520.6
Interest expense	(10.6)	(19.3)	(34.5)	(31.6)
Total other income (expense)	\$ 235.9	\$ 736.5	\$ 658.5	\$ 1,489.0

Income Taxes

(In millions, except effective tax rate)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Income tax expense	\$ 335.4	\$ 303.3	\$ 670.3	\$ 526.7
Effective tax rate	14.7%	17.2%	14.4%	12.6%

Our effective tax rate for the three and nine months ended September 30, 2026 and 2025 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, tax benefits from cross-border tax laws and federal tax credits for research activities, partly offset by changes in unrecognized tax benefits (which, for the nine months ended September 30, 2025, included the release of liabilities upon the settlement of an IRS audit). In addition, our effective tax rate for the three and nine months ended September 30, 2025 was negatively impacted by the enactment of the "One Big Beautiful Bill Act," including the re-measurement of our U.S. net deferred tax assets.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

<i>(In millions)</i>	September 30, 2026	December 31, 2025	\$ Change
Financial assets:			
Cash and cash equivalents	\$ 3,659.1	\$ 3,118.1	\$ 541.0
Marketable securities - current	5,642.0	5,487.1	154.9
Marketable securities - noncurrent	9,557.4	10,260.6	(703.2)
	<u>\$ 18,858.5</u>	<u>\$ 18,865.8</u>	<u>\$ (7.3)</u>
Working capital:			
Current assets	\$ 20,795.1	\$ 18,021.9	\$ 2,773.2
Current liabilities	6,202.1 *	4,368.4	1,833.7
	<u>\$ 14,593.0</u>	<u>\$ 13,653.5</u>	<u>\$ 939.5</u>
Borrowings and finance lease liabilities:			
Long-term debt	\$ 1,987.0	\$ 1,985.9	\$ 1.1
Finance lease liabilities	\$ 720.0 *	\$ 720.0	\$ —

* The \$720.0 million related to finance lease liabilities is classified within current liabilities as of September 30, 2026

As of September 30, 2026, we also had borrowing availability of \$750.0 million under a revolving credit facility.

Sources and Uses of Cash

<i>(In millions)</i>	Nine Months Ended September 30,		\$ Change
	2026	2025	
Cash flows provided by (used in):			
Operating activities	\$ 3,675.3	\$ 3,808.2	\$ (132.9)
Investing activities	\$ (809.7)	\$ (849.4)	\$ 39.7
Financing activities	\$ (2,317.0)	\$ (2,935.3)	\$ 618.3

Cash Flows from Investing Activities

Capital expenditures for the nine months ended September 30, 2026 included costs incurred in connection with the expansion of our research and support facilities at our Tarrytown, New York corporate headquarters, as well as costs associated with the expansion of our manufacturing facilities. We expect to incur capital expenditures of \$1.050 billion to \$1.100 billion for the full year of 2026.

Cash Flows from Financing Activities

Share Repurchase Programs

Our board of directors has authorized share repurchase programs, including a share repurchase program for up to \$3.0 billion of our Common Stock which was authorized in April 2026. The programs have no time limit and can be discontinued at any time. As of September 30, 2026, \$2.157 billion remained available for share repurchases under the program.

Dividends

In each of the first, second, and third quarters of 2026, we declared a quarterly cash dividend of \$0.94 per share on our Common Stock and Class A Stock. Each quarterly dividend was paid to our shareholders in the quarter in which the dividend was declared.

Additionally, in October 2026, we declared a cash dividend of \$0.94 per share on our Common Stock and Class A Stock. The dividend will be payable on December 3, 2026 to our shareholders of record as of November 20, 2026.

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, 2025 (filed February 4, 2026). There have been no material changes to critical accounting estimates during the nine months ended September 30, 2026.

Future Impact of Recently Issued Accounting Standards

See Note 1 to our Condensed Consolidated Financial Statements included in this report for a description of recently issued accounting standards.

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, 2025 (filed February 4, 2026). There have been no material changes to our market risks or to our management of such risks as of September 30, 2026.

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 September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information called for by this item is incorporated herein by reference to the information set forth in Note 12 to our Condensed Consolidated Financial Statements included in this report.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. References to past events are provided as examples only and are not intended to be a complete listing or representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future. 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 Securities and Exchange Commission ("SEC") before making an investment decision regarding Regeneron.

Commercialization Risks

- We are substantially dependent on revenues derived from net product sales of EYLEA HD, EYLEA, and Dupixent.
- Sales of our products are dependent on the availability and extent of coverage and reimbursement or copay assistance from third-party payors and other third parties, including private payors and government programs such as Medicare and Medicaid.
- Product reimbursement and coverage policies and practices, pricing regulations and requirements, and our pricing strategy could change due to various factors (including those beyond our control), 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 or agreements we have entered into or may in the future enter into with the U.S. government or other governmental 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, including biosimilars.
- 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 and outside the United States.

Regulatory and Development Risks

- Drug development and obtaining and maintaining regulatory approval for drug and biological 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, have in the past reduced and could reduce in the future the duration of market exclusivity for our products.

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 potential regulatory approvals, 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 has been and will continue to 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 could adversely affect our ability to supply our products.
- Our or our collaborators' or contract manufacturers' 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, regulations, and policies affecting the healthcare industry could adversely affect our business.
- Tax liabilities, tariffs and other trade restrictions, and other risks associated with our operations outside 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, may 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 or failure to realize the expected benefits from 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 or retain key members of our senior management team, including 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 have adversely affected and may in the future adversely affect our business.
- 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.

* * *

Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products

We are substantially dependent on revenues derived from net product sales of EYLEA HD, EYLEA, and Dupixent.

We are substantially dependent on revenues derived from net product sales of EYLEA HD and EYLEA. Net product sales of these products have historically represented a substantial portion of our revenues, and we expect net sales of these products to continue to be a significant contributor to our revenues and operating results, with an increasing dependence on EYLEA HD relative to our historical dependence on EYLEA. For the nine months ended September 30, 2026 and 2025, our aggregate EYLEA HD and EYLEA net product sales in the United States represented 23% and 32% of our total revenues, respectively. For the nine months ended September 30, 2026, EYLEA HD U.S. net product sales represented 58% of our aggregate EYLEA HD and EYLEA U.S. net product sales. If we experience difficulty with the commercialization of EYLEA HD or EYLEA in the United States or if Bayer experiences any difficulty with the commercialization of EYLEA HD or EYLEA outside the United States beyond what has been experienced to date as described below, if EYLEA HD net product sales do not sufficiently offset any sustained decline of EYLEA net product sales in or outside the United States, or if we and Bayer are unable to maintain or obtain marketing approvals of these products (as applicable), 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.

Commercialization of EYLEA HD and EYLEA in the United States and elsewhere is subject to significant competition (as described further below under "*The commercial success of our products and product candidates is subject to significant competition*"), which we expect to continue to increase in the future. For each of the three and nine months ended September 30, 2026, EYLEA U.S. net product sales declined by 41% compared to the corresponding periods in 2025 as a result of competitive pressures and other factors described under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations." Following the expiration of the U.S. regulatory exclusivity period for EYLEA in May 2024, several biosimilar versions of EYLEA have been approved by the FDA, and some of these products have launched in the United States. EYLEA and/or EYLEA HD net product sales recorded by us are likely to continue to be negatively impacted by biosimilar competition in the United States, including competition from additional biosimilar versions of EYLEA expected to launch in the United States in the near future, which may have a material adverse impact on our results of operations. In addition, we expect that competition for EYLEA and/or EYLEA HD outside the United States will continue to increase as biosimilar versions of EYLEA (including those already approved but not yet launched) are brought to market in additional countries and if biosimilar versions of EYLEA HD are approved and launched, which may continue to negatively impact the amount of collaboration revenue we earn from Bayer. Payor preferences for biosimilar products outside the United States may exacerbate this risk. While the FDA recently approved EYLEA HD for the treatment of RVO and for

additional dosing regimens and we continue to work toward FDA approval of the EYLEA HD pre-filled syringe as discussed under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Additional Information - Clinical Development Programs - EYLEA HD," there can be no assurance that these enhancements (including potential FDA approval of the EYLEA HD pre-filled syringe) will help accelerate any potential future growth of EYLEA HD net product sales. The degree to which EYLEA HD net product sales may offset further potential decreases in EYLEA net product sales, resulting from the factors discussed above or otherwise, is uncertain.

We also are substantially dependent on our share of profits from the commercialization of Dupixent under our collaboration with Sanofi (the "Antibody Collaboration"). For the nine months ended September 30, 2026 and 2025, Sanofi collaboration revenue (most of which is attributable to our share of profits from the commercialization of Dupixent) represented 50% and 41% of our total revenues, respectively. 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 or copay assistance for, our marketed products by third-party payors and other third parties, 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 or agreements we have entered into or may in the future enter into with the U.S. government or other governmental authorities);
- our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development; and, in the case of EYLEA HD and EYLEA, the existing and potential new branded and biosimilar competition (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 such products or to switch from a competitive product to one of our products;
- the safety and efficacy of our marketed products seen in a broader patient group (i.e., real-world use);
- the effect of existing and new healthcare laws and regulations, pricing mandates, and agreements with government entities (including the U.S. Government Agreements) 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 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, 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 and bulk product manufacturing 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, and have been increasing their focus on, pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of our marketed products;
- the outcome of the pending proceedings relating to our products (described further in Note 12 to our Condensed Consolidated Financial Statements included in this report), as well as other risks relating to our marketed products 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 12 to our Condensed Consolidated Financial Statements included in this report (including the civil proceedings initiated or joined by the U.S. Department of Justice and 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 in the United States, EU, Japan, and other countries. If we or our collaborators fail to maintain regulatory compliance or satisfy other obligations for such products (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 and biological products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, or obtain regulatory approval for our product candidates, we will not be able to market or sell them; and if we do not obtain approvals for new indications for our marketed products, we may not be able to realize the full commercial potential of such products. Any of the foregoing may materially and negatively impact our business, prospects, operating results, and financial condition.*"), 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' or contract manufacturers' 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 coverage and reimbursement and copay assistance from third-party payors and other third parties.

Sales of our marketed products in the United States are dependent, in large part, on the availability and extent of coverage and 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. Such sales are also impacted by the ability of patients to afford copays and the availability and extent of copay assistance, including copay assistance provided by other third parties (such as not-for-profit patient assistance funds). Sales of our marketed products in other countries are also dependent, in large part, on complex coverage and reimbursement mechanisms and programs in those countries.

Our revenues and profitability will be materially adversely affected if such third-party payors and other third parties do not adequately defray or reimburse the cost of our marketed products. If third-party payors 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, require failure on another type of treatment, or impose other utilization management restrictions before covering a particular drug, particularly with respect to higher-priced drugs. Further, sales of our marketed products (such as EYLEA HD and EYLEA) in the United States may be adversely impacted by the lack of sufficient copay assistance from not-for-profit patient assistance funds. For example, a loss in market share to compounded bevacizumab due to patient affordability constraints impacted U.S. net product sales of EYLEA for the year ended December 31, 2025, as further described under Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (filed February 4, 2026). If independent not-for-profit patient assistance funds that provide patient copay assistance are unable to support eligible patients, this will likely have a continued negative impact on patient affordability resulting in lower utilization of higher-cost anti-VEGF agents.

As our currently marketed products and our product candidates are biologics, genetics medicines, peptides, or other complex therapeutics, 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 healthcare 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 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.

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 countries outside the United States, 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 of these 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 limitations on the profitability of the medicinal product placed on the market. In addition, in many countries outside the United States, we or our collaborators must participate in a tender process for public procurement of our products, and any failure to obtain acceptable pricing in the tender process could adversely affect our business. Our results of operations may suffer if we or our collaborators are unable to market our products in countries outside the United States or if coverage and reimbursement for our marketed products in such countries is limited or delayed. As discussed below under *"If we are unable to maintain or establish sufficient commercial capabilities outside the United States for products we currently commercialize or co-commercialize, or intend to commercialize or co-commercialize in the future, 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 maintain and/or further develop sufficient commercial capabilities outside the United States.

Product reimbursement and coverage policies and practices, pricing regulations and requirements, and our pricing strategy could change due to various factors beyond our control, which may adversely impact our business, prospects, operating results, and financial condition.

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). Private payor healthcare and insurance providers, health maintenance organizations, and PBMs are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment/coinsurance. In addition, many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient copay or coinsurance obligations, and limitations on patients' use of commercial manufacturer copay payment assistance programs (including through copay accumulator adjustment or maximization programs). Some states have also enacted or are considering legislation to control the prices and reimbursement of prescription drugs, including by establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs, setting upper payment limits, and/or implementing marketing cost disclosure and transparency measures. Additionally, state Medicaid programs have been increasingly requesting that manufacturers, including Regeneron, 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 healthcare 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, executive orders, and recently approved or proposed federal and state legislation, regulations, 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. Since 2023 and 2026, the government has been in the process of selecting Part D and Part B drugs, respectively, for inclusion in the Medicare Drug Price Negotiation Program, with established prices for the first cycle of selected Part D drugs having gone into effect at the beginning of 2026 and established prices for the first cycle of selected Part B drugs slated to go into effect in 2028, in each case absent certain disqualifying events.
- *Medicare Inflation Based Rebates*. The IRA includes measures requiring manufacturers to pay rebates where increases to the average sales price or average manufacturer price of drugs covered under Medicare Parts B and D, respectively, exceed 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.

It is currently unclear whether and to what extent the Medicare Drug Price Negotiation Program or the other policy changes described above will ultimately impact reimbursement levels of our marketed products covered under Medicare Part B or Medicare Part D, or our product candidates that may be covered under Medicare Part B or Medicare Part D in the future.

In addition, the current U.S. administration is pursuing other measures to reduce the cost of drugs in the United States. For example, in May 2025, an executive order directed the U.S. Department of Health and Human Services ("HHS") and other federal agencies to take certain steps intended to, among other things, reduce the prices of drugs sold in the United States to match the lowest price available for the same drugs in comparably developed nations. In addition, a prior executive order from April 2025 directed the HHS to take appropriate steps to, among other things, modify certain provisions of the Medicare Drug Price Negotiation Program, develop and implement a payment model to reduce the price of high-cost prescription drugs and biological products covered by Medicare, accelerate approval of generic and biosimilar products, and facilitate the ability of states to import pharmaceuticals from other countries.

In April 2026, in response to the May 2025 executive order described above and a related letter that we and certain other pharmaceutical companies received from President Trump, we entered into the U.S. Government Agreements, pursuant to which we have agreed, among other matters, to provide certain of our products that we wholly own in the United States to the Medicaid program, and to price certain future medicines in the United States, at prices no greater than Most-Favored-Nation Pricing. The U.S. Government Agreements further provide that Regeneron's products will not face tariffs as a result of the investigation under Section 232 of the Trade Expansion Act of 1962, as amended ("Section 232"), through January 2029 so long as the Company continues its commitments to invest in manufacturing and research and development infrastructure in the United States. The U.S. Government Agreements will likely result, and any potential future agreements with government entities could also result, in reduced prices and reimbursement for certain of our current and future marketed products and may impact our results of operations. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – U.S. Government Agreements."

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, price and marketing cost disclosure and transparency measures, and measures that could expand the applicability of the ceiling price under the federal government's 340B program (see also "Other Regulatory and Litigation Risks - *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.*"). 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 our marketed products. Economic pressure on state budgets may also have a similar impact. We also remain subject to any current or future pricing mandates implemented outside the United States, and it is possible that current or future pricing regulations may have a material impact on our business and results of operations.

The commercial success of our products and product candidates is subject to significant competition.

Marketed Products

We face substantial competition from pharmaceutical and biotechnology 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 HD and EYLEA. EYLEA HD and EYLEA face significant competition in the marketplace. For example, each of EYLEA HD and EYLEA competes in one or more of its approved indications with other VEGF inhibitors. These include Genentech/Roche's Vabysmo[®] (faricimab-svoa) and Susvimo[®] (ranibizumab ocular implant); Novartis and Genentech/Roche's Lucentis[®] (ranibizumab); Novartis' Beovu[®] (brolucizumab); and a biosimilar version of Lucentis commercialized in the United States by Harrow, Inc. In addition, biosimilar versions of EYLEA have been approved and/or launched both in and outside the United States, including Amgen's Pavblu[™] (aflibercept-ayyh) and Biocon's Yesafili[™] (aflibercept-jbvf) in the United States. We are aware of several other companies developing biosimilar versions of EYLEA, EYLEA HD, and/or other approved anti-VEGF treatments. We expect that biosimilar competition for EYLEA will continue to increase as additional biosimilar versions of EYLEA are launched in the United States and other countries, the timing of which will depend on, among other factors, the outcome of the pending patent litigation proceedings and the settlement terms of the previously pending litigation proceedings (including those described in Note 12 to our Condensed Consolidated Financial Statements included in this report) and the expiration of the patents protecting EYLEA (including those set forth under Part I - Item 1. "Business - Patents, Trademarks, and Trade Secrets" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (filed February 4, 2026)). 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 HD's and EYLEA's respective indications, and we are aware of another company with an ophthalmic formulation of such product that has been approved in the United States and the EU. In DME and RVO, EYLEA HD and EYLEA also compete 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 HD's and EYLEA's respective indications, including those that act by blocking VEGF and VEGF receptors (including therapies designed to extend the treatment interval) and/or other targets. 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, conjugated antibodies, 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.

EYLEA HD was launched in 2023 and entered the highly competitive environment described above. Our success in commercializing EYLEA HD will continue to depend on a number of factors, including the degree of success of our uptake efforts as compared to those of relevant competition, the extent to which we and our collaborators are able to differentiate EYLEA HD from competitive products (such as on the basis of dosing frequency, the method of administration, or the breadth of indications in which the product is approved), the safety and efficacy of EYLEA HD seen in a broader patient group (i.e., real-world use), the extent of payor coverage, reimbursement, and copay assistance, and the applicability of any restrictions imposed by payors, such as step therapy.

Dupixent. The market for Dupixent's current and potential future indications is also increasingly competitive. There are systemic JAK inhibitors and antibodies against IL-13 and IL-4Ra approved or in development for atopic dermatitis. There is also an antibody against IL-31R approved for atopic dermatitis and prurigo nodularis. In addition, a number of companies are developing therapeutics against other targets, including IL-2 receptor agonists, that may compete with Dupixent in atopic dermatitis. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or 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, EoE, COPD, and CSU where approved. There are several other potentially competitive products in development that may compete with Dupixent in atopic dermatitis, asthma, COPD, and potential future indications, including an antibody against IL-33, half-life extended antibodies against IL-13 and TSLP, STAT6 oral small molecules, and multispecific antibodies against IL-13 and TSLP, with and without IL-4. Dupixent also faces competition from a Bruton tyrosine kinase inhibitor in CSU and may in the future face competition from inhaled products in asthma, COPD, 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), AstraZeneca's Imfinzi® (durvalumab), and Sun Pharma's Unloxyt™ (cosibelimab). While Libtayo is currently approved for intravenous administration only, certain of these products are also approved or in development for subcutaneous use.

Other marketed products. There is significant actual and potential future competition for other products marketed or otherwise commercialized by us and/or our collaborators or licensees under our collaboration or license agreements with them. For example, Lynozyfic faces significant actual and potential future competition from other bispecific antibodies and CAR-T cell therapies targeting BCMA, GPRC5D, and/or other targets that are currently approved or in development for the treatment of relapsed/refractory multiple myeloma. In addition, there are several companies that are marketing and/or developing antibodies or other molecules (such as small interfering RNA molecules, or siRNAs, and oral small molecules) against PCSK9, ANGPTL3 and IL-6 and/or IL-6R, which currently (or, for product candidates in development, may in the future if approved) treat the same conditions as Praluent, Evkeeza, and Kevzara, respectively. In addition, our products or product candidates, including our collaborated or licensed products or product candidates, may face additional competition from products or product candidates of our collaborators or licensees, depending on the terms of the applicable agreements.

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, 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 (including bispecific antibodies, multispecific antibodies, and/or antibody-drug conjugates) and gene therapy-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 pharmaceutical 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. While we evaluate market opportunities for our product candidates, there can be no assurance that our estimates will accurately reflect the market opportunity at the time of launch or that our product candidates will meet internal or external expectations and be successful commercially due to existing or potential future competition or otherwise.

We face increasing competition from Chinese biotechnology and pharmaceutical companies, including Chinese state-owned or state-backed enterprises, with respect to both our marketed products and product candidates. China has become one of the world's leading developers of new drugs, and Chinese companies benefit from a regulatory regime that enables rapid, low-cost clinical trials that facilitate innovation. Furthermore, we compete with other large pharmaceutical companies, many of which have invested significantly in China, in acquiring or licensing Chinese product candidates, and we may not be as successful as our competitors in identifying or accessing such assets.

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 HD and EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA HD or 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 HD and EYLEA 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 adversely 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 many 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 continue to rely in considerable part on Sanofi's sales and marketing organization in such jurisdictions. Sanofi also leads or will lead the commercialization efforts for the other products and product candidates subject to the Antibody Collaboration, which now includes four new product candidates pursuant to the recent amendment to the Antibody Collaboration discussed under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Collaboration, License, and Other Agreements – Sanofi."

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. While we have some commercial presence outside the United States, our commercial capabilities outside the United States are still limited and would need to be further developed or outsourced. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration with Sanofi 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 HD and 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 HD and 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, may 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 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, tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA HD and EYLEA outside the United States are 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 and, as discussed above under "*Product reimbursement and coverage policies and practices, pricing regulations and requirements, and our pricing strategy could change due to various factors beyond our control, which may adversely impact our business, prospects, operating results, and financial condition,*" an executive order from April 2025 directed the Secretary of the HHS to take appropriate steps to facilitate such importation at the state level. If such or other similar proposals were to be 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 the ability of our Company, our collaborators, or other third parties on which we rely (as applicable) 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. In addition, we may need to further develop or acquire these capabilities as we and/or our collaborators continue to pursue the development of drugs generated by means other than our established "Trap" or *VelociSuite* technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. 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 marketed products and product candidates are typically delivered either by intravenous infusion or by intravitreal or subcutaneous injections. These methods of administration are generally disfavored by patients when compared to tablet or capsule delivery, which could adversely affect the commercial success of such marketed products or, if they receive marketing approval, product candidates.

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 (collectively, "distributor customers"), which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For each of the nine months ended September 30, 2026 and 2025, our product sales to two distributor customers accounted on a combined basis for 77% of our total gross product revenue. We expect significant distributor customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of our products will depend, in part, on the extent to which our distributor customers are able to provide adequate distribution of our 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 distributor customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large distributor 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. Commercialization of any of our marketed products may also be adversely impacted by vertical integration of private payor healthcare and insurance programs, health maintenance organizations, and PBMs, or further consolidation among the healthcare providers served or operated by our distributor customers if, for example, one or more consolidated groups of healthcare providers determines not to use (or decides to switch from) such marketed product in favor of a competing product. See also "*The commercial success of our products and product candidates is subject to significant competition - Marketed Products*" above.

