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, 2025
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 000-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

The number of shares outstanding of each of the registrant's classes of common stock as of October 23, 2025:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,817,146
Common Stock, $.001 par value	103,282,318

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
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"Altibodies™," "ARCALYST®," "Evkeeza®," "EYLEA®," "EYLEA HD®," "Inmazeb®," "Libtayo®," "Lynozyfic™," "Ordspono™," "Praluent®" (in the United States), "REGEN-COV®," "Regeneron®," "Regeneron Genetics Center®," "RGC®," "*Veloci-Bi*®," "*VelociGene*®," "*VelociHum*®," "*VelociMab*®," "*VelocImmune*®," "*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, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,506.4	$ 2,488.2
Marketable securities	5,937.2	6,524.3
Accounts receivable, net	5,687.1	6,211.9
Inventories	3,254.4	3,087.3
Prepaid expenses and other current assets	595.6	349.2
Total current assets	17,980.