If we are unable to maintain or establish sufficient commercial capabilities outside the United States for products we currently commercialize or co-commercialize, or intend to commercialize or co-commercialize in the future, outside the United States, our business, prospects, operating results, and financial condition may be adversely affected.

While we have made progress with establishing commercial capabilities in certain jurisdictions outside the United States in recent years (primarily in connection with our acquisition of the worldwide rights to Libtayo in 2022), our commercial capabilities and experience with commercializing products outside the United States (as well as obtaining and/or maintaining regulatory approvals and securing pricing and reimbursement for our products outside the United States) are still somewhat limited. There may be other circumstances in which we need to establish further commercial capabilities outside the United States, including because we decide to commercialize other products 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 or enhance 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 requisite commercial capabilities outside the United States 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

Obtaining and maintaining regulatory approval for drug and biological products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, or obtain regulatory approval for our product candidates, we will not be able to market or sell them; and if we do not obtain approvals for new indications for our marketed products, we may not be able to realize the full commercial potential of such products. Any of the foregoing may 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, or 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.

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 and biologic we intend to sell. We must obtain and maintain similar regulatory approvals from comparable foreign regulatory authorities in order to sell drugs and biologics outside the United States. Obtaining FDA or comparable foreign regulatory authority approval for a new drug or biologic 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 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, in the United States, 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 or biologic, depending on what the FDA considers necessary for the safe use of the drug or biologic. 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 from us an application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies or additional analyses of data from existing studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies or analyses that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend considerably more resources. Any such additional studies or analyses, 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 applications for approval. For example, in October 2023, the FDA issued a Complete Response Letter ("CRL") for the sBLA for Dupixent in CSU stating that additional efficacy data were required to support an approval, which delayed by nearly 18 months the FDA's April 2025 approval of Dupixent in this indication.

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 for 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 studies), labeling changes based on new safety information, and compliance with FDA-approved REMS. 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 jurisdictions outside the United States.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs and biologics includes standard review and priority review. While the FDA has performance goals that provide for action on NDA and BLA submissions by certain deadlines, 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. The FDA's review of our regulatory submissions has in the past been delayed, and may be delayed in the future, due to the FDA's request for additional information or for other reasons, including those beyond our control (such as recent changes in FDA leadership, the 2025 reduction in staffing at the FDA, and any future reductions of staffing or other resources at the FDA, as discussed further below).

The functioning of the FDA is affected by a variety of factors, such as shifting government priorities, budgets and funding levels, authorization and payment of user fees, the ability to hire and retain key personnel, as well as other statutory, regulatory, and policy changes impacting HHS, the FDA, or other HHS agencies. U.S. policy changes have recently been implemented at a rapid pace, and additional changes may occur. For example, there have been recent efforts to reduce the size and budgets of U.S. government agencies, downsize the federal workforce, and restructure parts of the executive branch of the federal government. These efforts have directly or indirectly impacted agencies that support research and development activities or are otherwise important to our business, including the HHS and the FDA. There have also been ongoing senior leadership changes at the HHS and the FDA. If legislation, administrative action, changes in policy, or the continued loss of experienced senior leadership and career staff prevent the FDA or other regulatory authorities from conducting routine inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to provide feedback on our clinical programs, meet with or engage in other informal interactions with us, and review and process our regulatory submissions (including our pending regulatory submissions) in a timely manner. These developments may also reduce the FDA's capacity to engage in pre-approval or guidance meetings or meetings to negotiate labeling or post-marketing commitments. Furthermore, changes in FDA personnel and policy (such as those referenced above) may negatively impact the transparency of agency actions, lead to modifications in FDA approval requirements and related FDA review and approval delays, and alter the FDA's existing guidance pertinent to the development strategy for our products and product candidates. In addition, the U.S. government has shut down multiple times in the recent past and certain regulatory agencies, such as the FDA, have had to furlough employees and stop some of their activities. A prolonged government shutdown or a widespread freeze on federal funding could significantly impact the ability of the FDA to timely review and process our regulatory submissions or cause other agencies that support the FDA to slow their work. Any such factors could have a material adverse effect on our business.

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, priority review, or the Commissioner's National Priority Voucher (CNPV) program, where potentially 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 may fail to obtain beneficial regulatory designations from the FDA or other regulatory agencies. Even if obtained, such designations may not result in faster development processes, reviews, or approvals compared to drugs or biologics 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. FDA 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 marketing application 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 and related rules 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. For example, in March 2024, the FDA issued CRLs concerning our BLA for odronextamab for the treatment of relapsed/refractory FL and DLBCL due to the enrollment status of confirmatory Phase 3 trials, which, along with the July 2025 CRL discussed below, has delayed the potential FDA approval of odronextamab.

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 biological 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 drugs and 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 NDA or 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, the manner in which such principles are implemented may not be specifically delineated, which can be challenging as the FDA and comparable foreign regulatory authorities increasingly scrutinize compliance with these requirements and regulations. As a result, 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 biological product, or revocation of a pre-existing approval. We have recently received several CRLs from the FDA for regulatory submissions concerning our products or product candidates due to the FDA's findings from inspections at third-party manufacturers responsible for filling drug product. These include the July 2025 CRL concerning the BLA for odronextamab in relapsed/refractory FL, which has delayed further the potential FDA approval of odronextamab in this indication; and the October 2025 CRL concerning our regulatory application seeking approval of the EYLEA HD pre-filled syringe, which has delayed further the potential FDA approval of the EYLEA HD pre-filled syringe. For additional information, see "Risks Related to Manufacturing and Supply - *Our or our collaborators' or contract manufacturers' 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 NDA, BLA, or foreign equivalent is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the application. The holder of an approved NDA, BLA, or foreign equivalent must also submit new or supplemental applications and obtain FDA or other regulatory 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 jurisdictions outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

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, and commercial sale and distribution of drugs and biologics in jurisdictions outside the United States. The foreign regulatory approval process is similarly a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements generally include the risks associated with FDA approval as well as jurisdiction-specific regulations. We and our collaborators must maintain regulatory compliance for the products we or they commercialize in jurisdictions outside the United States. From time to time, we may hold a product's marketing approval in a jurisdiction outside the United States where we have less experience and where our regulatory capabilities are more limited; for example, this is now the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) due to our acquisition of the worldwide rights to Libtayo in 2022. 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 an 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 a 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 jurisdictions outside the United States before we can market that product or any other product in those jurisdictions.

Furthermore, we are subject to extensive pharmacovigilance reporting and other pharmacovigilance requirements, which may differ in the numerous jurisdictions 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"), our clinical trials may be closed prematurely, our marketing authorization may be 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 make it impossible 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 Good Laboratory Practice requirements ("GLPs") or GCPs. Given the evolving standards of care for certain conditions, approval of a product candidate to treat such conditions may rely on clinical endpoints that are no longer fit-for-purpose, and there may not be a consensus between clinical trial sponsors (including us) and the FDA or other regulatory authorities as to which other endpoints are adequately validated as a substitute and should be sufficient as a basis for regulatory approval. Certain of these risks may be exacerbated as we pursue development of drugs generated by means other than our established "Trap" or *VelociSuite* technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. 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 countries outside the United States presents additional risks, including political and economic risks 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, Ukraine, and/or Israel. While we currently do not expect the Russia-Ukraine war, armed conflicts in the Middle East, or related developments to have a significant impact on our ability to obtain results from clinical trials conducted by us or our collaborators, further escalation (whether in these countries or 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 or samples 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 such countries 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, an increasing number of our products and product candidates (including Libtayo) are being 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. 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, which may require significant time and resources. Further, we may be unable to pursue our research and development efforts if the relevant facility were to be impacted by 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 products. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for particular product candidates in particular 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. For example, in May 2026, we announced that a Phase 3 trial evaluating fianlimab in combination with Libtayo in first-line metastatic melanoma did not reach statistical significance for its primary endpoint compared to pembrolizumab monotherapy. 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/or 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. Furthermore, changes in FDA personnel may alter the FDA's advice with respect to our development strategy and lead to delays or rejections of our clinical trial protocols or data. Any such clinical program delays or terminations may adversely affect our business.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees ("IDMCs"). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. 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 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, 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 or complex clinical programs (including those evaluating combination therapies), 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.

For example, with respect to EYLEA HD and EYLEA, there are many potential safety concerns associated with significant blockade of VEGF, as well as risks inherent in their intravitreal administration. While the safety of EYLEA HD was similar to EYLEA in clinical trials, it is possible that the use of EYLEA HD outside the clinical trial setting in a broader patient group (i.e., real-world use) may yield different outcomes or patient experiences. In addition, there are risks inherent in subcutaneous injections (which are used for administering most of our antibody-based products and product candidates, such as Dupixent) and intravenous administration (which is used for some of our other antibody-based products and product candidates, such as Libtayo). Some of our marketed products, such as 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 the safety data from these trials will be consistent with the known safety profiles of these products or that regulatory approval of any of these additional indications will be successfully obtained. Commercialization of our other products and potential future commercialization of our product candidates may also 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 our products and product candidates.

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, 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 2 mg pre-filled syringe; and in the EU, EYLEA HD is approved in the 8 mg 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. The FDA has substantial discretion in the approval process 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 drug-delivery device. For example, in October 2025, the FDA issued a CRL for the regulatory application seeking approval of the EYLEA HD pre-filled syringe, which has delayed further the potential FDA approval of the EYLEA

HD pre-filled syringe. There can be no assurance that FDA approval of the EYLEA HD pre-filled syringe will be obtained in the currently anticipated time frame or at all. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Additional Information - Clinical Development Programs - EYLEA HD" for more information.

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. 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 of 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 - *The use of social media platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage,*" "Other Regulatory and Litigation Risks - *There are inherent risks related to our increasing use of artificial intelligence-based solutions,*" 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. Certain of our U.S. patents (including those pertaining to our key products, such as EYLEA HD and 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. For example, in March 2026, the Patent Trial and Appeal Board of the United States Patent and Trademark Office (the "USPTO") instituted a post-grant review of U.S. Patent No. 12,168,036 relating to EYLEA HD (see Note 12 to our Condensed Consolidated Financial Statements included in this report for additional information). 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. Similarly, such opposition proceedings are increasingly common in Europe and are costly to defend. For example, certain of our European patents, including those pertaining to EYLEA HD, EYLEA, and Dupixent, are subject to opposition proceedings before the European Patent Office (the "EPO") and/or patent offices of various European countries (see Note 12 to our Condensed Consolidated Financial Statements included in this report for additional information). We have pending patent applications in 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 2022, allowing Russian companies and individuals to exploit inventions owned by patent holders from the United States without consent or compensation. Consequently, we are not 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. 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 EYLEA HD, as described in Note 12 to our Condensed Consolidated Financial Statements included in this report.

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 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 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, under the Orphan Drug Act in the United States, if a product candidate with an orphan drug designation subsequently receives FDA approval for indication(s) within the scope of such designation, the product will be entitled to orphan drug exclusivity for such indication(s), barring the FDA from approving for seven years in such approved indication(s) another sponsor's application for a product candidate considered under the FDA regulations to be the same drug as the previously-approved drug with orphan drug exclusivity. This orphan drug exclusivity does not block approval of competing products intended for the orphan exclusivity-protected indication but containing a different active moiety or principal molecular structure, or containing the same active moiety or principal molecular structure but intended for a different indication. Similarly, 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. In both the United States and the EU, if a sponsor can demonstrate that a new product is safer, more effective, or otherwise clinically superior to the original orphan product, orphan exclusivity will not bar approval of the new product.

Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, have in the past reduced and could reduce in the future 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 or biosimilar 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 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 biologics that are similar to innovative biologics 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 the United States (such as the EU) have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products.

The increased likelihood of generic and biosimilar competition has exacerbated the risk of loss of innovators' market exclusivity. It is also not possible to predict changes in U.S. regulatory law that might reduce drug or biological product regulatory exclusivity and/or requirements to demonstrate biosimilarity. Due to this risk, and uncertainties regarding patent protection, the length of market exclusivity for any particular product we currently or may in the future commercialize is inherently uncertain. Biosimilar versions of EYLEA have been recently approved and/or launched in the United States, EU, and other jurisdictions, with additional biosimilar versions of EYLEA and/or EYLEA HD in development, 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. As EYLEA biosimilars have been launched in the United States following the expiration of the U.S. regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product could be approved by the FDA) in May 2024, EYLEA no longer has U.S. market exclusivity. Similarly, as EYLEA biosimilars have also been launched in certain jurisdictions outside the United States, EYLEA no longer has market exclusivity in those jurisdictions. In addition, as EYLEA HD does not benefit from regulatory exclusivity in the United States, market exclusivity for EYLEA HD in the United States is

based solely on our patent rights pertaining to this product (which are subject to the risks and uncertainties discussed 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."). Any future loss of market exclusivity for a product would likely negatively affect revenues from product sales of that product and thus our financial results and condition and could have a material negative impact on our business.

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/or 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 exacerbated, and this or other public health outbreaks, epidemics, or pandemics may in the future further exacerbate, certain of these risks. For example, the impact of having to prioritize certain manufacturing-related resources for our COVID-19 monoclonal antibodies included, among other things, drawing down inventory safety stock levels for certain of our other products. Depending on the demand for our products 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 currently rely entirely on other parties (such as contract manufacturers) and our collaborators for filling and finishing services, and expect to increase our reliance on other parties and/or our collaborators for bulk product manufacturing in the future. 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 depend on the parties we have engaged for these purposes 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 has been and will continue to be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures, time, and various regulatory approvals and permits. This also holds true for establishing fill/finish capabilities in the future, for which we have constructed a fill/finish facility in Rensselaer, New York that is currently undergoing process validation and has yet to be approved for commercial production. In addition, we may need to develop or acquire additional manufacturing capabilities as we and/or our collaborators continue to pursue the development of drugs generated by means other than our established "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 any existing and expanded manufacturing facilities and any fill/finish activities conducted by us, our collaborators, or our contract manufacturers 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 in a cost-effective manner or in compliance with cGMPs and other regulatory requirements, and we and our collaborators or contract manufacturers may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our products (or 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 or contract manufacturers 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 contract manufacturers or 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. 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 related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers that currently, or may in the future, perform services for us. In addition, if we or our collaborators carry 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 substantial charge to write down inventory related to REGENCOV®.

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 contract manufacturers, or the facilities of any other party participating in the supply chain, could 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' and contract manufacturers' facilities. We and our collaborators and contract manufacturers 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. For example, during the first and second quarters of 2026, bulk manufacturing production at our facility in Limerick, Ireland was temporarily interrupted due to unanticipated facility repairs that commenced during the first quarter of 2026. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Operating Expenses" for more information, including the interruption's impact on our reported financial results.

Many of our products and product candidates are very difficult to manufacture. As our currently marketed products and our product candidates are biologics, genetics medicines, peptides, or other complex therapeutics, 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), have led in the past and could lead in the future to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and/or 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 public health outbreaks, epidemics, or pandemics or other geopolitical developments, such as the armed conflicts between Russia and Ukraine and in the Middle East). Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or the BIOSECURE Act that was enacted into law in 2025. See also "Other Regulatory and Litigation Risks - *We face risks associated with tariffs and other trade restrictions, which may have a material adverse impact on our results of operations and financial condition*" below. 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 or advance our or our collaborators' preclinical research or clinical development programs, 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 or contract manufacturers 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' or contract manufacturers' 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, contract manufacturers, 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 the relevant application(s) relating to our products or product candidates 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. In recent years, the FDA issued CRLs to multiple companies (including us, as further discussed in this report or previously disclosed) citing unresolved inspection findings at third-party manufacturers, which prevented the timely approval of such companies' marketing applications. Our inability, or the inability of our collaborators, contract manufacturers, and third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance has in the past required us, and could in the future require us, to engage in lengthy and expensive remediation efforts, identify and onboard new service providers, 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, contract manufacturers, 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, 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. In recent years, we have received several CRLs from the FDA for regulatory submissions concerning our products or product candidates due to the FDA's findings from inspections at third-party manufacturers responsible for filling drug product, as discussed above 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 and biological products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, or obtain regulatory approval for our product candidates, we will not be able to market or sell them; and if we do not obtain approvals for new indications for our marketed products, we may not be able to realize the full commercial potential of such products. Any of the foregoing may materially and negatively impact our business, prospects, operating results, and financial condition.*" 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. From time to time, we are subject to claims by patients that they have been injured by a side effect associated (or alleged to be associated) with one of our products or product candidates. For example, we are currently subject to product liability lawsuits relating to Dupixent, as described in Note 12 to our Condensed Consolidated Financial Statements included in this report. Any such product liability claim, regardless of merit, may be costly and time consuming to investigate and defend and may have a negative impact on our reputation or business, including the degree to which we or our collaborators are able to successfully commercialize the applicable product or, if regulatory approval is obtained, product candidate. See also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *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*" above. 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 ("DTC") advertising, certain communications regarding unapproved uses, industry-sponsored scientific and educational activities, and sales representatives' communications. In 2025, the current U.S. administration, HHS, and FDA announced an initiative intended to ensure transparency and accuracy in DTC prescription drug advertisements through a series of reforms that have included and are expected to continue to include FDA rulemaking, additional enforcement action, and expanded regulatory oversight of social media promotional activities. Failure to comply with applicable FDA requirements for advertising and promotional activities (including those that currently apply or may apply in the future to DTC advertising) may subject a company to adverse enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties or other consequences that could have a significant commercial impact, including warning letters, 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 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 healthcare "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 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, administrative fines and 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 12 to our Condensed Consolidated Financial Statements included in this report, we are party to civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts concerning certain 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.

We continue to dedicate significant resources to comply with these requirements. In addition, a number of 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 copay 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 program (which is administered by the Health Resources and Services Administration ("HRSA")), the U.S. Department of Veteran Affairs ("VA") Federal Supply Schedule ("FSS") pricing program, the Tricare Retail Pharmacy Program, and other federal and state government pricing programs. Such programs often require us to provide discounts and/or pay rebates to certain government payors and/or private purchasers. See Part I, Item 1, "Business - Government Regulation - Pricing and Reimbursement" of Regeneron's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (filed February 4, 2026) for additional information on these programs.

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. For example, 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 fail to pay the required rebate, 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 knowingly and intentionally 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 operating results. 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. There is ongoing litigation involving other parties that may change the number of third-party contract pharmacies that can dispense drugs that manufacturers sell to 340B covered entities. The outcome of this litigation may change the scope of the 340B program in the coming years. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our operating results. Moreover, HRSA established an administrative dispute resolution ("ADR") process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. Further, any 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, including provisions included in the recent CMS calendar year 2026 Medicare Physician Fee Schedule final rule, could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

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, could 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 expanded and continue to expand due to, in part, our efforts to establish further 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 healthcare 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. 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 (including the imposition of monetary penalties), which could exceed our resources or insurance coverage. In addition, if we fail to obtain or maintain required permits and registrations, we may be subject to administrative fines and penalties or other regulatory actions, which could adversely affect our business.

Changes in laws, regulations, and policies 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 U.S. federal, state, and foreign laws and agency regulations and policies could have a materially negative impact on our business.

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. In addition, it is expected that in 2026 the revised EU pharmaceutical legislative framework will be adopted and enter into force, with a transition regime until 2028. The revised EU legislative framework is expected to facilitate earlier generic and biosimilar market entry, including by generally reducing regulatory data protection and market exclusivity periods.

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 or the PPACA or other healthcare reform laws. As discussed above under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *Product reimbursement and coverage policies and practices, pricing regulations and requirements, and our pricing strategy could change due to various factors beyond our control, which may adversely impact our business, prospects, operating results, and financial condition,*" the current U.S. administration is pursuing various measures to reduce the cost of drugs in the United States, and different or additional measures may be pursued in the future. 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. The FDA's ability to timely review and process any submissions we have filed or may file in the future may also be affected by the recent efforts to reduce the size and

budgets of U.S. government agencies, downsize the federal workforce, and implement other U.S. policy changes, as discussed above 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 and biological products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, or obtain regulatory approval for our product candidates, we will not be able to market or sell them; and if we do not obtain approvals for new indications for our marketed products, we may not be able to realize the full commercial potential of such products. Any of the foregoing may materially and negatively impact our business, prospects, operating results, and financial condition.*"

Risks associated with our operations outside the United States could adversely affect our business.

We have operations and conduct business in many countries outside the United States and have been significantly expanding the scope of these activities in existing and/or additional countries, including EU countries and Japan. For example, as discussed above, we now have commercial presence in many jurisdictions outside the United States, and we expect this commercial presence to continue to increase as we expand our commercialization activities for other products outside the United States. Consequently, we are, and will continue to be, subject to risks related to operating in countries outside the United States, 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, and the cost of compliance with such foreign laws and regulatory requirements;
- 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*"), as well as labor and employment laws and regulations;
- changes in the political or economic condition of a specific country or region, including as a result of the Russia-Ukraine war, or armed conflicts in the Middle East;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries (discussed in greater detail below under "*We face risks associated with tariffs and other trade restrictions, which may have a material adverse impact on our results of operations and financial condition*");
- 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, Japan, and other countries outside the United States. Changes impacting our ability to conduct business in 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 face risks associated with tariffs and other trade restrictions, which may have a material adverse impact on our results of operations and financial condition.

Our Company faces risks associated with tariffs and other trade protection measures (including tariffs that have been or may in the future be imposed by the United States or other countries), import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries.

In 2025, the U.S. administration imposed an array of tariffs under the International Emergency Economic Powers Act ("IEEPA"). In July 2025, the United States and the EU announced the framework of a trade agreement that generally imposes a 15% tariff on imports from the EU. Under this agreement, pharmaceutical products would not be subject to any future duties under Section 232 in excess of this 15% rate. IEEPA tariffs prompted retaliatory measures from several countries.

On February 20, 2026, the U.S. Supreme Court ruled that IEEPA does not confer the authority to impose tariffs. In response, the U.S. administration ceased collecting these duties and, on February 24, 2026, imposed a temporary 10% surcharge on

imports from all trading partners under Section 122 of the Trade Act of 1974 ("Section 122"). This surcharge expired on July 24, 2026.

In addition, in April 2026, the United States announced new tariffs on imports of patented pharmaceuticals and associated pharmaceutical ingredients under Section 232, which became effective for those companies that had not entered into a qualifying agreement with the U.S. government by September 29, 2026. The Section 232 tariffs create a tiered structure with multiple rates depending on the country of origin, the importing company's status concerning onshoring and pricing agreements, and the nature of the product. As discussed under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – U.S. Government Agreements," we have entered into the U.S. Government Agreements and thus have exemptions from the Section 232 tariffs through January 2029, subject to certain conditions.

Since March 11, 2026, the Office of the U.S. Trade Representative ("USTR") has initiated four new investigations under Section 301 of the Trade Act of 1974 ("Section 301") covering forced labor in supply chains; industrial overcapacity; intellectual property protection and enforcement concerns; and underpayment for certain pharmaceutical products. These investigations collectively target nearly 80 countries. As described below, the forced labor investigation has already resulted in new tariffs, effective July 24, 2026, and the remaining investigations could result in additional new tariffs impacting our business.

On July 23, 2026, USTR issued a notice of action in the Section 301 investigation into forced labor. As a result of this notice, tariffs of either 10% or 12.5%, effective July 24, 2026, apply to imports from 60 countries, including locations where we have operations, such as Canada, the European Union, India, Japan, and the United Kingdom. These tariffs essentially replace the 10% Section 122 surcharge that expired on July 24, 2026. USTR has provided a number of exemptions to the new tariffs, including exemptions for 700 specific articles used in pharmaceutical applications. While these exemptions limit the direct impact of the forced labor Section 301 tariffs on our import activities, some of our imports may not qualify for the exemptions and may be subject to the new tariffs. Additionally, because the scope, timing, and applicability of any tariffs resulting from the other ongoing Section 301 investigations remain uncertain, it is unclear what impact they may have on our supply chain and operations.

We face significant risks from the existing tariffs imposed by the United States (such as those discussed above) and potential new tariffs as well as their secondary effects, including other countries' imposition of retaliatory tariffs and non-tariff barriers. Depending on how the existing tariffs are applied and whether additional tariffs are imposed, our products that are manufactured partly or entirely outside of the United States could be subject to tariff duties when they are imported to the United States for further manufacturing, packaging, and/or sale to customers. In addition, like all U.S. importers, our Company could pay more for foreign-sourced inputs, which could adversely affect our operating costs in the United States. Our results of operations and financial condition may be materially adversely affected due to the impact of the foregoing.

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, tax effects of stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control), and changes in tax laws or regulations. For example, the OECD Pillar Two framework has influenced tax laws in countries in which we operate, including the implementation of minimum taxes. Changes to these or other laws and regulations or their interpretations, including those resulting from the "One Big Beautiful Bill Act" signed into law in 2025, 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 privacy and data protection laws in and outside the United States, including health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws. Such laws may apply to our operations and/or those of our collaborators and business partners and may impose restrictions on our collection, use, and dissemination of individuals' health and other personal data, including data that we may receive throughout the clinical trial process, in the course of our research collaborations, from individuals who enroll in our patient assistance programs, from

healthcare professionals that interact with us, or from our own employees. Laws and regulations in this area are constantly evolving and are often not interpreted consistently by regulatory authorities, institutional review boards/ethics committees, or clinical trial sites.

In the United States, there are numerous federal and state laws and regulations governing data privacy of personal data and the collection, use, disclosure, and protection of health data, genetic data, consumer data, and children's data. At the federal level, most U.S. healthcare providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). While Regeneron is not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we, our affiliates, or our agents knowingly receive protected health information in a manner that is not permitted under HIPAA. The FTC also sets expectations for taking appropriate steps to safeguard consumers' personal information and for providing a level of privacy or security commensurate to promises made to individuals. Failure to meet these FTC standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions. In addition, at the state level, many state consumer privacy laws recently went into effect and many other consumer privacy laws are expected to go into effect in the near future. These laws include certain transparency and other requirements to protect personal data and grant residents with certain rights regarding their personal data. These laws and regulations are constantly evolving and may impose limitations on our business activities.

Outside the United States, we have operations and conduct business in several countries and have been significantly expanding the scope of these activities in those and/or additional countries, as discussed above under "*Risks associated with our operations outside the United States could adversely affect our business.*" We also conduct clinical trials in these and many other countries around the world. These activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws. Such laws include the EU's General Data Protection Regulation ("GDPR"), which has a wide range of compliance obligations relating to the processing and protection of personal data. Violations of the GDPR carry significant financial penalties for noncompliance. The GDPR also confers a private right of action on data subjects and consumer associations to file complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Many other jurisdictions outside the United States have adopted and continue to adopt varying privacy and data protection legislation, the continued emergence of which has increased the costs and complexity of compliance.

If we or any of our 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 result in fines or other penalties or otherwise affect our or any such collaborators' ability to commercialize our products. Any threatened or actual government enforcement action could also generate adverse publicity and could result in additional regulatory oversight.

The use of social media platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage.

We use social media to communicate about our products and our business. The misuse of social media platforms by our employees or third parties on which we rely in contravention of our social media policy or other legal or contractual requirements may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of sensitive data. Social media posts may also include statements about efficacy or adverse events related to our products or product candidates that could create reporting obligations or lead to regulatory scrutiny. Furthermore, negative, inaccurate, or misleading posts or comments about us or our products on social media or any online platform, including posts or comments generated using artificial intelligence ("AI"), could seriously damage our reputation, brand image, and goodwill.

There are inherent risks related to our increasing use of artificial intelligence-based solutions.

We are increasingly utilizing AI-based solutions in various facets of our research, development, and other operations and continue to explore further use cases for AI. The use of AI solutions by our employees or third parties on which we rely may lead to the impermissible use or public disclosure of sensitive data. AI systems may generate inaccurate, incomplete, misleading, or biased outputs that may not be readily detectable by users, or may produce unreliable outputs over time. Reliance on such outputs could result in errors, inefficiencies, compliance issues, or other adverse consequences. Employee use of unapproved AI tools could create ungoverned data flows, unmonitored compliance gaps, and data protection risks that are not visible until an adverse event occurs. In addition, the increasing use of agentic and autonomous AI systems may create additional operational, cybersecurity, compliance, and data protection risks. Failures in the design, governance, or monitoring of such systems could result in unauthorized actions, inaccurate and/or biased outputs, disruption of business processes, or unauthorized access to sensitive information.

In the United States and in many jurisdictions outside the United States, new regulations have recently passed or have been proposed to ensure the ethical use, privacy, and security of AI solutions and the data processed thereby. The misuse of AI solutions in contravention of our internal policies, data protection laws, other applicable laws, or contractual requirements may give rise to liability, lead to the loss of trade secrets or other intellectual property, result in reputational harm, or lead to outcomes with unintended biases or other consequences. The misuse of AI solutions could also result in unauthorized access and use of personal data of our employees, clinical trial participants, collaborators, or other third parties. Additionally, AI-assisted analysis or AI-generated content embedded in regulatory submissions may be challenged or require additional justification if the underlying methodology cannot be fully defended or if applicable regulatory guidance evolves. 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, may be materially harmed.

We rely on support from Sanofi to develop, manufacture, and commercialize certain of our products and product candidates under the Antibody Collaboration. We expect this reliance to continue for the foreseeable future following the recent amendment to the Antibody Collaboration to add four new product candidates to the Antibody Collaboration, as discussed under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Collaboration, License, and Other Agreements – Sanofi." Under the Antibody Collaboration, agreed-upon development costs incurred with respect to the products and product candidates covered thereby are shared equally. In addition, we rely on Sanofi to assist with or lead 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 obligations thereunder, our business, prospects, operating results, and financial condition may be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our development efforts or cut back on such activities. If Sanofi does not perform its obligations with respect to the products and product candidates subject to the Antibody Collaboration, our ability to develop, manufacture, and commercialize these products and product candidates may be adversely affected. While we have some commercial presence outside the United States, our commercial capabilities outside the United States are still limited and would need to be further developed or outsourced 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 maintain or establish sufficient commercial capabilities outside the United States for products we currently commercialize or co-commercialize, or intend to commercialize or co-commercialize in the future, outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Antibody Collaboration may create substantial new and additional risks to the successful development and commercialization of the products and product candidates subject to the Antibody Collaboration, particularly outside the United States.

If our collaboration with Bayer for EYLEA HD and 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 HD and EYLEA outside the United States would be materially harmed.

We rely on Bayer with respect to the commercialization of EYLEA HD and EYLEA outside the United States. Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA HD and 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 HD and 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 HD and 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 maintain or establish sufficient commercial capabilities outside the United States for products we currently commercialize or co-commercialize, or intend to commercialize or co-*

commercialize in the future, 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 HD and EYLEA.

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) 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' or contract manufacturers' 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 and September 2023, we completed our acquisition of Checkmate Pharmaceuticals, Inc. and Decibel Therapeutics, Inc., respectively; and in April 2024, we acquired full development and commercialization rights to 2seventy bio, Inc.'s oncology and autoimmune preclinical and clinical stage cell therapy pipeline. 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, controls, systems, practices, policies, and procedures of our Company and the acquired business 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, research and development, regulatory, 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, product development or regulatory setbacks (including those relating to issues that may have arisen before we completed the transaction in question), 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 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 to consummate a particular transaction are successful, we may incur substantial charges for closure costs associated with elimination of duplicate operations and facilities, acquired in-process research and development charges, or intangible asset impairment 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 or 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 Board co-Chair, President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., our Board co-Chair, 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, manufacturing, 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. The size and complexity of our computer systems could give rise to unidentified or unremedied systems weaknesses or breakdowns and malicious intrusions, which could impact key business processes, including those related to drug manufacturing. We 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. We may also be exposed to vulnerabilities due to end-of-life issues impacting hardware or software utilized in our operations.

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 extortion, 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. Recent developments in the threat landscape, including the use of adversarial AI techniques and machine learning to rapidly identify vulnerabilities, amplify these risks. As a company with an increasingly global presence, our systems are subject to frequent attacks and incidents. For example, in the past we have experienced, and may experience in the future, various types of cybersecurity incidents, including unauthorized access to our IT systems, data security breaches, malware incursions, denial-of-service attacks, phishing campaigns, and other similar disruptions. Similar incidents have been experienced and may in the future be experienced by certain third parties on which we rely. Although we believe, based on an assessment of the relevant facts available to us, that none of these incidents has had a material adverse impact on our operations to date, there can be no assurance that a future incident would not result in material harm to our business, prospects, operating results, and financial condition. There is also the potential that our systems may be directly or indirectly affected as nation-states conduct global cyberwarfare.

Due to the nature of some of these attacks, there is a risk that an intrusion may remain undetected for a period of time. While we continue to make investments to improve the protection and resilience 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 or that our business continuity and disaster recovery plans will effectively remedy any such issues or other adverse developments in a timely manner or at all. 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, detect, plan for, or manage disruptions to these systems, we or our suppliers and/or service providers could have difficulty preventing, detecting, or mitigating the impact of such disruptions or security breaches, which could result in disruptions to our operations, legal proceedings, liability under U.S.

and foreign laws (including those that protect the privacy of personal information), 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.

The foregoing risks may be exacerbated as we periodically upgrade or enhance our information technology systems, including as part of our broader digital transformation efforts. For example, we are in the early stages of a multi-year project to implement a new enterprise resource planning ("ERP") system. Upgrading or implementing new business processes and information technology systems, including our new ERP system, requires the commitment of significant personnel, training, and financial resources, and includes risks to our business operations. If we do not successfully implement our new systems or other information technology systems improvements, or if there are delays or difficulties in implementing these systems, we may not realize anticipated productivity improvements or cost efficiencies, and we may experience operational difficulties and challenges in effectively managing our business, any of which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Public health outbreaks, epidemics, or pandemics have adversely affected and may in the future adversely affect our business.

The COVID-19 pandemic previously adversely affected, and 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.

Such disruptions in our operations could 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.

Our indebtedness could adversely impact our business.

We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of September 30, 2026, we had an aggregate of \$2.707 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, assuming all other variables remained constant, 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, assuming all other variables remained constant, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our Company.

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

As of September 30, 2026, we had \$3.659 billion in cash and cash equivalents and \$16.014 billion in marketable and other securities, as further described in Note 5 and Note 6 to our Condensed Consolidated Financial Statements included in this report. 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 HD, EYLEA, Dupixent, and Libtayo, 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, and our overall operating results;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and the market share for, our marketed products, especially EYLEA HD, EYLEA, Dupixent, and Libtayo;
- whether our net product sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- U.S. or other major market launch of a biosimilar version of one of our key marketed products (such as EYLEA or EYLEA HD);
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- 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 and developments relating to patent litigation and other proceedings and government investigations relating to our Company and operations;
- 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) and pricing agreements with government entities (including the U.S. Government Agreements) affecting the coverage, reimbursement, copay assistance, or use of any of our marketed products or competitors' products;
- 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;
- changes in trade, economic, and other policies of the United States or other countries, such as the imposition or threat of tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), other trade barriers, or protectionist or retaliatory measures taken by the United States or other countries;
- other market conditions;
- impact of public health outbreaks, epidemics, or pandemics on our business;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all and our ability to continue to declare cash dividends on our Common Stock and Class A Stock;
- 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. Securities class action litigation is often initiated against companies following periods of volatility in their stock price. For example, in July 2026, a putative class action civil complaint was filed against the Company and certain employees of the Company asserting violations of federal securities laws, as further described in Note 12 to our Condensed Consolidated Financial Statements included in this report. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2026, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 31.3% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2026. If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

There can be no assurance that we will continue to repurchase shares of our Common Stock or continue to declare cash dividends.

In April 2026, our board of directors authorized a share repurchase program to repurchase up to \$3.0 billion of our Common Stock (of which \$2.157 billion remained available as of September 30, 2026). In 2025, our board of directors also initiated a quarterly cash dividend program. Any future share repurchases, share repurchase program authorizations, or dividend declarations 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. Our share repurchases and dividend payments may change from time to time, and we can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, in particular amounts, or at all, or that we will maintain or increase our quarterly cash dividend payments or declare future cash dividends. A reduction in our share repurchases or reduction in, or elimination of, our quarterly cash dividend payments could have an adverse effect on our stock price.

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 September 30, 2026, holders of Class A Stock held 15.2% 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 September 30, 2026:

- our current executive officers and directors beneficially owned 5.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options and release of all restricted stock units held by such persons which are exercisable or releasable within 60 days of September 30, 2026, and 17.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options and release of all restricted stock units held by such persons which are exercisable or releasable within 60 days of September 30, 2026; and

- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 31.3% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2026. In addition, these five shareholders plus our Chief Executive Officer held approximately 40.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2026.

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 (which, pursuant to an amendment to our certificate of incorporation approved by shareholders in 2025, is in the process of being phased out, resulting in the annual election of all of our directors commencing with the 2028 annual meeting of shareholders);
- 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 current or former 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, which contractually prohibits Sanofi from seeking to directly or indirectly exert control of our Company or acquiring more than 30% of our Class A Stock and Common Stock, taken together.

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 September 30, 2026. 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 our 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)
7/1/2026–7/31/2026	569,723	661.91	569,723	\$ 2,157.1
9/1/2026–9/30/2026	5,340	802.50	—	\$ 2,157.1
Total ^(a)	575,063		569,723	

^(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

During the three months ended September 30, 2026, no director or executive officer adopted, modified, or terminated any trading arrangement intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

Item 6. Exhibits
(a) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
10.1	Award agreement and related notice of grant in connection with the 2026 grant of performance restricted stock units (the "2026 PSUs") to Leonard S. Schleifer, M.D., Ph.D. (Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. (the "Registrant"), filed September 30, 2026.)
10.2	Award agreement and related notice of grant in connection with the grant of the 2026 PSUs to George D. Yancopoulos, M.D., Ph.D. (Incorporated by reference from the Form 8-K for the Registrant, filed September 30, 2026.)
10.3*	Form of restricted stock purchase agreement in connection with the grant of equity in Three Sevens Holding Corp. to each of Leonard S. Schleifer, M.D., Ph.D. and George D. Yancopoulos, M.D., Ph.D.
10.4**	Sixth Amendment to Amended and Restated License and Collaboration Agreement, dated as of October 1, 2026, by and between the Registrant, Sanofi Biotechnology SAS, and Sanofi.
19.1	Insider Trading Policy.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Condensed Consolidated Balance Sheets as of September 30, 2026 and December 31, 2025; (ii) the Registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2026 and 2025; (iii) the Registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2026 and 2025; (iv) the Registrant's Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2026 and 2025; and (v) the notes to the Registrant's Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Certain of the exhibits and/or schedules to this Exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of all omitted exhibits and schedules of this Exhibit to the SEC upon its request.

** 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 SEC upon its request.

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: October 30, 2026

By: /s/ Christopher Fenimore

Christopher Fenimore
Executive Vice President, Finance and
Chief Financial Officer
(Duly Authorized Officer)

THREE SEVENS HOLDING CORP.**RESTRICTED STOCK PURCHASE AGREEMENT**

This Restricted Stock Purchase Agreement, dated as of September 24, 2026 (“**Effective Date**”), is between Three Sevens Holding Corp., a Delaware corporation (“**Company**”), and [] (“**Purchaser**”), and is subject to the attached Terms and Conditions (“**Terms and Conditions**”), which are incorporated herein by reference (together, the “**Agreement**”). Capitalized terms not defined herein are defined in the Terms and Conditions.

1. **Shares.** 2,000,000 shares of the Company’s Common Stock (“**Shares**”).
2. **Price.** \$0.00001 per share (“**Purchase Price**”), for a total purchase price of \$20.00.
3. **Form of payment.** \$20.00 in cash or by check or other electronic payment method.
4. **Vesting.** The Shares will be released from the Repurchase Option as follows:

4.1 1,625,000 Shares (the “**Vested Shares**”) shall be fully vested and released from the Repurchase Option as of the Closing, and 375,000 Shares (the “**Restricted Shares**”) shall be subject to the Repurchase Option and shall be released therefrom only in accordance with this Section 4 and **Schedule I**. The Restricted Shares shall be released from the Repurchase Option upon satisfaction of the milestone set forth on **Schedule I** (the “**Milestone**”) if both (1) the Milestone occurs within two years of the Effective Date (the “**Milestone Period**”) and (2) Purchaser’s continuous status as a Service Provider either continues through the occurrence of the Milestone or ceases prior to the occurrence of the Milestone by reason of a Qualifying Termination (as defined on **Schedule I**) (satisfaction of both (1) and (2), the “**Vesting Conditions**”). Upon satisfaction of the Milestone and provided the Vesting Conditions are met, all of the Restricted Shares shall be released from the Repurchase Option. For clarity, if prior to the occurrence of the Milestone, Purchaser’s status as a Service Provider terminates for any reason or no reason other than a Qualifying Termination, the Vesting Conditions shall not be met and the Restricted Shares shall be purchased pursuant to the Repurchase Option as described in Section 2 of the Terms and Conditions.

4.2 **Forfeiture Upon Failure to Achieve Milestone.** If the Milestone is not satisfied during the Milestone Period, then, effective upon the expiration of the Milestone Period, all of the Restricted Shares shall be repurchased pursuant to the Repurchase Option as described in Section 2 of the Terms and Conditions.

(signature page follows)

The parties have read and agree to the Agreement (including the Terms and Conditions) and have caused the Agreement (as subject to the Terms and Conditions incorporated by reference) to be duly executed and delivered as of the Effective Date.

COMPANY

Signature

Print signatory name

Print signatory title

Address 1

Address 2

Email

PURCHASER

Signature

Print signatory name

Print signatory title (only if signing for an entity)

Address 1

Address 2

Email

TERMS AND CONDITIONS
RESTRICTED STOCK PURCHASE AGREEMENT

The Company and Purchaser agree to these Terms and Conditions by signing the Agreement. Capitalized terms not defined in Section 6 or elsewhere in these Terms and Conditions have the meanings set forth in the Agreement.

1. Purchase and Sale of Shares.

1.1 **Purchase and Sale.** The Company agrees to sell to Purchaser, and Purchaser agrees to purchase from the Company, the Shares at the Purchase Price at a closing ("**Closing**") to be held as of the Effective Date, or at any other time mutually agreed upon by the Company and Purchaser on or prior to the date that is 30 days following the Effective Date. Purchaser's right to purchase the Shares will terminate, and Purchaser will have no further right to purchase the Shares, if the Closing does not occur on or prior to the date that is 30 days following the Effective Date.

1.2 **Closing.** The Closing will take place (a) remotely via the exchange of documents and signatures; (b) at the principal office of the Company; or (c) at such other place as designated by the Company. At the Closing, Purchaser shall deliver the total Purchase Price to the Company by check, wire transfer or other electronic payment method, cancelation of indebtedness, assignment of rights or any other method of payment permissible under applicable law (or any combination thereof), and the Company (or its transfer agent) shall enter the Shares in Purchaser's name in the stock records of the Company as of the date of the Closing and shall, within a reasonable time after the Closing, furnish Purchaser with evidence of ownership of the Shares.

2. Repurchase Option.

2.1 **Option.** If (1) Purchaser's status as a Service Provider ceases for any reason or no reason other than a Qualifying Termination prior to the satisfaction of the Milestone or (2) the Milestone has not occurred on or prior to the date that is two years following the Effective Date (the earlier of (1) and (2), if applicable, a "**Repurchase Event**"), the Company will have an irrevocable, exclusive option to repurchase ("**Repurchase Option**") any Shares that have not at that time been released from the Repurchase Option ("**Unreleased Shares**"), at a price per share equal to the Purchase Price (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or similar recapitalization) (the "**Repurchase Price**"). For purposes of determining the number of Unreleased Shares, the Shares released from the Repurchase Option will be rounded down to the nearest whole Share.

2.2 **Exercise.** The Company may exercise its Repurchase Option as to any or all of the Unreleased Shares by providing notice to Purchaser (or, in the event of Purchaser's death, Purchaser's executor) at any time after the Repurchase Event through the date that is 60 days thereafter; however, without requirement of further action on the part of either party to the Agreement, the Repurchase Option will be deemed to have been automatically exercised as to all Unreleased Shares at 5:00 p.m. (Eastern time) on the date that is 60 days following the Repurchase Event, unless and to the extent that the Company notifies Purchaser (or, in the event of Purchaser's death, Purchaser's executor) prior to that time that the Company expressly declines to exercise its Repurchase Option. If the Repurchase Option is exercised or deemed exercised, the Company shall, on or prior to the date that is 90 days following the date of the Repurchase Event, deliver payment of the aggregate Repurchase Price to Purchaser or Purchaser's executor by (in the Company's sole discretion) check, wire transfer or other electronic payment method, cancelation of indebtedness, assignment of rights or any other method of payment permissible under applicable law (or any combination thereof).

2.3 **Rights upon Exercise.** If the Repurchase Option is exercised or deemed exercised, (a) Purchaser will hereby be deemed to have sold, assigned and transferred the Unreleased Shares being repurchased, without any further action by Purchaser or the Company; (b) the Company will become the legal and beneficial owner of the Unreleased Shares being repurchased and the rights and interests therein or relating thereto, and the Company will have the right to transfer to its own name or cancel the Unreleased Shares being repurchased, without any further action by Purchaser or the Company; and (c) the sole right and remedy of Purchaser thereafter will be to receive the aggregate Repurchase Price, and Purchaser will have no claim of ownership as to any of the repurchased Unreleased Shares.

2.4 **Assignability.** The Company may assign all or part of the Repurchase Option to any Person or Persons.

2.5 **Leave of Absence.** Unless the Company provides otherwise, or unless otherwise required by applicable law, the release of the Shares from the Repurchase Option will be suspended during any period when Purchaser is on an unpaid leave of absence.

3. **Transfer Restrictions.**

3.1 **Limitations on Transfer.** Purchaser shall not Transfer any Unreleased Shares, nor any beneficial interest therein, other than as expressly required or permitted by Section 2 of these Terms and Conditions. Further, Purchaser shall not Transfer the Vested Shares, any Shares released from the Repurchase Option, nor any beneficial interest therein, without the prior approval of the Company's board of directors. Notwithstanding the foregoing, Purchaser may transfer the Shares, without the prior approval of the Company's board of directors (but with notice to the Company's board of directors), to an affiliate of Purchaser and in connection with Purchaser's estate and family wealth planning, including (A) to or for the benefit of Purchaser, to Purchaser's spouse or domestic partner, or any of their respective ancestors, descendants (whether natural or adopted), siblings or other family members; (B) to any trust, or other estate-planning arrangement in respect of which one or more of the persons described in clause (A) are beneficiaries; (C) to any corporation, partnership, limited liability company or other entity that is directly or indirectly owned or controlled by, or established for the benefit of, Purchaser or one or more of the persons or arrangements described in clauses (A) or (B); (D) by will, intestacy, operation of law or otherwise upon the death or incapacity of Purchaser; or (E) to, from or among any of the persons, entities or arrangements described in the foregoing clauses (A) through (D), including in connection with the establishment, funding, administration or distribution of any such entity or arrangement, subject to the conditions that (i) the transferee agrees in writing to receive and hold the Shares so Transferred subject to all of the provisions of the Agreement, any Stockholder Agreements, any restrictions in the Company's bylaws and applicable securities laws and (ii) Purchaser shall retain sole voting control over the Shares. Neither Purchaser nor any transferee shall Transfer any Shares, nor any beneficial interest therein, other than in compliance with the provisions of the Agreement, any Stockholder Agreements, any restrictions in the Company's bylaws and applicable securities laws. Any Transfer of Shares (or any beneficial interest in Shares) in violation of any restriction on Transfer contained in the Agreement will be void, unless such restriction is waived in accordance with the provisions of the Agreement.

3.2 **Legends.** The legends set forth below, or substantially equivalent legends, will be placed on a notice of issuance of uncertificated stock (or any certificates evidencing ownership of the Shares, as applicable), together with any other legends that may be required by the Company or by applicable securities laws:

THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED ("ACT"), AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR, IN THE OPINION OF COUNSEL SATISFACTORY TO THE ISSUER OF THESE SHARES, SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT.

THE SHARES REPRESENTED HEREBY ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER AND A REPURCHASE OPTION HELD BY THE ISSUER OR ITS ASSIGNEE(S), EACH AS SET FORTH IN THE RESTRICTED STOCK PURCHASE AGREEMENT BETWEEN THE ISSUER AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE ISSUER. SUCH TRANSFER RESTRICTIONS AND REPURCHASE OPTION ARE BINDING ON TRANSFEREES OF THE SHARES.

3.3 **Stop-Transfer.** The Company may make notations in its records, and may issue stop-transfer instructions to its transfer agent, in connection with any restrictions on Transfer applicable to Company securities.

3.4 **Refusal to Transfer.** The Company is not required to (a) transfer on its books any Company securities that are not Transferred in accordance with the Agreement, any Stockholder Agreements, the Company's bylaws and applicable securities laws; (b) treat any purported transferee of such securities as the owner thereof; or (c) accord the right to vote or pay dividends with respect to such securities to any purported transferee.

3.5 **Surrender of Share Certificates.** Upon any disposition of Shares, Purchaser shall surrender any certificates evidencing those Shares for transfer or cancellation.

3.6 **Restrictions Binding on Transferees.** All transferees of Shares (or any interests therein) shall receive and hold such Shares or interests subject to all provisions of the Agreement, any Stockholder Agreements, any restrictions in the Company's bylaws and applicable securities laws, and there will be no further Transfer of such Shares except in accordance therewith.

3.7 **RESERVED.**

3.8 **Escrow of Unreleased Shares.** For purposes of facilitating the enforcement of Section 2 of these Terms and Conditions, the parties agree to the following escrow arrangements:

(a) (i) Purchaser shall deliver, upon the Closing, a stock power in the form attached as Exhibit B to the Agreement duly endorsed in blank by Purchaser to the Secretary (or another designee) of the Company (the "**Escrow Agent**"); and (ii) the Unreleased Shares will, upon issuance, be subject to the exclusive control of the Escrow Agent to facilitate compliance by Purchaser with the provisions in the Agreement relating to Unreleased Shares, and any certificates with respect to the Unreleased Shares will be deposited upon issuance with the Escrow Agent, in each case to be held in escrow in accordance with the provisions of the Agreement. Subject to this Section 3.8 and the other provisions of the Agreement, Purchaser will have all rights of a stockholder (including voting rights) with respect to the Shares held in escrow.

(b) Purchaser hereby irrevocably constitutes and appoints the Escrow Agent as Purchaser's attorney-in-fact and agent, with full power of substitution, for the term of this escrow to take any actions as may be required in connection with the repurchase of Unreleased Shares pursuant to Section 2 of these Terms and Conditions. Purchaser acknowledges that the appointment of the Escrow Agent is a material inducement to enter the Agreement, is coupled with an interest and is irrevocable. If the Secretary of the Company resigns as Secretary, the successor Secretary will be the Escrow Agent. If the Escrow Agent otherwise resigns as the Escrow Agent, the Company will have the power to appoint a successor. The Escrow Agent may delegate any duties to Wilson Sonsini Goodrich & Rosati, P.C. or any other law firm, which delegation will survive resignation of the Escrow Agent.

(c) If, from time to time during the term of the Repurchase Option, there is any dividend or other distribution (whether in the form of cash, securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange, or other change in the corporate structure of the Company, affecting Unreleased Shares, then any cash, securities or other property to which Purchaser is entitled with respect to the Unreleased Shares ("**Associated Property**") will immediately be subject to this escrow and deposited with the Escrow Agent, to be handled in the same manner as the related Unreleased Shares.

(d) Unreleased Shares, including any Associated Property, will be transferred to the Company upon exercise (or deemed exercise) of the Repurchase Option. Shares, including any Associated Property, released from the Repurchase Option in accordance with the Agreement will be released from escrow.

(e) The Escrow Agent will not be liable for any acts or omissions of any kind as the Escrow Agent, unless due to willful misconduct or gross negligence. The Escrow Agent may rely upon (i) any instrument reasonably believed by the Escrow Agent to be genuine and signed or presented by the proper party or parties; and (ii) the advice of legal counsel (including any in-house counsel of the Company) in reference to matters related to the Agreement, the reasonable legal fees and expenses (if any) of which will be reimbursed by the Company. The Company and Purchaser jointly and severally agree to indemnify and hold harmless the Escrow Agent (and any other designees) against any claims, losses, liabilities, damages, deficiencies, costs and expenses, including reasonable legal fees and expenses of investigation and defense, incurred directly or indirectly as a result of any acts or omissions by the Escrow Agent (or any other designees) in the good faith exercise of judgment under the Agreement. The Escrow Agent and any other designees are intended third-party beneficiaries of this Section 3.8.

(f) The failure to comply with this Section 3.8 will not affect the rights and obligations of the Company and Purchaser under Section 2 of these Terms and Conditions. If requested by the Company, Purchaser shall promptly take all other action, and execute and deliver all other documents and instruments, necessary or reasonably desirable in the view of the Company to facilitate the enforcement of Section 2 of these Terms and Conditions.

4. **Purchaser Representations.** Purchaser represents and warrants to the Company as follows as of the Effective Date and as of the Closing date:

4.1 **Risk.** Purchaser (a) can properly evaluate the merits and risks of an investment in the Shares and can protect Purchaser's own interests in this regard, whether by reason of Purchaser's own business and financial expertise, the business and financial expertise of certain professional advisors unaffiliated with the Company with whom Purchaser has consulted, or Purchaser's preexisting business or personal relationship with the Company or any of its officers,

directors or controlling Persons; (b) is sufficiently aware of the Company's business affairs and financial condition to reach an informed and knowledgeable decision to acquire the Shares; (c) has received all information Purchaser deems appropriate for assessing the risks of an investment in the Shares; (d) realizes that the purchase of the Shares involves a high degree of risk and that the Company's prospects are uncertain; and (e) can incur a complete loss of the investment without impairing Purchaser's financial condition and is able to bear the economic risk of the investment for an indefinite period.

4.2 **Purchase for Own Account.** Purchaser is acquiring the Shares for investment for Purchaser's own account and not with a view to or in connection with any resale or distribution. Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the Shares. If an entity, Purchaser has not been formed for the specific purpose of acquiring the Shares. Neither Purchaser nor anyone related to Purchaser has either directly or indirectly (including, without limitation, through a broker or finder) engaged in any general solicitation or published any advertisement in connection with the offer and sale of any Company securities.

4.3 **Restricted Securities.** Purchaser understands that the Shares have not been registered under the Securities Act or any state securities laws by reason of specific exemptions that depend on, among other things, the bona fide nature of Purchaser's investment intent and the accuracy of Purchaser's representations in the Agreement. Purchaser's principal residence (or, in the case of an entity, place of business) is located at the address set forth below Purchaser's signature on the Agreement. Purchaser understands that the Shares are "restricted securities" under the Securities Act and must be held indefinitely unless registered or qualified under applicable U.S. federal and state securities laws or exemptions are available therefrom. Purchaser acknowledges that the Company has no obligation to register or qualify the Shares for resale. Purchaser further acknowledges that, even if an exemption is available, it may be conditioned on various requirements, including, but not limited to, the time and manner of sale, a holding period and requirements relating to the Company that are outside of Purchaser's control and that the Company is under no obligation, and may not be able, to satisfy. Purchaser understands that no public market now exists for the Shares and that no such market may ever exist.

4.4 **Compliance with Non-U.S. Law.** If Purchaser is not a United States person (as defined by Section 7701(a)(30) of the Code), (a) the offer and purchase of the Shares; (b) the execution and delivery of the Agreement and any related documents; and (c) the performance and consummation of the transactions contemplated thereby, will not violate any securities or other laws of Purchaser's jurisdiction.

5. Tax Matters.

5.1 **Section 83(b) Election.** Purchaser understands that Section 83 of the Code taxes as ordinary income the difference, if any, between the purchase price for the Shares and the fair market value of the Shares as of each date any restrictions on the Shares lapse. In this context, "restriction" includes the right of the Company to repurchase the Shares pursuant to the Repurchase Option. Purchaser understands that Purchaser may elect to be taxed at the time the Shares are purchased rather than when and as the Repurchase Option expires by filing an election under Section 83(b) of the Code ("**83(b) Election**") with the Internal Revenue Service within 30 days from the date of purchase. **PURCHASER (AND NOT THE COMPANY NOR ANY OF ITS ATTORNEYS OR OTHER AGENTS) SHALL BE SOLELY RESPONSIBLE FOR APPROPRIATELY AND TIMELY FILING THIS 83(B) ELECTION WITH THE INTERNAL REVENUE SERVICE, EVEN IF PURCHASER REQUESTS THE COMPANY OR ITS ATTORNEYS OR OTHER AGENTS TO MAKE THIS FILING ON PURCHASER'S BEHALF. THE INSTRUCTIONS FOR FILING THIS 83(B) ELECTION, INCLUDING A FORM FOR MAKING THIS 83(B) ELECTION BY CERTIFIED MAIL, ARE ATTACHED TO THE AGREEMENT AS EXHIBIT A.**

5.2 **Tax Withholding.** Pursuant to such procedures as the Company's board of directors may specify from time to time, the Company shall withhold the minimum amount required to be withheld for the payment of income, employment and other taxes that the Company determines must be withheld ("**Withholding Taxes**") with respect to the filing of an 83(b) Election, or, if an 83(b) Election is not filed or not timely filed, with respect to Shares released from the Repurchase Option by, in the discretion of the Company's board of directors, (a) withholding otherwise deliverable Shares upon release from the Repurchase Option having a fair market value, as determined by the Company's board of directors in good faith and in its sole discretion, equal to the amount of such Withholding Taxes (or such greater amount as Purchaser may elect if permitted by the Company's board of directors, if such greater amount would not result in adverse financial accounting consequences); (b) withholding the amount of such Withholding Taxes from one or more of Purchaser's paychecks; (c) requiring Purchaser to make appropriate arrangements with the Company (or the Parent or Subsidiary of the Company employing or retaining Purchaser) for the satisfaction of all Withholding Taxes; or (d) any combination of the foregoing. The Company shall not retain fractional Shares to satisfy any portion of the Withholding Taxes. Accordingly, if any withholding is done through the withholding of Shares, Purchaser shall pay to the Company an amount in cash sufficient to satisfy the remaining Withholding Taxes due and payable as a result of the Company not retaining fractional Shares. Should the Company be unable to procure such cash amounts from Purchaser, Purchaser authorizes the Company to withhold from one or more of Purchaser's paychecks an amount equal to the remaining Withholding Taxes due and

payable as a result of the Company not retaining fractional Shares. Purchaser acknowledges and agrees that the Company may refuse to deliver the Shares if all withholding amounts are not delivered at the time the Withholding Taxes become due and payable.

5.3 **Tax Liability.** Purchaser understands that (a) the Company's board of directors believes its valuation of the Shares represents a fair appraisal of their worth, but it remains possible that, with the benefit of hindsight, the Internal Revenue Service may successfully assert that the value of the Shares on the date of Purchaser's purchase was substantially greater than the board of directors' appraisal; (b) any additional value ascribed to the Shares by such an Internal Revenue Service determination will constitute ordinary income to Purchaser as of the purchase date, and any additional taxes and interest due as a result will be Purchaser's sole responsibility payable only by Purchaser, and the Company need not and will not reimburse Purchaser for that tax liability; and (c) Purchaser (and not the Company) is responsible for all of Purchaser's own tax liability that may arise as a result of the transactions contemplated by the Agreement.

6. **Definitions.** For purposes of the Agreement:

6.1 **"Code"** means the Internal Revenue Code of 1986, as amended.

6.2 **"Parent"** means a "parent corporation," as defined in Section 424(e) of the Code.

6.3 **"Person"** means any individual, corporation, partnership, trust, limited liability company, association or other entity.

6.4 **"Securities Act"** means the Securities Act of 1933, as amended.

6.5 **"Service Provider"** means an employee or consultant of the Company or a member of the Company's board of directors.

6.6 **"Stockholder Agreements"** mean stockholder agreements, investors' rights agreements, right of first refusal and co-sale agreements, voting agreements and/or similar agreements (in such forms as are commonly entered by significant holders of stock in private, investor-backed companies and approved by the Company's board of directors), which may, among other things, subject Purchaser to first refusal, co-sale, drag-along and take-along rights; lock-up provisions; other Transfer restrictions; voting provisions and/or irrevocable proxies.

6.7 **"Subsidiary"** means a "subsidiary corporation," whether now or hereafter existing, as defined in Section 424(f) of the Code.

6.8 **"Transfer"** means sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right or warrant to purchase; assign; gift; lend; pledge; encumber; offer; or otherwise transfer or dispose of in any way, directly or indirectly (whether by operation of law or otherwise).

7. **General.**

7.1 **Dispute Resolution.** The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the federal and state courts of the State of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the federal or state courts of the State of Delaware, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT

TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

7.2 At-Will Relationship. PURCHASER ACKNOWLEDGES AND AGREES THAT THE VESTING OF SHARES PURSUANT TO THE AGREEMENT IS EARNED ONLY BY CONTINUING SERVICE AS A SERVICE PROVIDER AT WILL (AND NOT THROUGH THE ACT OF BEING HIRED OR PURCHASING SHARES HEREUNDER) AND MEETING THE MILESTONE CONDITIONS SET FORTH IN THIS AGREEMENT. PURCHASER FURTHER ACKNOWLEDGES AND AGREES THAT THE AGREEMENT, THE TRANSACTIONS CONTEMPLATED UNDER THE AGREEMENT AND THE VESTING SCHEDULE SET FORTH IN THE AGREEMENT DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, OR FOR ANY PERIOD AT ALL, AND WILL NOT INTERFERE WITH PURCHASER'S RIGHT OR THE RIGHT OF THE COMPANY OR ANY PARENT OR SUBSIDIARY OF THE COMPANY TO TERMINATE PURCHASER'S RELATIONSHIP WITH THE COMPANY OR ANY PARENT OR SUBSIDIARY OF THE COMPANY AT ANY TIME, WITH OR WITHOUT CAUSE OR NOTICE.

7.3 Notices. Any notice or other communication required or permitted under the Agreement ("**Notice**") must be provided in writing to the other party through one of the following methods: (a) in person; (b) by registered or certified mail, return receipt requested; (c) by nationally recognized overnight courier service, specifying next-business-day delivery, with written verification of receipt; or (d) via email (and, if receipt is not confirmed within two business days, supplemented by one of the methods specified in (a), (b) or (c) of this Section 7.3), in each relevant case properly posted and fully prepaid. Notices to Purchaser should be sent to the address or email address set forth below Purchaser's signature on the Agreement or any other current address or email address in the Company's records for Purchaser. Purchaser shall notify the Company of any change in Purchaser's contact information. Notices to the Company must be sent to the Company's principal executive office to the attention of the CEO. Either party may change such party's address or email address for Notice by providing Notice of the change in accordance with this Section 7.3. Notices will be considered to have been given upon the earlier of actual receipt or (i) at the time of actual delivery in person; (ii) three business days after deposit in the mail as set forth above; (iii) one business day after deposit with an overnight courier service; or (iv) for email, the earlier of the date receipt is acknowledged by recipient or the date the supplemental Notice would otherwise be deemed given in accordance with this Section 7.3.

Subject to the limitations set forth in Section 232(g) of the Delaware General Corporation Law ("**DGCL**"), Purchaser consents to the delivery of any notice to stockholders given by the Company under the DGCL or the Company's certificate of incorporation or bylaws by (1) facsimile telecommunication directed to any facsimile number for Purchaser in the Company's records; (2) posting on an electronic network together with separate notice to Purchaser of such specific posting; or (3) any other form of electronic transmission directed to Purchaser. This consent may be revoked by Purchaser by written notice or electronic transmission to the Company and is subject to the limitations specified in DGCL Section 232(e). For purposes of this paragraph, "electronic transmission" has the meaning set forth in DGCL Section 232.

7.4 Specific Performance. Purchaser and the Company hereby acknowledge and agree that (a) money damages are inadequate to compensate the Company for its rights to repurchase Shares (including, without limitation, under Section 2 of these Terms and Conditions) and to enforce Transfer restrictions under the Agreement; and (b) the Company is entitled to specific enforcement of those rights.

7.5 Additional Documents. Upon request by the Company, Purchaser shall execute any additional documents or instruments necessary or reasonably desirable in the view of the Company to carry out the purposes or intent of the Agreement, including (but not limited to) the applicable exhibits and attachments to the Agreement.

7.6 Amendment; Waiver. Except as expressly provided in the Agreement, the Agreement may not be amended, waived, discharged or terminated other than by a written instrument referencing the Agreement and signed by the Company and Purchaser. Either party's failure to enforce any provision of the Agreement will not in any way be construed as a waiver of that provision nor prevent that party from enforcing any other provision of the Agreement or asserting any other legal remedy available to it.

7.7 Successors. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall receive the rights, and shall assume the obligations, of the Company under the Agreement and shall agree expressly to perform the obligations under the Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under the Agreement, the term

“Company” includes any successor to the Company’s business and/or assets that executes and delivers the assumption agreement described in this Section 7.7 or that becomes bound by the provisions of the Agreement by operation of law. Subject to the Transfer restrictions set forth in the Agreement, the Agreement will be binding upon and inure to the benefit of Purchaser and Purchaser’s heirs, executors, administrators, successors and permitted assigns.

7.8 **Assignment.** Except as set forth in the Agreement, the Agreement, and any rights, duties and obligations under the Agreement, may not be assigned, transferred, delegated or sublicensed by Purchaser without the prior written consent of the Company. Any attempt by Purchaser without such consent to assign, transfer, delegate or sublicense any rights, duties or obligations under the Agreement will be void.

7.9 **Adjustment.** In the event that any dividend or other distribution (whether in the form of cash, securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange, or other change in the corporate structure of the Company, affecting the Shares occurs, the kind, class, number and price of shares of stock covered by the Agreement as “Shares” will be appropriately adjusted (and any cash, securities or other property received by Purchaser with respect to any Unreleased Shares also will be subject to the Repurchase Option and the other provisions of the Agreement to the same extent that such Unreleased Shares are, or would have been, so subject).

7.10 **Construction.** The parties and their respective counsel, if any, have reviewed and negotiated the Agreement and waive the application of any law or rule of construction that ambiguities will be construed against the drafting party.

7.11 **Integration.** The Agreement, including all exhibits and attachments to the Agreement, represents the entire agreement between the parties with respect to the subject matter of the Agreement and supersedes and replaces any prior written or oral agreements relating to the subject matter of the Agreement (including, but not limited to, any representations made during any interviews, relocation discussions or negotiations, whether written or oral).

7.12 **Severability.** If any provision of the Agreement is found to be illegal or unenforceable, (a) the other provisions will nevertheless remain effective and will remain enforceable to the greatest extent permitted by law; and (b) the parties shall cooperate in good faith to amend such provision, to the extent reasonably practicable, to make it legal and enforceable and to reflect the original economic intent of the parties.

7.13 **Titles and Subtitles.** The titles and subtitles used in the Agreement are used for convenience only and are not to be considered in construing or interpreting the Agreement.

7.14 **Counterparts.** The Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via email or other transmission method, and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes. Facsimile copies of signed signature pages will be binding as if originals.

(remainder of page left intentionally blank)

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

SIXTH AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

THIS SIXTH AMENDMENT TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT (this “Sixth Amendment”), dated as of October 1, 2026 (the “Sixth Amendment Effective Date”), is by and between Sanofi Biotechnology SAS, a société par actions simplifiée, organized under the laws of France, as successor in interest to Aventis Pharmaceuticals Inc., having a principal place of business at 82 avenue Raspail, 94250 Gentilly, France (“Sanofi”), Sanofi, a société anonyme organized under the laws of France with its principal headquarters at 46-48 Avenue de la Grande Armée, 75017 Paris, France (“Sanofi Parent”), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of the state of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 (“Regeneron”) (with each of Sanofi and Regeneron being sometimes referred to herein individually as a “Party” and collectively as the “Parties”).

RECITALS

WHEREAS, Regeneron, Sanofi, and Sanofi Parent are parties to that certain Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, as amended as of May 1, 2013, July 1, 2015, April 5, 2020, October 6, 2021, and June 1, 2022 (the “LCA”) for the Development, Manufacture, and Commercialization of Licensed Products (as such terms are defined therein);

WHEREAS, the Parties desire to amend the terms and conditions of the LCA to add certain New Licensed Products (as defined below) to the Collaboration; and

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

AGREEMENT

1. Definitions.

1.1 Unless otherwise specifically provided herein, capitalized terms used, but not otherwise defined, in this Sixth Amendment shall have the meanings ascribed to them in the LCA.

1.2 Addition of Appendices. The LCA is hereby amended to add Appendix A, Appendix B, Appendix C, Appendix D, Appendix E, Appendix F, and Appendix G attached hereto. All references in the LCA to Appendix A, Appendix B, Appendix C, Appendix D, Appendix E, Appendix F, and Appendix G shall be deemed to refer to such Appendix A, Appendix B, Appendix C, Appendix D, Appendix E, Appendix F, and Appendix G as attached to this Sixth Amendment.

1.3 Discovery Agreement Definitions. Article 1 of the LCA is hereby amended so as to, for each of the definitions set forth in Appendix A, either delete the existing definitions in the LCA for each such term and replace them with the new definitions, or include such additional definition, as applicable, for each such term as is set forth in Appendix A. The Parties acknowledge and agree that an express purpose of Appendix A and the foregoing amendment is

to update certain defined terms in the LCA that currently cross-refer to that certain Amended and Restated Discovery And Development Agreement by and between the Parties dated November 10, 2009, as amended (the “Discovery Agreement”) to instead directly refer to the relevant definition (subject to certain updates and amendments thereto as set forth in Appendix A), thereby avoiding the need for the Parties to have recourse to the Discovery Agreement for the purposes of interpreting their obligations under the LCA.

1.4 Additional Definitions. Article 1 of the LCA is hereby amended by adding the following definitions:

(a) “Allergy” shall mean (a) an inappropriate, undesirable, or exaggerated reaction of the body’s immune system to a substance that is not ordinarily harmful to the general population and/or (b) any condition, disease or physiological response resulting from such reaction.

(b) “Clinical Combination” shall mean, for each Licensed Product, a single therapeutic regimen of the concomitant or sequential administration of (a) such Licensed Product, on the one hand, and (b) one (1) or more other product(s) that are not Licensed Products (“Other Agents”), on the other hand, where each of such Licensed Product and Other Agents are packaged and labelled and offered for sale separately (i.e., not as a co-packaged or co-formulated presentation). For clarity, a Combination Product itself is not a Clinical Combination.

(c) “Market Access” shall mean any and all activities relating to access, utilization, pricing (including any discounts and/or rebates), terms of sale, coverage, formulary placement, reviewing/awarding tenders, and/or reimbursement for any Licensed Products.

(d) “Market Access Entities” shall mean any and all pharmacy benefit managers (“PBM”), group purchasing organizations (“GPOs”), health plans, integrated delivery networks (“IDNs”), specialty pharmacies, the Federal Employee Program, government purchasers or payers (inclusive of the U.S. Department of Veterans Affairs (“VA”), the U.S. Department of Defense (“DoD”), Tricare, other Federal Supply Schedule accounts, state prescription drug affordability review boards (“PDABs”), and state Medicaid programs (including multistate Medicaid pharmaceutical purchasing pools)), commercial purchasers or payers, and other similar Third Parties for all engagements, books of business, and/or agreements.

(e) “Mutual Consent Matter” shall mean [* * *].

(f) “New Licensed Product” shall mean each of (a) the Antibody known as REGN20423 as of the Sixth Amendment Effective Date (the “IL-13 Product”) that directly interacts with interleukin-13 (Entrez ID 3596) (“IL-13”), (b) the Antibody known as REGN23149 as of the Sixth Amendment Effective Date (the “IL-4R α Product”) that directly interacts with interleukin-4 receptor (Entrez ID 3566) (“IL-4R α ”), (c) the Antibody known as REGN23262 as of the Sixth Amendment Effective Date (the “IL-4 Product”) that directly interacts with interleukin-4 (Entrez ID 3565) (“IL-4”), and (d) the Bi-Specific/Multi-Specifics known as REGN35937 and REGN36405 as of the Sixth Amendment Effective Date (each, an “IL-13 IL-4 Bi-Specific Product”) that directly interacts with IL-13 and IL-4, in each case ((a)-(d)), including any backup, successor, follow-on compound, and any related sequences, in each case, to the extent developed as

part of the same Development program, and solely to the extent directly interacting with the applicable foregoing Target(s).

(g) “New Major Indication” shall mean, for any New Licensed Product, any [* * *] (“NMI Countries”); *provided* that, if at the time of receipt of first Marketing Approval of such New Licensed Product for the applicable indication, such indication does not satisfy this clause (iii), but at any time following such Marketing Approval, aggregate Net Sales of such New Licensed Product for such indication in the Territory in any twelve (12)-month period equal or exceed [* * *] ([* * *]) (the “Target Net Sales Amount”), then such indication shall be deemed to satisfy this clause (iii) as of the date the Target Net Sales Amount is achieved, and, for clarity, solely from and after such date, and without retroactive effect: (x) any Net Sales of such New Licensed Product for such indication shall be included in the aggregate Net Sales thresholds for purposes of Milestone Event (5) and Milestone Event (6) set forth in Schedule 3 to this Agreement and not, for clarity, counted towards Milestone Event (3) set forth in Schedule 3; (y) each Net Sale for such New Licensed Product may only be counted once as between satisfaction of Milestone Events (5) and (6), on the one hand, or Milestone Event (3), on the other hand, and in no circumstances shall any such Net Sale be counted more than once or retroactively recharacterized or reallocated as between Milestone Event (3) on the one hand, or Milestone Events (5) and (6), on the other hand; and (z) if Milestone Event (4) set forth in Schedule 3 to this Agreement has not previously been achieved, it shall be due and payable to Regeneron as of such date. For clarity, the Target Net Sales Amount must be achieved with respect to a single indication (i.e., aggregation of Net Sales across multiple indications is not permitted in determining whether the Target Net Sales Amount has been achieved).

For clarity, and notwithstanding clause (ii) above, [* * *] but (A) increases the patient population by at least [* * *] ([* * *]) in the aggregate across the NMI Countries beyond that of the Reference Indication (including by virtue of a broader disease stage, disease setting, biomarker population, treatment regimen, or line of therapy) or (B) aggregate Net Sales of such New Licensed Product for such Expanded Indication in the Territory, that are not Net Sales of such New Licensed Product for the Reference Indication in the Territory, in any twelve (12)-month period, [* * *]. Notwithstanding the foregoing, solely for purposes of Milestone Event (4), Milestone Event (5), and Milestone Event (6) set forth in Schedule 3 to this Agreement, in determining if the applicable indication is a “New Major Indication”, clause (i) above shall be deemed satisfied if the applicable indication is expressly referenced in the FDA approval letter (including in any attached approved prescribing information) for such Marketing Approval for such New Licensed Product in the United States. For further clarity, any dispute over whether an indication is a New Major Indication shall be addressed in accordance with the governance procedures set forth in Section 3.11(b); *provided* that any disputes that persist after the foregoing shall be treated as a Technical Development Matter.

(h) “NLP Annual Aggregate Cap” shall mean: (a) for Contract Year 2026, [* * *] ([* * *]); and (b) for any subsequent Contract Year, subject to Section 5.3(c), [* * *] ([* * *]); *provided* that, if for any given subsequent Contract Year, the Parties’ representatives at the JSC (or, after escalation pursuant to Section 3.11(b), the Parties’ Executive Officers) agree to a Global Development Budget in excess of [* * *] ([* * *]) in the aggregate (such that such Global Development Budget is approved without [* * *] at the JSC), the “NLP Annual Aggregate Cap” for such Contract Year shall be equal to the total amount of the agreed Global Development Budget solely for such Contract Year.

(i) “NLP Specific Co-Co Countries” shall mean (a) each country set forth on Appendix B (each such country, a “Dupixent Co-Co Country”) and (b) any other Co-Commercialization Country where Regeneron has exercised its option to Co-Promote the New Licensed Products in accordance with Section 6.5(a), in each case ((a) and (b)), unless and until Regeneron exercises its rights to discontinue Co-Commercialization of the applicable New Licensed Product in such country in accordance with Section 6.5(c).

(j) “Registration Trial” shall mean, with respect to a New Licensed Product, (a) a Phase 3 Trial, (b) a human clinical trial (whether or not designated a Phase 3 Trial) that is designed to be adequate to gather sufficient evidence of safety, data, results, and efficacy to support a Registration Filing for a Marketing Approval for such New Licensed Product in the U.S., and/or (c) a human clinical trial that does not satisfy the foregoing requirements (clause (a) or (b)) at the time of initiation but satisfies at least one (1) of the following criteria: (i) it is modified to satisfy the requirements of 21 CFR 312.21(c); or (ii) it is otherwise determined following an initiation to be adequate to support an application for Marketing Approval of a New Licensed Product in the U.S.

(k) “Manufacturing Technology Transfer” shall mean, on a New Licensed Product-by-New Licensed Product basis, any activities conducted by or on behalf of either Party to transfer the validated Manufacturing process, technology and analytical methods for such New Licensed Product from an existing Manufacturing location to a new Manufacturing location (including, for clarity, a new suite at an existing site, or a new line within an existing suite), to enable such new Manufacturing location to Manufacture such New Licensed Product, including to test and validate the reproducibility of such process at such new Manufacturing location. For clarity, any technical development changes, including changes to the formulation, a new device, batch size or scale up, applicable to all Manufacturing sites do not constitute Manufacturing Technology Transfer [***].

(l) “Manufacturing Technology Transfer Costs” shall mean costs and expenses incurred by a Party in connection with any Manufacturing Technology Transfer for a New Licensed Product in the Field in the Territory, in accordance with this Agreement.

1.5 Amended Definitions.

(a) The definition of “Commercialize” or “Commercialization” is hereby amended by adding the following as a new sentence at the end of such definition:

“Notwithstanding the foregoing definition, solely with respect to each New Licensed Product, Commercialization shall include all pre-launch commercialization activities (and the parenthetical above limiting the date on which pre-launch marketing is considered Commercialization shall not apply).”

(b) The definition of “Committee” is hereby amended by adding “JMAC” after “JFC”.

(c) The definition of “Competing Product” is hereby amended to read in its entirety as follows:

““Competing Product” shall mean (a) with respect to a Licensed Product [* * *] and (b) with respect to the New Licensed Products, [* * *].”

(d) The definition of “Co-Promote” or “Co-Promotion” is hereby amended to read in its entirety as follows:

““Co-Promote” or “Co-Promotion” shall mean the joint marketing and promotion of Licensed Product(s) by the Parties (or their respective Affiliates) under the same trademark in a Major Market Country (which would be or are performed pursuant to the applicable Country/Region Commercialization Plan); *provided, however*, that solely in respect of each of the New Licensed Products in the NLP Specific Co-Co Countries, Co-Promotion shall include the Commercialization activities set forth in Section 6.5(h), which shall be allocated (including with respect to FTEs and sharing of costs) as set forth therein.”

(e) The definition of “Develop” or “Development” is hereby amended by adding the following as a new sentence at the end of such definition:

“Notwithstanding the foregoing definition, (x) solely with respect to each New Licensed Product and each Competing Product with respect thereto, the reference to “after the Initial IND Filing Date” above shall instead be deemed to be “on or after the Sixth Amendment Effective Date” and (y) clause (b) regarding pre-launch commercialization activities shall not apply to New Licensed Products (and such activities, for clarity, shall be Commercialization activities with respect to New Licensed Products).”

(f) The definition of “Development Costs” is hereby amended by adding the following at the end of such definition:

“With respect to each New Licensed Product, “Development Costs” shall not include any Manufacturing Technology Transfer Costs. Sanofi shall be deemed to have delivered an Opt-In Notice for each New Licensed Product as of the Sixth Amendment Effective Date. Notwithstanding anything to the contrary in this Agreement, a cost or expense incurred in the Development of a Clinical Combination shall be allocated as follows:

(i) if the Other Agent(s) in such Clinical Combination are owned or controlled by one (1) or more Third Party(ies), then [* * *]. Without limiting the foregoing, solely to the extent Regeneron has the right under any such executed Clinical Combination Agreement to disclose a copy thereof to Sanofi (and Regeneron will use diligent efforts to obtain such right), Regeneron shall provide to Sanofi a copy of the applicable Clinical Combination Agreement (including by and through the JDC) promptly following execution thereof (which copies may be redacted with respect to any information that is not necessary to determine compliance with this Agreement (including clause (i) of this Section)).

(ii) if one (1) or more of the Other Agent(s) in such Clinical Combination are owned or controlled by Regeneron, Sanofi, or any of their respective Affiliates, the Parties, through the JSC, shall determine the portion of such costs and expenses incurred in the Development of such Clinical Combination that are allocable to the New Licensed Product in such Clinical Combination (which allocable costs shall thereafter constitute Development Costs). In the event that the JSC cannot arrive at a consensus in respect of such

allocation, the portion of such costs and expenses incurred in the Development of such Clinical Combination that may be treated as Development Costs shall be determined by [* * *].

For clarity, to the extent a Clinical Combination includes one (1) or more Other Agent(s) that are owned or controlled by a Third Party and one (1) or more Other Agents that are owned or controlled by Regeneron, Sanofi, or any of their respective Affiliates, then both clauses (i) and (ii) shall apply, and [* * *].”

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

“Licensed Products shall, from and after the Sixth Amendment Effective Date, include all New Licensed Products.”

(h) The definition of “Sales Force Cost” is hereby amended by adding the following as a new sentence at the end of such definition:

“Notwithstanding the foregoing, with respect to each New Licensed Product, clause (b) shall be [* * *] ([* * *]) of the applicable Sales Force FTE Rate.”

(i) Clause (a) of the definition of “Shared Commercial Expenses” is hereby amended to read in its entirety as follows:

[* * *]

2. Amendments to Certain Provisions of the LCA.

2.1 Section 2.6(a) of the LCA is hereby amended and restated in its entirety as follows:

“(a) Non-Compete.

(i) [* * *], except as otherwise set forth in this Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Competing Product; *provided* that the foregoing shall not apply to activities undertaken by or on behalf of either Party related solely to research, candidate selection, discovery, and other pre-clinical activities conducted prior to the first IND submission for the applicable Competing Product (“IND Inflection Point”).

(ii) If a Party or its Affiliate owns or controls an Antibody that constitutes a Competing Product and desires to clinically Develop, Manufacture, and/or Commercialize such Antibody after the IND Inflection Point, such Party (or its Affiliate) shall notify the other Party, and the Parties shall, prior to the IND Inflection Point, discuss in good faith, including whether to add such Antibody to the Collaboration (“Competing Product Discussions”) until such time as a Party notifies the other Party in writing that it is not interested in continuing such discussions. If the applicable Antibody is not included in the Collaboration at the conclusion of such discussions, the Party that owns or controls such Antibody

shall (A) Divest such Competing Product and/or (B) terminate and cease all development and associated manufacturing, as applicable, of such Competing Product, in each case ((A) and (B)), within [* * *] Competing Product Discussions [* * *] (such [* * *] period, the “Competing Product Divestiture Period”); *provided* that such Party shall not conduct any clinical, commercial, or other activities in breach of the non-compete obligations set forth herein during such Competing Product Discussions or during such Competing Product Divestiture Period. For purposes of this Agreement, “Divest”, with respect to a Party and a Competing Product, shall mean that such Party exclusively (including with respect to such Party and its Affiliates) licenses or otherwise transfers to a Third Party all of its right, title and interest in and to such Competing Product and upon any license or transfer of such Competing Product to a Third Party, such Party may retain the right to (1) [* * *], (2) receive reports, audit and otherwise enforce such payment rights, (3) prosecute, maintain and enforce such Party’s intellectual property rights (excluding any patents that solely cover such Competing Product, which must be controlled by such Third Party following such license or transfer), (4) perform customary pharmacovigilance activities, and (5) perform a reasonable technology transfer and/or perform such other short-term customary, transitional arrangements (*e.g.*, a transition services agreement, manufacturing and supply agreement, or clinical supply agreement) in connection with any license or transfer of such Competing Product to a Third Party; *provided* that, other than the foregoing (1) through (5), following the completion of such license or transfer, such Party may not retain any continuing participation rights (including through decision-making or other governance rights) in respect of the development, manufacture, commercialization, or other exploitation of such Competing Product by such Third Party (or such Third Party’s Affiliates, sublicensees, or its or their successors or assigns).

(iii) Notwithstanding Section 2.6(a)(i), Sanofi shall have the right to complete the ongoing clinical studies (each, a “Permitted Study”) for each of Sanofi’s proprietary Bi-Specific/Multi-Specific that directly interacts with IL-13 and TSLP (also known as lunsekimig or SAR443765) (the “IL-13/TSLP Bi-Specific/Multi-Specific”) and one other Sanofi early development product known as of the Sixth Amendment Effective Date as [* * *] (the “Early Development Competing Product”, and together with the IL-13/TSLP Bi-Specific/Multi-Specific, in each case, the “Permitted Study Assets”), that are ongoing as of the Sixth Amendment Effective Date, in each case, solely to the extent such Permitted Study Assets and, solely in respect of the IL-13/TSLP Bi-Specific/Multi-Specific, such Permitted Studies, are listed on Appendix C; *provided* that [* * *] further disclose to Regeneron any other ongoing clinical studies for the Early Development Competing Product (to the extent not disclosed on Appendix C) within ten (10) Business Days of the Sixth Amendment Effective Date. For each such Permitted Study Asset, Sanofi’s conduct of the Permitted Studies shall not be deemed in breach of its non-compete obligations herein, and Section 2.6(a)(ii)(A) and (B) shall not apply in respect of the Permitted Study Assets, *provided* that Sanofi complies with this Section 2.6(a)(iii), Section 2.6(a)(iv), and Section 2.6(a)(v) and [* * *].

(iv) Regeneron shall have the exclusive irrevocable option (which shall survive the termination of this Agreement with respect to the IL-13 Product or otherwise), on a Permitted Study Asset-by-Permitted Study Asset basis, to include

such Permitted Study Asset in the Collaboration as a New Licensed Product as provided in this Section 2.6(a)(iv). Promptly after completion of all Permitted Studies applicable to a given Permitted Study Asset, Sanofi shall notify Regeneron thereof and provide Regeneron (pursuant to a customary confidentiality agreement) with (A) all material clinical study reports for each such Permitted Study, together with any material data, results and analyses generated, collected, prepared or performed by or on behalf of Sanofi or its Affiliates with respect to such Permitted Study Asset, (B) a statement of all Development Costs (with such term to apply to such Permitted Study Asset *mutatis mutandis* as if such product had been a New Licensed Product) actually incurred by Sanofi in the performance of (1) for the IL-13/TSLP Bi-Specific/Multi-Specific, each of the three (3) Permitted Studies [* * *] listed on Appendix C for the IL-13/TSLP Bi-Specific/Multi-Specific as of the Sixth Amendment Effective Date and (2) for the Early Development Competing Product, the Permitted Study that is listed on Appendix C for the Early Development Competing Product as of the Sixth Amendment Effective Date [* * *], such counterpart study to be disclosed to Regeneron pursuant to Section 2.6(a)(iii)(B) above (in each case of (1) and (2), the “Actual Permitted Study Costs”), (C) Sanofi’s anticipated plan and budget for further Development and Commercialization of such Permitted Study Asset were it added to the Collaboration and (D) such other information or materials in Sanofi’s or its Affiliates’ possession or control (which Sanofi has a right to disclose to Regeneron and which may be necessary or reasonably useful in assessing whether to include such Permitted Study Asset in the Collaboration) as Regeneron may request in writing, with such requests to be made to Sanofi no later than thirty (30) days after Regeneron’s receipt of the documents and information described in the foregoing (A) through (C) (collectively, ((A)-(D))), for each such Permitted Study Asset, the applicable “Product Report”). On a Permitted Study Asset-by-Permitted Study Asset basis, Regeneron shall have the option for a period of [* * *] after receipt of the applicable and complete Product Report to elect, on written notice to Sanofi, to include such Permitted Study Asset in this Agreement as a New Licensed Product, whereupon the terms of this Agreement shall thereafter apply to such Permitted Study Asset *mutatis mutandis* (i.e., the rights and responsibilities of the Parties with respect to the Development, Manufacturing, and Commercialization of such Permitted Study Asset shall be the same as for the other New Licensed Products); *provided, however*, that any such Permitted Study Asset shall not be taken into account for the purpose of determining whether any Milestone Event has been achieved (including, for clarity, that no Net Sales of any Permitted Study Assets shall count towards satisfaction of any of the Milestone Events). After such election by Regeneron, Sanofi shall invoice Regeneron for an amount equal to: (x) with respect to the IL-13/TSLP Bi-Specific/Multi-Specific, [* * *]; and (y) with respect to the Early Development Competing Product, [* * *], and in each case of ((x) and (y)), Regeneron shall pay any undisputed amounts to Sanofi within sixty (60) days of such invoice and, with respect to any disputed amounts, shall pay any such disputed amounts owed by such other Party within sixty (60) days after final resolution of the dispute (and Regeneron shall have the right to verify such Actual Permitted Study Costs pursuant to an audit conducted by Regeneron pursuant to Section 14.2, *mutatis mutandis*).

(v) If, for any such Permitted Study Asset: (A) Regeneron declines its option in writing during the [* * *] period after Regeneron’s receipt of the

applicable complete Product Report or (B) such [* * *] period expires without Regeneron providing written notice of its exercise of the option, then Sanofi shall, in its discretion, either Divest or wind down such Permitted Study Asset, *provided* that, consistent with Section 2.6(a)(iii), Sanofi shall not initiate any new clinical studies for, launch or otherwise Commercialize such Permitted Study Asset.

(vi) Each Party acknowledges and agrees that (A) Section 2.6 has been negotiated by the Parties, (B) the limitations on activities outside the Collaboration with respect to Targets as set forth in this Section 2.6 are reasonable, valid and necessary in light of the Parties' circumstances and necessary for the adequate protection of the business of the Licensed Products, and (C) neither Party would have entered into this Agreement without the protection afforded it by the noncompete provisions. If, notwithstanding the foregoing, a court of competent jurisdiction determines that the restrictions set forth in Section 2.6 are too broad or otherwise unreasonable (for example, due to a change in circumstance) under applicable Law, including with respect to duration, scope or space, the court is hereby requested and authorized by the Parties to revise Section 2.6 to include the maximum restrictions allowable under applicable Law."

2.2 Solely with respect to each New Licensed Product, each reference to "Regeneron" in Section 2.6(b) and Section 5.5 of the LCA is hereby deleted and replaced with "Sanofi", and each reference to "Sanofi" in Section 2.6(b) of the LCA is hereby deleted and replaced with "Regeneron".

2.3 Section 3.1(a) of the LCA is hereby amended to read in its entirety as follows:

"The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), CRCCs to the extent provided in Section 3.5, and such other commercialization sub-committee as the JCC shall deem to be appropriate, a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC"), a Joint Market Access Committee ("JMAC"), and such other Committees as the Parties deem appropriate. The JSC, JDC, JFC, and JMC shall each be established within thirty (30) days after the Effective Date. The JMAC shall be established within three (3) months of the Sixth Amendment Effective Date. The JCC shall be established at least two (2) years prior to the anticipated filing date for Marketing Approval for the first Licensed Product under this Agreement. It is understood that the Parties may wish to establish multiple Committees reporting to the JSC, JDC, and JCC with responsibility for different Licensed Products. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines."

2.4 Section 3.4(b)(xviii) of the LCA is hereby amended by adding "JMAC" after "JFC".

2.5 The following Section is hereby added to the LCA as a new Section 3.7A:

“3.7A Joint Market Access Committee.

(a) Composition and Purpose. The purpose of the JMAC shall be to serve as the primary forum for planning, coordination, discussion, and oversight of Market Access matters relating to Licensed Products (including, for clarity, New Licensed Products) [* * *]. The JMAC shall not engage in communications (oral, electronic, or in writing) or exchange any non-public information on market access matters (including any pricing, costs, profit margins, market access strategies, or R&D plans, commercial terms, or other competitively sensitive information) that is (i) related to Sanofi products that are not Licensed Products (nor, for clarity, New Licensed Products), and (ii) is not related to any Licensed Product (including, for clarity, any New Licensed Product) (such information, “Sanofi Restricted Information”), directly or indirectly. The JMAC shall be composed of [* * *].

(b) Specific Responsibilities. In particular, the JMAC shall be responsible for (in each case solely to the extent consistent with applicable Law):

(i) advising, and providing recommendations to, the JCC and JSC on all matters related to Market Access [* * *], including strategy and tactics for interacting with Market Access Entities and the negotiation of agreements therewith;

(ii) planning, developing, reviewing, preparing, discussing, and approving (A) Market Access strategy and tactics [* * *] and (B) materials (including business case materials) for, strategies for meetings and discussions with, negotiations with, and submissions (including any Market Access Agreements and drafts/proposals thereof) and communications (other than any unscheduled or ad hoc phone calls, text messages, or similar types of informal, unplanned communications that are not substantive) [* * *] relating to Market Access;

(iii) developing the strategy and tactics for engaging [* * *], and preparing for negotiations and preparation of materials in advance of meetings with, and submissions to, [* * *] (which preparation may occur directly at the JMAC or through Working Groups reporting to JMAC);

(iv) [* * *];

(v) reviewing and discussing the ongoing status of negotiations with and outcomes relating to any payer, account, or other Market Access Entity with respect to the Licensed Products;

(vi) [* * *];

(vii) establishing and overseeing strategic plans (which may be conducted through Working Groups) for each [* * *] to coordinate account relationships, proposals, negotiations, and meetings;

(viii) [* * *]; and

(ix) considering and acting upon such other matters related to U.S. or ROW Market Access as specifically assigned to the JMAC under this Agreement or by the JSC or JCC.

(c) Meetings. Without limiting Section 3.9, the JMAC shall meet at least [* * *] or as often as the JCC otherwise mutually agrees. For clarity, the JMAC is not intended to replace any other business communications that occur in the ordinary course of business between the Parties' commercial teams or at the JCC.

(d) Escalations. Given the time sensitive nature of certain Market Access submissions, either Party may request to convene the JMAC for urgent matters [* * *].

(e) Compliance. The JMAC shall not discuss any Sanofi Restricted Information. To the extent any materials proposed to be shared with the JMAC contain Sanofi Restricted Information, such Sanofi Restricted Information shall be redacted from such materials prior to their disclosure to the JMAC."

2.6 Section 3.11(a) of the LCA is hereby amended by adding "JMAC" after "JFC".

2.7 The last sentence in Section 3.11(b) of the LCA is hereby amended to read in its entirety as follows:

"The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which, [* * *]."

2.8 Section 3.11(d) of the LCA is hereby amended to read in its entirety as follows:

"(d) [* * *]."

2.9 The following Section is hereby added to the LCA as a new Section 5.1A:

"5.1A Pre-Clinical Development of New Licensed Products. For each New Licensed Product, Regeneron shall be the lead Party with respect to pre-clinical Development activities in a manner consistent with the applicable Global Development Plan and Global Development Budget (and which Development Costs shall be shared fifty percent / fifty percent (50% / 50%) in accordance with this Agreement)."

2.10 The following Section is hereby added to the LCA as a new Section 5.1B:

"5.1B Development of Combination Products. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of their respective Affiliates, either alone, or through any Third Party, shall Develop, Manufacture, and/or Commercialize any Combination Product unless and until the Parties agree mutually in writing (either through a separate written agreement or an amendment to this Agreement) on the terms of such Development, Manufacture, and Commercialization, including the allocation and sharing of Development Costs and the appropriate method for accounting for sale of such Combination Product for purposes of calculating Net Sales; *provided* that any disputes regarding the foregoing (including, for clarity, whether or not to Develop such Combination Product in the first instance) [* * *]."

2.11 Section 5.2 of the LCA is hereby amended, solely for New Licensed Products, to read in its entirety as follows:

“5.2 Global Development Plans for New Licensed Products. With respect to each New Licensed Product, as further set forth in this Section 5.2, the JDC shall prepare and present a Global Development Plan (including a Global Development Budget), for review and endorsement by the JFC and for approval by the JSC, and the JSC shall approve a Global Development Plan (including a Global Development Budget) for such New Licensed Product.

(a) The initial Global Development Plan (including the initial Global Development Budget) for the IL-13 Product is attached as Appendix D, which shall be presented on an Indication-by-Indication basis where applicable. All other initial Global Development Plans (including each additional initial Global Development Budget) for all other New Licensed Products shall be prepared by the JDC, reviewed and endorsed by JFC, and approved by the JSC, and shall be presented on an Indication-by-Indication basis where applicable. The Parties shall obtain such JSC approval, on a New Licensed Product-by-New Licensed Product basis, by the later of: (i) three (3) months after Sixth Amendment Effective Date, and (ii) twelve (12) months prior to the anticipated Initial IND Filing Date for such New Licensed Product.

(b) Unless otherwise agreed by the Parties, an updated Global Development Plan for each New Licensed Product will be presented to the JDC, reviewed by the JFC, and approved by the JSC, at least one (1) month prior to the end of each Contract Year.

(c) For clarity, to the extent any review, endorsement or approval by the JDC, JFC or JSC is contemplated in this Section 5.2, the escalation procedures set forth in Section 3.11 shall apply and all such matters shall be subject to Regeneron’s final decision-making authority with respect to any Global Development Plan or amendment thereto as set forth in Section 3.11(b).

(d) Each Global Development Plan for a New Licensed Product will set forth the plan for Development of such New Licensed Product in the Field over at least three (3) Contract Years and will include (i) strategies and timelines for Developing and obtaining Approvals for such New Licensed Product in the Field in the Territory, and (ii) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers. Each Global Development Plan will be reviewed and informally updated by the JDC not less frequently than once every six (6) months for the ensuing three (3) year period.

(e) Unless otherwise agreed by the Parties, Regeneron will be the POC Principal Party and the Post-POC Principal Party for each New Licensed Product and, as such, will have principal responsibility for formulating and carrying out clinical trials and other principal Development activities for each New Licensed Product under the applicable Global Development Plan.”

2.12 Section 5.3 of the LCA is hereby amended to read in its entirety as follows:

“5.3 Global Development Budgets. Each Global Development Plan for a Licensed Product shall include a related Global Development Budget (each individually, a “Global Development Budget”, and collectively, “Global Development Budgets”), and each

Global Development Budget shall be prepared, updated, reviewed, and approved as part of the preparation, update, and approval of the Global Development Plan of which such Global Development Budget is a part in accordance with this Agreement. Amendments and updates to any Global Development Budget shall not be effective without the approval of the JSC.

Notwithstanding the foregoing, the following shall apply to the Global Development Budget for each New Licensed Product:

(a) Budget Cap. If the amount of (i) Development Costs (including Shared Phase 3 Trial Costs) for Development activities, in the aggregate, across all New Licensed Products under all applicable Global Development Plans, in any given Contract Year minus (ii) any Sanofi Overages in such Contract Year, exceeds the NLP Annual Aggregate Cap (such excess, the “Annual Excess Cap Costs”), then, notwithstanding Section 5.1A and Section 9.1, Regeneron shall be initially responsible for one hundred percent (100%) of such Annual Excess Cap Costs, which may be carried forward or offset in accordance with clause (b) below. For clarity, the foregoing shall not operate to restrict Regeneron from incurring any Annual Excess Cap Costs, and any such Annual Excess Cap Costs shall not be counted against any Global Development Budget, Quarterly True-Up, or Regeneron Reimbursement Amount, or other true-up or shared cost obligation under this Agreement, except as set forth in clause (b) below or as otherwise mutually agreed in writing by the Parties. For purposes of this Agreement, “Sanofi Overages” shall mean, with respect to a Contract Year, the greater of (x) zero and (y) (1) all Development Costs incurred by or on behalf of Sanofi or its Affiliates with respect to activities allocated to Sanofi pursuant to the applicable Global Development Plan of New Licensed Products in such Contract Year minus (2) [* * *] ([* * *]) of the amounts set forth in the corresponding applicable Global Development Budget (having regard to any amendments thereto) for Sanofi’s performance of such activities for New Licensed Products in such Contract Year; *provided, however*, such Sanofi Overages shall not include any such excess costs to the extent (A) [* * *] any Global Development Plan to add additional Development activities, or to otherwise increase the scope of any then-current Development activities, performed, or to be performed, by Sanofi as set forth in the then-existing Global Development Plan (including by modifying the design and implementation of any Sanofi-led clinical trial) and Regeneron does not update the corresponding then-current Global Development Budget to account for (and commensurate to) such additions or increases in the Development activities or (B) the Parties agree at the JDC that Sanofi shall perform Development activities in a Contract Year that are not contemplated by the Global Development Budget for such Contract Year (e.g., accelerated enrollment).

(b) Excess Costs Balance. [* * *].

(i) [* * *].

(ii) Upon expiration or termination of this Agreement with respect to all New Licensed Products, Sanofi shall pay to Regeneron an amount equal to [* * *] of any then-remaining Excess Costs Balance upon the effective date of such expiration or termination.

(iii) For the avoidance of doubt, any Excess Costs Balance or Development Costs carried forward herein shall not bear interest, finance charges, or other similar adjustments, regardless of the duration for which such amounts remain outstanding.

Example Calculation:

2027

[* * *]

2028

[* * *]

2029

[* * *]

2030

[* * *]

2031

[* * *]

2032

[* * *]

(c) NLP Annual Aggregate Cap Changes. Promptly following the date on which: (i) a Target applicable to a New Licensed Product is terminated; (ii) a decision is made by the JSC (or by Regeneron exercising its decision-making authority) to discontinue or otherwise cease all Development of any New Licensed Product; (iii) a New Licensed Product has achieved a First Commercial Sale in a Major Market Country; or (iv) a Party otherwise requests to increase or decrease the NLP Annual Aggregate Cap based on anticipated Development activities for New Licensed Products, including material increases or decreases to such Development activities, the Parties shall promptly meet, review, and discuss, for a period of thirty (30) days, whether to implement and, if so, in what amount to implement, an appropriate increase or decrease, as applicable, to the NLP Annual Aggregate Cap; *provided, however*, (x) the Parties acknowledge and agree that no reduction to the NLP Annual Aggregate Cap shall occur unless and until the Excess Costs Balance is [* * *] ([* * *]), and any obligation to meet and discuss contemplated in this subsection (c) concerning such reduction may be tolled until such time, and (y) if the Parties are unable to agree to such an increase or decrease to the NLP Annual Aggregate Cap within such thirty (30)-day period, such dispute shall be a

Guardrail Dispute. For clarity, any increase or decrease to the NLP Annual Aggregate Cap shall [* * *].

(d) Guardrail Disputes. Any dispute relating to whether the NLP Annual Aggregate Cap should be increased or decreased pursuant to clause (c) above shall constitute a “Guardrail Dispute”. Any Guardrail Dispute shall be deemed to be a dispute relating to payment obligations or reports under Article IX for purposes of Section 9.12 and shall be resolved in accordance with Section 9.12, [* * *].”

2.13 The last sentence of Section 5.4 of the LCA is hereby amended to read in its entirety as follows:

“At the next JSC meeting held following such forty-five (45) day period, the JSC will approve the final Development Costs to be used in calculating the Quarterly True-Up. Without limiting the foregoing, Regeneron shall provide to Sanofi updates and information with respect to the Development of New Licensed Products that are consistent with the updates and information shared by Sanofi with respect to Development of Dupilumab as of the Sixth Amendment Effective Date.”

2.14 Section 5.6 of the LCA shall not apply to New Licensed Products, and the term “Licensed Product” as used in the foregoing provision shall exclude New Licensed Products.

2.15 Section 6.2(b) of the LCA is hereby amended to read in its entirety as follows:

“(b) [* * *];”

2.16 Without limiting Section 6.6, the reference to [* * *], and the last sentence in Section 6.3 of the LCA is hereby amended to read in its entirety as follows:

“In those countries where the Parties are Co-Promoting a Licensed Product (other than a New Licensed Product), such Country/Region Commercialization Plans shall include more detailed information on the coordination of detailing and promotional efforts and activities, including the estimated number of detailing FTEs for each Party (based on the number and position of Details required to meet the market and sales forecasts) and the specific allocation of Co-Promotion efforts and activities between the Parties. In the NLP Specific Co-Co Countries, such Country/Region Commercialization Plans shall include more detailed information on the coordination of Co-Promotion efforts and activities, including the estimated number of Co-Promoting FTEs for each Party and the specific allocation of Co-Promotion efforts and activities between the Parties, consistent with the allocation of responsibility (including with respect to FTEs) set forth in Section 6.5(h).”

2.17 Section 6.5(a) of the LCA is hereby amended by adding the following at the end of such Section:

“As of the Sixth Amendment Effective Date, Regeneron shall be deemed to have exercised its option to Co-Promote the New Licensed Products in each Dupixent Co-Co Country. For each Contract Year, unless otherwise agreed by the Parties, the Regeneron Commitment Level for each New Licensed Product in each NLP Specific Co-Co Country shall be fifty percent (50%) of the total anticipated FTE effort by both Parties (taken together) in Co-Promoting such New Licensed Product in such NLP Specific Co-Co Country. For clarity, the foregoing is not intended, and shall not be construed, to limit

and/or otherwise affect Regeneron's option to Co-Promote a New Licensed Product in any country other than a Dupixent Co-Co Country."

2.18 Section 6.5(b) of the LCA is hereby amended by adding the following at the end of such Section:

"With respect to New Licensed Products, the Country/Region Commercialization Plan for the NLP Specific Co-Co Countries shall be consistent with the allocation of responsibility (including with respect to FTEs) set forth in Section 6.5(h)."

2.19 The third sentence of Section 6.5(e)(i) of the LCA is hereby amended to read as follows:

"Subject to Section 6.5(h), with respect to the total anticipated FTE effort by both Parties in Detailing a Licensed Product in a Co-Commercialization Country, such FTE effort shall be based upon the forecasted number and position of Details required to meet the market and sales forecasts in such Co-Commercialization Country, and their conversion (by the JCC or applicable Country/Region Commercialization Committee) into the equivalent number of Detailing FTEs according to applicable weighting factors, based upon the sales force and marketing practices in such Co-Commercialization Country."

2.20 The penultimate sentence of Section 6.5(e)(i) of the LCA shall not apply to New Licensed Products, and for clarity, Regeneron shall be deemed to have in place a field force of qualified sales representatives to satisfy the Regeneron Commitment Level for the NLP Specific Co-Co Countries as of the Sixth Amendment Effective Date.

2.21 A new Section 6.5(h) is hereby added to the end of Section 6.5 of the LCA, with such new Section 6.5(h) as set forth as Appendix E hereto.

2.22 Section 6.6 of the LCA is hereby deleted in its entirety and replaced with the following (but for clarity any reference to "Licensed Products" as used below shall expressly exclude sarilumab (under the brand name Kevzara)):

"6.6 Licensed Product Pricing and Pricing Approvals in the Territory.

(a) General. Without limiting the responsibility and authority of the Committees with respect to pricing matters as provided herein[* * *]; *provided* that all such pricing decisions (including rebates or discounts) shall be made in a manner (i) intended to optimize the economic value of the Licensed Products in the Territory, (ii) consistent with the Collaboration Purpose, and (iii) in conformance with the Marketing Guidelines.

(b) Joint Participation Market Access Entities.

(i) "Joint Participation Market Access Entities" or "JPMAE" shall mean with respect to the Licensed Products in the U.S., as of the Sixth Amendment Effective Date, solely the Market Access Entities in the U.S. set forth on Appendix F; *provided* that the Joint Participation Market Access Entities for Licensed Products in the U.S. as set forth on Appendix F may be updated by Regeneron from time to time (but no more often than annually); *provided, further*, that Regeneron shall discuss any such updated list with Sanofi reasonably in

advance of any such selection and consider any comments from Sanofi to such list in good faith. [* * *].

(ii) JPMAE Meetings; Discussions.

(A) Regeneron shall have the right to [* * *] participate in [* * *] meetings with Joint Participation Market Access Entities ("JPMAE Meetings"), including: [* * *]. Sanofi shall provide reasonable advance written notice to Regeneron of any such JPMAE Meeting (of which Sanofi has advance notice and/or that are initiated by or on behalf of Sanofi) sufficiently in advance to allow for a reasonable opportunity for Regeneron to participate[* * *].

(B) Notwithstanding clause (A), if any JPMAE has a policy that would prevent, or if such JPMAE otherwise prohibits, Regeneron from attending any JPMAE Meeting[* * *], Sanofi shall [* * *] provide written notice to the applicable JPMAE requesting written consent from such JPMAE to permit Regeneron's attendance and participation as set forth in clause (A). [* * *].

(C) With respect to any (1) JPMAE Meeting that Regeneron does not attend and (2) meeting or interaction with a Joint Participation Market Access Entity that is not a JPMAE Meeting [* * *] Sanofi shall

[* * *] provide a comprehensive, written update to Regeneron reporting on each such meeting or interaction, including the outcome thereof. [* * *].

(D) Sanofi's and Regeneron's participation in any JPMAE Meeting for the Licensed Products shall be consistent with the applicable JMAC-approved Market Access strategy for such account.

(E) With respect to any JPMAE Meeting attended by Regeneron, Regeneron shall comply with the Rules of Market Access Participation. "Rules of Market Access Participation" means: [* * *].

(F) For clarity, Sanofi shall have no obligation to summarize or provide feedback (written, formal, or otherwise) on any JPMAE Meeting in which the Regeneron representative attended.

(iii) Consequences for Material Non-Compliance with the Rules of Market Access Participation. [* * *].

(iv) JPMAE Communications and Other Submissions. Regeneron shall have the right to participate in the preparation of all submissions (including material written communications) to, and the negotiation of all agreements and amendments with, any Joint Participation Market Access Entity relating to Market Access in the U.S. through the JMAC (or any Working Group or by any other means agreed by the Parties). Sanofi shall [* * *].

(v) JPMAE Strategy. The JMAC shall develop and approve the strategies for Market Access engagement with JPMAEs.

(vi) Other Market Access Entities. With respect to any and all Market Access Entities that are not Joint Participation Market Access Entities, (A) Sanofi shall [* * *]. For clarity, Regeneron shall have no right to attend or participate in any meetings or negotiations with such other Market Access Entities.

(c) Market Access Agreements. Without limiting clause (b):

(i) As used herein, “Market Access Agreement” shall mean all applicable agreements, together with all Licensed Product attachments thereto, with all Market Access Entities with respect to any Licensed Product.

(ii) Copies.

(A) With respect to any Market Access Agreement with respect to Dupilumab in effect as of the Sixth Amendment Effective Date (each such Market Access Agreement, an “Existing Agreement”) that Sanofi has the right, under such Existing Agreement or otherwise (including via a consent from the applicable Market Access Entity), to disclose to Regeneron as of the Sixth Amendment Effective Date, Sanofi shall provide to Regeneron a full and complete copy of such Existing Agreement [* * *], which copy may be redacted solely to remove Sanofi Restricted Information.

(B) With respect to any Existing Agreement that Sanofi does not have the right to disclose to Regeneron as of the Sixth Amendment Effective Date, [* * *], Sanofi shall [* * *] provide written notice to the applicable Market Access Entity with respect to such Existing Agreement requesting written consent from such Market Access Entity to disclose the applicable Existing Agreement(s) to Regeneron. [* * *]. Upon receipt of the applicable consent [* * *], Sanofi shall provide to Regeneron a full and complete copy of such Existing Agreement, which may be redacted solely to remove Sanofi Restricted Information.

(C) Sanofi shall [* * *] provide Regeneron full and complete copies of all Market Access Agreements executed after the Sixth Amendment Effective Date [* * *] following execution thereof, which may be redacted solely to remove Sanofi Restricted Information[* * *]. If Sanofi is not able to obtain such terms or such a consent from such a Market Access Entity [* * *], upon Regeneron’s request, Sanofi shall facilitate discussions among Sanofi, Regeneron, and such Market Access Entity [* * *]. Upon [* * *], Sanofi shall provide to Regeneron a full and complete copy of such Market Access Agreement, which may be redacted solely to remove Sanofi Restricted Information. For clarity, no such Market Access Agreement with a Joint Participation Market Access Entity shall be entered into or amended outside of the process outlined in Section 6.6(b).

(iii) Audits. Without limiting the foregoing or Section 14.2, Regeneron shall have the right[* * *] to conduct audits of all Market Access Agreements to ensure Sanofi’s (and its Affiliates’) compliance with this Section 6.6[* * *]. Such audit shall be performed through a Third Party, independent, nationally-

recognized auditor of Regeneron's choosing under reasonable appropriate confidentiality provisions consistent with those set forth in Article XVI. Such auditor shall be permitted to have access to complete and unredacted copies of such Market Access Agreements. [* * *] The results of any such audit shall be delivered in writing to each Party. Each Party shall bear its own costs in connection with such audit[* * *].

(iv) Separation. [* * *].

(v) IRA. The Parties acknowledge that, with respect to any Licensed Product (including, for clarity, any New Licensed Product) that is a "selected drug" under the Medicare Drug Price Negotiation Program established under Section 1191-1198 of the Social Security Act (as added by the Inflation Reduction Act of 2022, and any successor or analogous program, the "Negotiation Program"), Regeneron, as the holder of the applicable Marketing Approval (i.e., the applicable NDA or BLA) for such Licensed Product in the United States, shall serve as the "Primary Manufacturer" (as defined by Centers for Medicare & Medicaid Services ("CMS")) of record for purposes of the Negotiation Program and shall be responsible for satisfying the requirements imposed on the Primary Manufacturer thereunder, including the submission to CMS of all required and voluntary data and information, offers, counteroffers, and any final agreement regarding the maximum fair price (each, an "MFP Negotiation"). [* * *].

(A) Direction and Control. [* * *] Regeneron shall only submit, agree to, or otherwise communicate to CMS substantive positions, offers, or counteroffers with respect to the maximum fair price that are consistent with the applicable MFP Strategy.

(B) Attendance and Advance Review. To the extent permitted by CMS [* * *], Sanofi shall have the right to have its head of Market Access [* * *] attend, in a decision making capacity related to the maximum fair price and consistent with the applicable MFP Strategy, all meetings and substantive communications between Regeneron and CMS in connection with an MFP Negotiation. [* * *].

(C) Cooperation. [* * *] following Regeneron's written request, Sanofi shall provide Regeneron with any pricing, cost, and other information or materials necessary or reasonably requested by Regeneron to satisfy its submission obligations under the Negotiation Program. Regeneron shall have the right to use such information and materials to prepare documentation, and conduct negotiations or other discussions with CMS, under or in connection with the MFP Negotiation for the applicable Licensed Product. [* * *]. Notwithstanding anything to the contrary, each Party shall comply with its obligations under or in connection with the MFP Negotiation and any negotiated maximum fair price, including that Sanofi shall price products in the U.S. consistent with the negotiated maximum fair price.

(D) Escalations. Given the time sensitive nature of submissions under or in connection with the MFP Negotiations for the Licensed Products, the Parties agree to convene the JMAC as necessary [* * *].

(E) Coordination. The JMAC shall [* * *] approve a strategy for any MFP Negotiation[* * *] (once approved, the “MFP Strategy”). The JMAC shall serve as the forum for the Parties to coordinate with respect to any MFP Negotiation and subsequent effectuation procedures.

(vi) Most Favored Nations Drug Pricing Agreements and CMS Pricing Models. [* * *].”

2.23 Section 7.1(a) of the LCA is hereby amended to read in its entirety as follows:

“(a) Unless otherwise agreed to by the Parties (including as set forth below), the Post-POC Principal Party (i) shall be the Lead Regulatory Party, (ii) shall own (A) all Approvals with respect to Licensed Product in the Territory and (B) the IND for Licensed Products during such time as it is the Post-POC Principal Party, and (iii) shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto. The POC Principal Party shall own all INDs and be the Lead Regulatory Party for such Licensed Product(s), during such time as it is such POC Principal Party. With respect to Licensed Products other than New Licensed Products, if Regeneron does not have an Affiliate in a given country and Regeneron would otherwise be the Lead Regulatory Party for that country, then Sanofi shall instead be the Lead Regulatory Party for that country. For clarity, the Parties’ costs and expenses in maintaining any Approval shall constitute Shared Commercialization Expenses.

Notwithstanding the foregoing and notwithstanding anything to the contrary in this Agreement (including Section 5.2), with respect to each New Licensed Product, unless otherwise agreed by the Parties in writing:

(X) except to the extent set forth in clause (Y), Regeneron shall be the Lead Regulatory Party for all regulatory activities and regulatory submissions related to the Development of all New Licensed Products and shall hold the related IND filings reasonably necessary to support the initiation and conduct of Development activities of each applicable New Licensed Product.

(Y) Sanofi shall be the Lead Regulatory Party in all ROW Countries and Regeneron shall be the Lead Regulatory Party in the U.S., in each case, for all regulatory activities and regulatory submissions related to the Commercialization of all New Licensed Products, and, notwithstanding Section 1.35, for preparing, obtaining and maintaining any Marketing Approval for such New Licensed Products in such country (including, for clarity, preparing, obtaining, and maintaining any and all Registration Filings, and conducting communications with the applicable Regulatory Authorities with respect thereto).

(Z) In accordance with Section 7.1(b), Section 7.1(c) and Section 7.2 of this Agreement, each Party shall provide to the other Party all information in its possession and control necessary to enable the other Party to prepare, obtain, and maintain all such Registration Filings, Marketing Approvals or other Approvals and conduct any related Regulatory Authority interactions pursuant to clause (X) or (Y). At any time when Sanofi holds the Marketing Approval for a New Licensed Product in a ROW Country, Sanofi shall, upon Regeneron’s request and at Regeneron’s direction, perform any regulatory activities (including the submission of any IND (or supplement or amendment thereto) in Regeneron’s

name, if requested) reasonably necessary to support the conduct of Development of such New Licensed Product in such ROW Country.”

2.24 Section 9.1 of the LCA is hereby amended to read in its entirety as follows:

“9.1 Development Costs. Prior to October 1, 2026, Sanofi shall be responsible for paying one hundred percent (100%) of the total Development Costs for each Licensed Product (excluding New Licensed Products) incurred by or on behalf of Sanofi, Regeneron, and/or their respective Affiliates, except that Shared Phase 3 Trial Costs will be shared eighty percent (80%) by Sanofi and twenty percent (20%) by Regeneron. Effective on and after the Sixth Amendment Effective Date for New Licensed Products and on and after October 1, 2026 for each other Licensed Product, total Development Costs for each Licensed Product (including New Licensed Products) incurred by or on behalf of Sanofi, Regeneron, and/or their respective Affiliates will be shared fifty percent / fifty percent (50% / 50%) by the Parties, including any Shared Phase 3 Trial Costs, and shall not be allocated to the Global Development Balance. The Parties acknowledge that payments made by a Party pursuant to this Section 9.1 are being made as research and development expenses, as defined in Section 41 of the US Internal Revenue Code, and agree that any and all credits and/or deductions to which either Party may be entitled on account of research performed pursuant to such payments shall be allocated to such Party to the extent of such payments. Effective on and after the Sixth Amendment Effective Date for New Licensed Products and on and after October 1, 2026 for all other Licensed Products (as applicable), with respect to any Development Costs for a Licensed Product incurred by or on behalf of Sanofi, Regeneron, and/or their respective Affiliates, each Party shall, for clarity, deliver a report of such Development Costs to the other Party in accordance with Section 5.4 within forty-five (45) days after the end of each Quarter. Subject to accounting for any remaining Global Development Balance in calendar year 2026 as part of the final Quarterly True-Up for such year, the Parties agree to discontinue the Parties’ use of the Global Development Balance from and after October 1, 2026. For the avoidance of doubt, no research, pre-clinical, clinical, or other costs incurred by Regeneron with respect to Development or Manufacture of any New Licensed Product prior to the Sixth Amendment Effective Date shall constitute Development Costs subject to reimbursement or cost-sharing, and the Parties acknowledge that the upfront payment constitutes good and valuable consideration for, *inter alia*, Regeneron’s investments in the New Licensed Products incurred prior to the Sixth Amendment Effective Date.”

2.25 Section 9.2 of the LCA is hereby amended to read in its entirety as follows:

“9.2 Milestone Payments. In addition to the other payments contemplated herein, Sanofi shall be obligated to pay, in accordance with Schedule 3, the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the first occurrence of the applicable milestone event, which payments shall not be reduced by any withholding or similar taxes.”

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

“(c) Within forty-five (45) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, Sanofi shall deliver to Regeneron, in electronic form, a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency

and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size, (iii) gross Licensed Product Sales in the Field and (iv) a report of the deductions from gross sales consistent with the reports shared by Sanofi as of the Sixth Amendment Effective Date for Dupilumab;”

2.27 The following Section is hereby added to the end of Article 9 of the LCA as a new Section 9.15:

“9.15 Sixth Amendment Upfront Payment. In partial consideration for the rights granted by Regeneron to Sanofi with respect to the New Licensed Products hereunder, no later than ten (10) Business Days following the Sixth Amendment Effective Date, Sanofi shall pay to Regeneron a non-refundable, irrevocable, and non-creditable upfront payment in an amount equal to One Billion US Dollars (US\$1,000,000,000).”

2.28 The last sentence of Section 10.2 of the LCA is hereby amended to read in its entirety as follows:

“For the purposes of this Agreement, the term “Technical Development Matter” shall mean (a) any dispute concerning a Party’s refusal to approve a clinical trial proposed pursuant to Section 2.6(b), (b) any dispute concerning standard distribution cost per unit of New Licensed Product applicable to a given Contract Year pursuant to clause (a)(i) of the definition of “Shared Commercial Expenses”, and/or (c) any dispute concerning whether an indication constitutes a “New Major Indication”.”

2.29 The following Section 15.3A is hereby added to the LCA.

“15.3A Additional Regeneron Representations and Warranties.

Regeneron additionally represents and warrants to Sanofi that, as of the Sixth Amendment Effective Date:

(a) Regeneron owns all right, title, and interest in and to the Regeneron Patent Right that is in existence as of the Sixth Amendment Effective Date that is listed on Appendix G;

(b) Regeneron has the right and authority to grant the rights with respect to the New Licensed Products granted pursuant to the terms and conditions of this Agreement, and Regeneron has not granted any rights with respect to such New Licensed Products that would be inconsistent with, or in conflict with, or in derogation of, the rights granted herein;

(c) there is no pending litigation that alleges that any of Regeneron’s activities relating to the Regeneron Intellectual Property existing as of the Sixth Amendment Effective Date that is specific to the New Licensed Products (the “Regeneron NLP IP”) have violated, or would violate, the intellectual property rights of any Third Party (nor, to Regeneron’s knowledge, has it received any written communication threatening such litigation);

(d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Regeneron NLP IP have violated, or would violate, any intellectual property rights of any Third Party;

(e) the conception, development, and reduction to practice of any Regeneron NLP IP has not constituted or involved the misappropriation of trade secrets or other rights of any Third Party (nor, to Regeneron's knowledge, has it received any written communication alleging any such misappropriation);

(f) Regeneron has not received any written notice of claims or litigation (or, to its knowledge, any threatened claims or litigation) seeking to invalidate or otherwise challenge the Regeneron Patent Right set forth on Appendix G, or Regeneron's rights therein, and, to Regeneron's knowledge, such Regeneron Patent Right is not subject to any pending re-examination, opposition, interference, or litigation proceedings;

(g) Regeneron has written agreements (which have not been held unenforceable) with all of its employees who may participate in the Development or Manufacture of New Licensed Products hereunder assigning to Regeneron ownership of all intellectual property rights created in the course of their employment; and

(h) [* * *]

2.30 The following Section 19.9 is hereby added to the LCA:

“19.9 New Licensed Product Termination. With respect to any termination of this Agreement with respect to a New Licensed Product:

(a) termination of this Agreement with respect to any New Licensed Product that [* * *], whether or not such New Licensed Products also [* * *];

(b) termination of this Agreement with respect to any New Licensed Product that [* * *], whether or not such New Licensed Products also [* * *];

(c) termination of this Agreement with respect to any New Licensed Product that [* * *], whether or not such New Licensed Products also [* * *];

(d) termination of this Agreement with respect to any New Licensed Product that [* * *], whether or not such New Licensed Products also [* * *]; and

If Sanofi elects to terminate this Agreement with respect to one or more Targets (including New Licensed Products [* * *]) pursuant to Section 19.2(a), notwithstanding Section 19.2(a), the prior written notice period applicable to such termination shall be determined on a New Licensed Product-by-New Licensed Product basis and shall be as follows: [* * *]; provided that, for clarity, the obligations set forth in Section 2.6(a) shall continue to apply with respect to each such Target until this Agreement terminates with respect to the last New Licensed Product directed to such Target. For clarity, Regeneron's exclusive irrevocable option to include the Permitted Study Assets in the Collaboration as New Licensed Products as provided in Section 2.6(a)(iv) shall survive any termination of this Agreement.”

2.31 Notwithstanding anything in this Agreement to the contrary, including Schedule 1, (but without prejudice to the Letter Agreement, by and between the Parties, dated December 30, 2016, the terms of which shall continue to apply in respect of all Licensed Products other than New Licensed Products), any Manufacturing Technology Transfer Costs shall be deemed to be Manufacturing Costs under the LCA and, in respect of all New Licensed Products, shall be shared fifty percent (50%) to Sanofi and fifty percent (50%) to Regeneron.

2.32 The first paragraph of Schedule 2 to the LCA is hereby amended to read in its entirety as follows:

“At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the “Quarterly True-Up”) equal to (a) the U.S. Profit Split for such Quarter payable to Regeneron (as set forth in Part I), plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron (as set forth in Part II), minus (c) the Development Compensation Payment for such Quarter payable to Sanofi (as set forth in Part III (which, for clarity, shall not apply to Licensed Products (including New Licensed Products) from and after October 1, 2026)), plus (d) the Regeneron Reimbursement Amount for such Quarter payable to either Regeneron or Sanofi (as set forth in Part IV).”

2.33 Part II of Schedule 2 to the LCA shall apply to New Licensed Products as is; *provided* that the Applicable ROW Percentage and Target ROW Profit Split for any New Licensed Product in any Quarter shall be fifty percent (50%) Sanofi / fifty percent (50%) Regeneron.

2.34 Effective October 1, 2026, Part III of Schedule 2 to the LCA shall not apply to Licensed Products (including, for clarity, New Licensed Products). For clarity, the Parties shall calculate and settle a final true-up for the period ending on September 30, 2026 in accordance with the LCA as in effect immediately prior to October 1, 2026, which shall include all accrued amounts for such period. For further clarity, no Development Costs for any New Licensed Product that were incurred with respect to development performed prior to the Sixth Amendment Effective Date shall be included in such true-up, and each Party shall bear its own costs with respect to development performed prior to such date.

2.35 Effective October 1, 2026, Part IV of Schedule 2 to the LCA shall apply to Licensed Products (including, for clarity, New Licensed Products) as is; *provided* that the “Regeneron Reimbursement Amount” shall be defined as follows:

““Regeneron Reimbursement Amount” for a Quarter shall mean (a) aggregate Shared Commercial Expenses incurred by Regeneron in the U.S. and ROW in the Quarter for all Licensed Products, plus (b) aggregate Other Shared Expenses incurred by Regeneron in the U.S. and ROW in the Quarter for all Licensed Products, plus (c) an amount equal to (i) fifty percent (50%) of Development Costs incurred by Regeneron under a Global Development Plan in the Quarter for all Licensed Products (subject to Section 5.3(b)), minus (ii) fifty percent (50%) of Development Costs incurred by Sanofi under a Global Development Plan in the Quarter for all Licensed Products.”

2.36 The following is hereby added to the end of Schedule 3 to the LCA:

“Development, Sales, and Regulatory Milestones for New Licensed Products.

With respect to each of the development, sales, and regulatory milestone events (each, a “Milestone Event”) set forth in the table below that is first achieved by or on behalf of a Party or any of its Affiliates and/or Sublicensees, (a) such Party shall notify the other Party in writing of such achievement within thirty (30) days following such achievement, and (b) Sanofi shall pay Regeneron a non-refundable, irrevocable, and non-creditable milestone payment (“Milestone Payment”), which shall not be reduced by withholding or any similar taxes, within thirty (30) Business Days following such notice, as follows:

#	Milestone Event	Milestone Payment
(1)	Administration of the first dose of the IL-13 Product to the first patient in a Registrational Trial [* * *]	One Billion US Dollars (US\$1,000,000,000)
(2)	First Marketing Approval of [* * *]	One Billion Five Hundred Million US Dollars (US\$1,500,000,000)
(3)	Annual aggregate Net Sales of all New Licensed Products [* * *]	One Billion Five Hundred Million US Dollars (US\$1,500,000,000)
(4)	First Marketing Approval of [* * *]	One Billion US Dollars (US\$1,000,000,000)
(5)	Annual aggregate Net Sales of all New Licensed Products [* * *]	One Billion US Dollars (US\$1,000,000,000)
(6)	Annual aggregate Net Sales of all New Licensed Products [* * *]	One Billion US Dollars (US\$1,000,000,000)

Annual aggregate Net Sales of all New Licensed Products shall be determined based on the aggregate Net Sales thereof in any rolling twelve (12) month period, which for the avoidance of doubt, shall be aggregated across all New Licensed Products. The Parties acknowledge and agree that sales by Indication as set forth in Milestone Event (3), Milestone Event (5), and Milestone Event (6) shall be based on, and derived from, [* * *] data for each such New Licensed Product based on the approved Indications for each such New Licensed Product (unless the Parties mutually agree in writing to utilize a separate, analogous data vendor that provides information broken out by Indication); *provided* that, for Milestone Event (5) and Milestone Event (6), only sales for the Indications set forth in the applicable product label for such New Licensed Product(s) shall count.

In no event shall the total Milestone Payments paid by Sanofi to Regeneron for the above exceed Seven Billion US Dollars (US\$7,000,000,000) as each Milestone Event shall be payable only once.”

3. Miscellaneous Provisions.

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

3.2 Cooperation. Each Party will reasonably cooperate, and will cause its Affiliates to reasonably cooperate, with the other Party to perfect the rights of the Parties under the amended provisions of the LCA as set forth in this Sixth Amendment and to effectuate the terms and conditions of this Sixth Amendment, including by promptly entering into such additional amendments, agreements, and/or other documents as may be necessary to perfect such rights and/or effectuate such terms and conditions.

3.3 Miscellaneous. The provisions of Sections 20.1, 20.3, 20.5, 20.6, 20.7, 20.8, 20.11, 20.12, and 20.17 of the LCA shall apply *mutatis mutandis* to this Sixth Amendment as though set out in full in this Sixth Amendment.

3.4 No Other Amendments. Except as expressly amended hereby, all of the terms and conditions of the LCA shall remain in full force and effect, and the Parties hereby agree that the revisions in this Sixth Amendment are not intended, and shall not be construed, to constitute a waiver of any existing claims and/or any admission with respect to any ongoing and/or future dispute regarding the interpretation of any such terms and conditions, except as may expressly be set forth in a separate settlement agreement. For clarity, other than as expressly set forth herein, except for Section 1 and Section 4 thereof, the Fourth Amendment to the LCA, dated as of October 6, 2021, does not apply to the New Licensed Products.

[Signature Page Follows]

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

SANOFI BIOTECHNOLOGY SAS

By: /s/ Pauline Pereira

Name: Pauline Pereira

Title: Head of Finance BD&L and M&A

SANOFI

By: /s/ Loic Gonnet

Name: Loic Gonnet

Title: Head of M&A and Partnering

REGENERON PHARMACEUTICALS, INC.

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

Name: Leonard S. Schleifer, M.D., Ph.D.

Title: President and Chief Executive Officer

POLICY NAME:**230 Securities Investments****Effective Date: 01/14/01****Revised Date: 09/18/26****Contact: ***@REGENERON.COM****PURPOSE**

Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") and its directors, officers, and employees and certain other related persons are subject to "insider trading" laws. These laws prohibit individuals with material non-public information about a company from buying or selling securities of that company or from giving such information ("tipping") to another person. These laws also require companies and supervisory personnel to affirmatively supervise the actions of employees to ensure compliance. It is also Regeneron's policy to comply with applicable securities laws concerning trading in Company Securities (as defined below) on Regeneron's behalf.

To assure Regeneron and its directors, officers, and employees and certain other related persons are attentive to these laws and to promote compliance with these laws, as well as to maintain the integrity and reputation of both the Company and such individuals, Regeneron has adopted the following policy.

SCOPE

This policy applies to all employees of Regeneron.

POLICY**1. General Policy and Prohibitions**

No director, officer, or employee of the Company or any of its subsidiaries who is aware of material non-public information relating to the Company may, directly or indirectly through other persons or entities, (i) buy or sell Company Securities, except as expressly permitted under this policy, (ii) give, communicate, or in any way convey such information on a non-confidential basis to another person outside the Company (including, but not limited to, family, friends, business associates, investors, and expert consulting firms), (iii) recommend the purchase or sale of any Company Securities, or (iv) assist anyone engaged in the foregoing activities. The Company may also determine that other persons should be subject to this policy, such as contractors or consultants who have access to material non-public information. All of the persons referred to in the preceding two sentences of this paragraph are collectively referred to in this policy as "Company Personnel." Regeneron's policy also is to comply with applicable securities laws concerning trading in Company Securities on Regeneron's behalf.

Except as specifically noted in this policy, there are no exceptions to this policy. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not exempted from this policy. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

a. Scope of Information

This policy also covers information about any company (i) with which the Company does business, such as the Company's strategic partners, collaborators, distributors, vendors, customers, or suppliers, or (ii) that is involved in a potential transaction or business relationship with the Company (collectively, "Company Partners"). Any material non-public information obtained by Company Personnel which relates to a Company Partner should be treated as Regeneron's information and, accordingly, any such Company Personnel may not trade in that Company Partner's securities until the information becomes public or is no longer material.

b. Persons Covered

This policy applies to all Company Personnel, family members who live in their household (including a spouse, a child, a child away at college, step-children, grandchildren, parents, step-parents, grandparents, siblings, and in-laws), others who live in their household, and any other people or entities that might reasonably be deemed to have a relationship (legal, personal, or otherwise) meriting coverage, such as those whose transactions in Company Securities are directed by a member of Company Personnel (for example, a family trust of which such member is trustee) or are subject to such member's influence or control (collectively, the "Covered Persons").

c. Securities Subject to the Policy

This policy applies to transactions in the Company's securities, including without limitation the Company's common stock, Class A stock, options to purchase common stock, or any other type of securities that the Company issued or may issue from time to time, whether equity or debt securities and whether derivative or non-derivative and convertible or non-convertible, including (but not limited to) preferred stock, bonds, notes, debentures, and warrants, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to any securities of the Company. The securities referred to in the immediately preceding sentence are collectively referred to in this policy as "Company Securities."

d. Individual Responsibility

Company Personnel and their respective Covered Persons have ethical and legal obligations to maintain the confidentiality of information about the Company and other information as provided in this policy and other Company policies and not to engage in transactions in Company Securities while aware of material non-public information relating to the Company. Each member of Company Personnel is responsible for making sure that he or she complies with this policy and any Covered Person of such member also complies with this policy, including by making any such Covered Person aware of the need to confer with such member before trading in Company Securities. Each member of Company Personnel should treat all transactions by his or her Covered Persons covered by this policy for the purposes of this policy and applicable securities laws as if the transactions were for such member's own account. In all cases, the responsibility for determining whether an individual is aware of material non-public information rests with that individual, and any action on the part of the Company, the General Counsel (as defined below), or any other employee or director pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this policy or applicable securities

laws, as described below in more detail in paragraph 7 and under the heading "Legal Consequences."

e. **Administration of this Policy**

As used in this policy, "General Counsel" means the General Counsel of the Company or his or her designee, if any. The General Counsel shall be responsible for administration of this policy, and all determinations and interpretations by the General Counsel under this policy shall be final and not subject to further review.

f. **What is Material Information?**

The term "material information" should be construed broadly. Information is considered "material" if a reasonable investor would consider that information important in making a decision to buy, hold, or sell securities. Any information that could be expected to affect the price of Company Securities, whether it is positive or negative, should be considered material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight. While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

- i. projections of future earnings or losses, or other guidance (including, without limitation, projections or other guidance relating to product sales; research and development expenses; selling, general, and administrative expenses; capital expenditures; and income tax obligations), or changes thereof;
- ii. news of a pending or proposed merger, acquisition, or tender offer;
- iii. news of a significant new business transaction or license agreement;
- iv. significant regulatory developments or product approvals;
- v. a declaration of a stock split or the offering of additional Company Securities;
- vi. a change in management;
- vii. bank borrowings or other financing transactions out of the ordinary course;
- viii. a significant cybersecurity incident;
- ix. significant new clinical results or discoveries;
- x. significant litigation or litigation developments; and
- xi. significant new contracts or loss of business.

Developments in the Company's laboratories, clinical studies, the work of the Company's partners and collaborators, and other scientific developments are examples of potential material inside information. Information as to the success, failure, or even the unchanging status of particular aspects of the Company's business can be considered material.

g. When is Information Deemed Public?

Company Personnel may trade only when they are certain that official announcements of material information have been sufficiently publicized so the public has had the opportunity to evaluate the information and to absorb it. Company Personnel may not attempt to "beat the market" by trading simultaneously with, or shortly after, the official release of material information. Insider trading is not made permissible merely because material information is reflected by rumors or other unofficial statements in the marketplace. Information would likely not be considered widely disseminated if it is available only to the Company's employees, or if it is only available to a select group of analysts, brokers, and institutional investors. Company Personnel should presume that information is non-public unless they can point to the official release of that information by the Company in at least one of the following ways: (i) publicly available filings with the Securities and Exchange Commission (the "SEC"); (ii) issuance of press releases via a major newswire; or (iii) the Company's media and investor relations website. As a general rule, Company Personnel should not engage in any transactions until 24 hours after an announcement is publicly released, but in any event no earlier than the next business day following the date of such public release. Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply to the release of specific non-public information.

h. Prohibition of "Tipping"

Great care must be given to ensure that only approved non-public information is passed to persons outside the Company. Company Personnel have already signed confidentiality agreements. However, every practicable step to preserve the confidentiality of Company information must be affirmatively taken by all Company Personnel. For example:

- i. Don't discuss new developments in elevators, hallways, restaurants, airplanes, taxicabs, or any other place where you can be overheard.
- ii. Don't gossip.
- iii. Don't read documents containing non-public information in public places or discard them where they can be retrieved by others.
- iv. Don't carry documents with non-public information in elevators, hallways, etc., in an exposed manner.
- v. Beware of conducting sensitive conversations on speaker telephones in offices or on cellular phones in public, etc.
- vi. Cover confidential documents on your desk before you leave your room; don't leave confidential papers lying where visitors can see them.
- vii. Under no circumstances are Company Personnel to copy Regeneron documents for their personal use without express consent of a supervising employee. This includes but is not limited to any documents relating to any of our partners or collaborators.

i. **10b5-1 Trading Plans**

Notwithstanding the "General Prohibitions" in this paragraph 1 and the specific pre-clearance procedures set forth in paragraph 5, Company Personnel may, under the limited circumstances discussed below, establish written, predetermined trading programs ("Rule 10b5-1 Trading Plans") that meet the requirements of Rule 10b5-1(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Rule 10b5-1 provides for (i) scheduled trading of Company Securities based on predefined agreements, instructions or plans, or (ii) trading of Company Securities by an independent entity (such as a brokerage firm) when the individual making the investment decision is not aware of material nonpublic information regarding the Company and Company Securities, and the entity has implemented reasonable policies and procedures to prevent insider trading. Trading pursuant to a Rule 10b5-1 Trading Plan may occur even when the applicable Company Person is aware of material non-public information.

Each Rule 10b5-1 Trading Plan must be reviewed and pre-approved by the General Counsel on behalf of the Company prior to its effectiveness. Refer to the Company's Rule 10b5-1 Trading Plan Guidelines attached as Exhibit A to this policy for specific requirements for Rule 10b5-1 Trading Plans.

Rule 10b5-1 Trading Plans generally must be established at a time when the applicable Company Personnel member is not aware of material non-public information. The Rule 10b5-1 Trading Plan documentation must specify, among other things, the amount of Company Securities to be purchased or sold, the price at which the transaction is to take place, and the date on which each transaction is to be performed. Alternatively, the Rule 10b5-1 Trading Plan may establish an objective formula for any or all of these criteria. A Rule 10b5-1 Trading Plan may also be structured to give complete discretion to a third party to control how, when, or whether to effect purchases or sales, provided that the person effecting the transactions is not aware of any material non-public information when effectuating any purchases or sales.

Once a Rule 10b5-1 Trading Plan is prepared and becomes effective, it cannot be changed or deviated from except in extremely limited circumstances and (i) with notice to and pre-approval from the General Counsel, and (ii) only at a time when the applicable Company Personnel member is not aware of material non-public information. In addition, Company Personnel may not engage in any separate transactions that directly or indirectly alter or offset the authorized transactions under a Rule 10b5-1 Trading Plan (such as a hedging transaction). At the discretion of the Company, the existence and/or the terms of a Rule 10b5-1 Trading Plan may be disclosed to the public through a press release, a filing with the SEC, or through other means to be determined by the Company. Directors and designated officers of the Company subject to Section 16 of the Exchange Act (collectively, "Section 16 Insiders") should be aware that the Company will be required to make quarterly disclosures regarding all Rule 10b5-1 Trading Plans entered into, amended, or terminated by Section 16 Insiders and the material terms of such plans, other than pricing information.

Note that the Company's acceptance of a Rule 10b5-1 Trading Plan does **NOT** mean the plan meets the requirements of Rule 10b5-1. The Company has no obligation to monitor your trading activities (whether to ensure you are complying with your Rule 10b5-1 Trading Plan or otherwise); however, the Company reserves the right to halt any

transaction that fails to meet the terms of the applicable Rule 10b5-1 Trading Plan or this policy.

2. Additional Prohibited and Certain Specific Transactions

The Company has determined there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this policy engage in certain types of transactions. Therefore, it is the Company's policy that any Company Personnel and their respective Covered Persons may not engage in any of the following transactions or must otherwise comply with the requirements described below:

a. Short Sales

Short sales of Company Securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and, therefore, have the potential to signal to the market the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance.

For these reasons, short sales of Company Securities are prohibited. In addition, Section 16(c) of the Exchange Act prohibits officers and directors from engaging in short sales. (Short sales arising from certain types of hedging transactions are governed by the paragraph below captioned "Hedging Transactions.")

b. Publicly Traded Options

Transactions in options relating to Company Securities may create the appearance that a member of Company Personnel is trading based on material non-public information or focuses his or her attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options, or other similar derivative securities relating to Company Securities, on an exchange or in any other organized market, are prohibited by this policy. (Option positions arising from certain types of hedging transactions are governed by the next paragraph below.)

c. Hedging Transactions

Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds. Such hedging transactions may permit Company Personnel to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, Company Personnel may no longer have the same objectives as the Company's other shareholders. Therefore, Company Personnel and their respective Covered Persons are prohibited from engaging in any such transactions.

d. Margin Accounts and Pledged Securities

Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material non-public information or otherwise is not permitted to trade in Company Securities, Company Personnel and their respective

Covered Persons are prohibited from holding Company Securities in a margin account or otherwise pledging Company Securities as collateral for a loan.

e. **Standing and Limit Orders**

Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Trading Plans, as described above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and, as a result, the broker could execute a transaction when a director, officer or other employee is aware of material non-public information. If a member of Company Personnel determines that he or she must use a standing order or limit order, the order should be limited to short duration and must otherwise comply with the general prohibitions set forth in paragraph 1 above, as well as the restrictions and procedures outlined in paragraph 5 below (if applicable).

f. **Prediction Market Transactions**

Trading on prediction markets or similar platforms, including betting, wagering, or establishing positions in event contracts (collectively, "Predictions Market Trading"), presents heightened risks of misuse of Regeneron's proprietary or otherwise non-public information. To help protect against misuse, you are prohibited from Predictions Market Trading involving (i) any outcomes relating to Regeneron or any Company Partners, regardless of whether you are aware of non-public information about Regeneron, or (ii) the use of confidential or otherwise non-public information learned during the course of your service with the Company (including with respect to Company Partners and regulators). In addition, you are prohibited from "tipping" or recommending such activities to another person.

3. **Special Provisions for Lectures and Publications**

Any scientist, researcher, or other Regeneron employee who intends or plans to (i) speak or otherwise actively participate in any seminar, lecture, or other public function, (ii) publish, circulate, or otherwise distribute any article, research memorandum, or other piece of research writing (except for internal distributions within Regeneron), (iii) in any way disseminate any other material information, pertaining to Regeneron or to scientific developments with which Regeneron is involved, must, prior to engaging in such activity, consult with the General Counsel in order to determine the repercussions of such engagement upon the Company's policy as set forth herein, and take such actions prior to such engagement as the General Counsel may deem appropriate. This requirement is consistent with the Regeneron employment agreement and Regeneron's protection of intellectual property rights.

4. **Transactions Not Subject to Policy**

This policy does not apply in the case of the following transactions, except as specifically noted:

a. ***Bona Fide Gifts of Company Securities Not Treated as Charitable Deductions***

Bona fide gifts of Company Securities made in good faith for which the donor is not claiming a charitable deduction are not subject to this policy.

b. **Stock Option Exercises**

This policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's plans to the extent the exercise is done in a manner where there is no

market transaction and no transaction with a third party, nor does it apply to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. The payments in respect of the exercise price or tax withholding obligations can be made by cash, option shares, or tendered shares via "attestation" or actual share delivery. If you use attestation, you will not have to deliver physical Company Securities to the Company. Rather, you will provide the Company with evidence that you own and have held for at least six (6) months a number of Company Securities with a dollar value at least equal to the exercise price and/or the taxes. This policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

c. Restricted Stock Awards

This policy does not apply to the exercise of a tax withholding right pursuant to which you elect to have the Company withhold Company Securities to satisfy tax withholding requirements upon the vesting of any restricted stock. The payments in respect of the tax withholding obligations can be made by cash or tendered shares via "attestation" or actual share delivery. If you use attestation, you will not have to deliver physical Company Securities to the Company. Rather, you will provide the Company with evidence that you own and have held for at least six (6) months a number of Company Securities with a dollar value at least equal to the taxes. This policy does apply, however, to any market sale of restricted stock. For the avoidance of doubt, this policy does not apply to the vesting of restricted stock.

d. 401(k) Plan

This policy does not apply to your acquisition of Company Securities in the Company's 401(k) savings plan resulting from any annual or quarterly matching contribution in Company Securities made by the Company in its discretion. The Company's 401(k) savings plan does not provide for an allocation of a portion of your period contributions to a Company stock fund, nor does it allow a liquidation of some or all of your Company stock fund balance in the case of a loan against your 401(k) savings plan balance or a pre-payment of your plan loan balance resulting in an allocation of loan proceeds to the Company stock fund. This policy does apply, however, to an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund or any market sale of Company Securities out of a 401(k) savings plan balance, other than an automatic minimum annual distribution made in accordance with relevant tax rules and regulations initiated by a third party not controlled by or influenced by Company Personnel or their respective Covered Persons.

e. Other Similar Transactions and Other Company Plans

Except as may be determined by the General Counsel, any other purchase of Company Securities from the Company or sales of Company Securities to the Company are not subject to this policy. In addition, this policy does not apply to any conversion of the Company's Class A stock (whether optional or mandatory) into common stock (however, this policy does apply to any sale of the common stock issued upon such conversion). In addition, this policy applies to the conversion of other Company Securities (such as convertible notes), other than employee stock options acquired pursuant to the Company's plans as described in paragraph 4.b above. To the extent the Company in the future adopts an employee stock purchase plan, a dividend reinvestment plan, or other

similar plan, this policy will be amended to address such plan or plans and transactions and elections thereunder. In the absence of such an amendment, the General Counsel may, consistent with the principles set forth in this policy, address such issues in a written supplement to this policy, which shall be binding on Company Personnel and their respective Covered Persons.

5. Trading Window and Pre-Clearance Procedures

a. Additional Procedures Applicable to Designated Persons

Except for permitted transactions under Rule 10b5-1 Trading Plans, Section 16 Insiders, other designated officers of the Company, and other designated Company Personnel (together with their respective Covered Persons) (collectively, the "Designated Persons") may (i) buy or sell Company Securities in the market or (ii) make a gift of Company Securities treated as a charitable deduction only (A) outside of a Blackout Period (as defined below) and (B) after obtaining prior approval ("Pre-Clearance") from the General Counsel. The restrictions set forth in this paragraph 5 are in addition to the "General Prohibitions" in paragraph 1.

b. Pre-Clearance Procedures

Pre-Clearance shall be documented in a completed Transaction Authorization Form countersigned by the General Counsel, which shall be submitted to the General Counsel at least two business days in advance of the proposed transaction. The General Counsel is under no obligation to approve a transaction submitted for Pre-Clearance, and may determine not to permit the transaction. If a Designated Person seeks Pre-Clearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company Securities, and should not inform any other person of the restriction. When a request for Pre-Clearance is made, the requestor should carefully consider whether he or she may be aware of any material non-public information about the Company, and should describe fully those circumstances to the General Counsel. The requestor who is a Section 16 Insider should also indicate whether he or she has effected any non-exempt "opposite-way" transactions within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5. The requestor who is a Section 16 Insider should also be prepared to comply with Rule 144 under the Securities Act of 1933, as amended, and file Form 144, if necessary, at the time of any sale. Any transaction for which Pre-Clearance has been obtained must be effected within the number of days indicated in the Transaction Authorization Form (not to exceed five business days from the receipt of Pre-Clearance unless an extension or exception is granted by the General Counsel). Transactions not effected within this time frame are subject to new Pre-Clearance. If a request for Pre-Clearance is denied, the fact of such denial must be kept confidential by the person requesting such clearance.

c. Quarterly and Event-Specific Trading Restrictions

Designated Persons may not conduct any transactions involving Company Securities (other than as specified by this policy) during a "Blackout Period." As used in this policy, "Blackout Period" means (i) the period that generally begins on the first business day of the third month in the Company's fiscal quarter and ends at the start of market hours of the Nasdaq Stock Market regular trading session on the business day following the date on which the Company holds its quarterly conference call for investors and others (but, unless otherwise determined by the General Counsel, in any event no earlier than 24

hours after such call) (the "Quarterly Blackout Period") and (ii) an event-specific trading restriction period, as determined by the General Counsel (the "Event-Specific Blackout Period"). From time to time, an event may occur that is material to the Company and is known by only a few directors, officers, and/or employees. So long as the event remains material and non-public, the Designated Persons may not trade Company Securities. In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the General Counsel, the Designated Persons should refrain from trading in Company Securities even sooner than the typical Quarterly Blackout Period described above. In that situation, the General Counsel may notify the Designated Persons (or a subset thereof) that they should not trade in Company Securities, without disclosing the reason for the restriction. The existence of the Event-Specific Blackout Period or extension of a Quarterly Blackout Period will not be announced to the Company as a whole, and should not be communicated to any other person. Even if you are not a Designated Person, you should not trade while aware of material non-public information. Exceptions will not be granted during any Blackout Period.

d. Permissible Stock-for-Stock (Net) Option Exercise and Class A Stock Conversion by Designated Persons During Blackout Period

Designated Persons engaging in a permissible stock-for-stock option exercise described in paragraph 4.b above may not sell, pledge, or otherwise engage in any transactions with respect to the Company Securities they obtain upon the exercise (or any other Company Securities they hold) until the Blackout Period has ended and Pre-Clearance for the transaction has been obtained. Similarly, Designated Persons converting any shares of Class A stock into shares of common stock as permitted under paragraph 4.e above may not sell, pledge, or otherwise engage in any transactions with respect to common stock issued upon such conversion (or any other Company Securities they hold) until the Blackout Period has ended and Pre-Clearance for the transaction has been obtained.

6. Post-Termination Transactions

If an individual is aware of material non-public information when his or her service terminates, that individual may not trade in Company Securities until that information has become public or is no longer material. In addition, although the Pre-Clearance procedures under paragraph 5.b above will cease to apply upon termination of service, individuals subject to a Blackout Period at the time of termination may not trade in Company Securities until such Blackout Period has ended.

7. Company Sanctions

In addition to the legal consequences associated with violations of "insider trading" laws (described below), Company Personnel who fail to comply with the policy as set forth in this statement of policy can be subjected to sanctions imposed directly by the Company, including dismissal for cause.

Legal Consequences

The consequences of violating insider trading laws are severe for both employees and companies. Individuals who trade on inside information or who "tip" information to others can face a civil penalty of up to three times the profit gained or loss avoided, a criminal fine (no matter how small the profit) of up to \$5,000,000, and a jail term of up to 20 years. A company (as well as supervisory personnel) that fail

to take appropriate steps to prevent illegal trading is subject to a civil penalty of the greater of \$2,600,000 or three times the profit gained or loss avoided as a result of an employee's violation and a criminal penalty of up to \$25,000,000. Even if an investigation by the SEC does not result in criminal or civil sanctions, the investigation itself can tarnish a person's or a company's reputation and irreparably damage a person's career.

FURTHER INFORMATION

Questions concerning this policy should be directed to the General Counsel.

Regeneron Pharmaceuticals, Inc.

Rule 10b5-1 Trading Plan Guidelines

The following guidelines apply to all written trading plans ("Rule 10b5-1 Trading Plans") involving securities of Regeneron Pharmaceuticals, Inc. (the "Company") under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Capitalized terms not defined in these guidelines have the respective meanings given to such terms in the Insider Trading Policy (as defined below).

1. **Prior Approval.** All individuals subject to the Company's Policy 230, *Securities Investments* (the "Insider Trading Policy") (all such individuals, collectively, "Company Personnel") who wish to enter into a Rule 10b5-1 Trading Plan must comply in all respects with the Insider Trading Policy and applicable law and submit the Rule 10b5-1 Trading Plan to the General Counsel for advance approval (generally at least five business days prior to the planned entry into the Rule 10b5-1 Trading Plan). In addition, prior submission to the General Counsel is required for any amendment or early termination of an effective Rule 10b5-1 Trading Plan.
2. **Entry into a Plan.** A member of Company Personnel may enter into a Rule 10b5-1 Trading Plan only at a time when he or she is not aware of material non-public information regarding the Company or its securities and when a Blackout Period is not in effect with respect to such member under the Insider Trading Policy. Each Rule 10b5-1 Trading Plan must include a representation that, as of the date of adoption of such Rule 10b5-1 Trading Plan, the member of Company Personnel who wishes to enter into such Rule 10b5-1 Trading Plan is not aware of any material non-public information about the Company or its securities, and that the Rule 10b5-1 Trading Plan is being adopted in good faith and not as a part of a plan or scheme to evade the prohibitions of Rule 10b5-1.
3. **Waiting Period.** The waiting periods from the time a Rule 10b5-1 Trading Plan is adopted until the time of the first trade under the Rule 10b5-1 Trading Plan must comply with requirements of Rule 10b5-1. Specifically, Rule 10b5-1 Trading Plans established by directors and officers subject to Section 16 of the Exchange Act (collectively, "Section 16 Insiders") must include a waiting period consisting of the later of (i) 90 days after the adoption of the Rule 10b5-1 Trading Plan, or (ii) the period ending two business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Trading Plan was adopted (but in any event, this waiting period is subject to a maximum of 120 days after adoption of the Rule 10b5-1 Trading Plan). For all other individuals, the waiting period must be at least 30 days from adoption of the Rule 10b5-1 Trading Plan. For the avoidance of doubt, subject to further guidance from the SEC, Section 16 Insiders may not begin the first trade under a Rule 10b5-1 Trading Plan until the later of the 91st day from adoption of the Rule 10b5-1 Trading Plan or the third business day after the Company's filing of the applicable Form 10-Q or Form 10-K (but in any event no later than the 121st day from adoption of the Rule 10b5-1 Trading Plan), and individuals other than Section 16 Insiders may not begin the first trade until the 31st day from adoption of the Rule 10b5-1 Trading Plan.
4. **Multiple Plans.** Generally speaking, a member of Company Personnel entering into a Rule 10b5-1 Trading Plan may have only one Rule 10b5-1 Trading Plan in place at any time. An exception to this restriction applies for certain separate Rule 10b5-1 Trading Plans with different brokers that would be treated as a single "plan" such as

when a person holds Company securities in multiple brokerage accounts. Additionally, a member of Company Personnel may enter into one later-commencing Rule 10b5-1 Trading Plan so that the waiting period of the later plan can begin to run while an existing Rule 10b5-1 Trading Plan is in place, provided that the individual does not early terminate the first Rule 10b5-1 Trading Plan, in which case a full waiting period from the time of such termination must occur. Finally, Company Personnel may have an additional Rule 10b5-1 Trading Plan providing only for eligible sell-to-cover transactions, where the plan provides for sales of securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory stock award.

5. **Single Transaction.** Rule 10b5-1 prohibits more than one Rule 10b5-1 Trading Plan in any 12-month period that is designed to effect a single transaction. Single transaction Rule 10b5-1 Trading Plans are generally discouraged.
6. **Amendments.** Amendments to Rule 10b5-1 Trading Plans will be permitted only at a time when: (i) the member of Company Personnel is not aware of material non-public information regarding the Company or its securities and (ii) a Blackout Period is not in effect with respect to such member under the Insider Trading Policy. Furthermore, any amendment relating to the amount, price, or timing of the purchase or sale of securities will be subject to the same waiting periods as would be applicable to a new Rule 10b5-1 Trading Plan, as described above.
7. **Termination.** A Rule 10b5-1 Trading Plan may be terminated upon notification to the General Counsel at a time when the member of Company Personnel is not aware of material non-public information regarding the Company or its securities and a Blackout Period is not in effect with respect to such member under the Insider Trading Policy. However, terminating a Rule 10b5-1 Trading Plan is strongly discouraged because it may call into question whether the plan was entered into in good faith and not as part of a plan or scheme to evade the insider trading rules, which could affect the availability of the Rule 10b5-1 affirmative defense.
8. **Outside Trades.** Adoption of a Rule 10b5-1 Trading Plan does not preclude trading outside the Rule 10b5-1 Trading Plan that otherwise is in accordance with the Insider Trading Policy. However, Company Personnel should be cognizant of the fact that the Rule 10b5-1 affirmative defense will not apply to such trades outside a Rule 10b5-1 Trading Plan. In addition, under Rule 10b5-1, Company Personnel may not have further influence over whether, when, or how the trades under the Rule 10b5-1 Trading Plan are made once the Rule 10b5-1 Trading Plan is put in place, and, therefore, their trading outside the Rule 10b5-1 Trading Plan must not have direct or indirect influence on the trading instructions under the Rule 10b5-1 Trading Plan.
9. **Section 16.** Each Section 16 Insider understands that the approval or adoption of a Rule 10b5-1 Trading Plan in no way reduces or eliminates such Section 16 Insider's obligations under Section 16 of the Exchange Act, including such Section 16 Insider's disclosure and potential short-swing trading liabilities thereunder. If any questions arise, such Section 16 Insider should consult with his or her own counsel in implementing a Rule 10b5-1 Trading Plan. In addition, each Section 16 Insider must agree to cooperate with the Company in any reporting of the Rule 10b5-1 Trading Plan in the Company's SEC filings.

**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: October 30, 2026

/s/ Leonard S. Schleifer

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

**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, Christopher Fenimore, 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: October 30, 2026

/s/ Christopher Fenimore

Christopher Fenimore
Executive Vice President, Finance and Chief
Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2026 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 Christopher Fenimore, 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)
October 30, 2026

/s/ Christopher Fenimore

Christopher Fenimore
Executive Vice President, Finance and Chief
Financial Officer
(Principal Financial Officer)
October 30, 2026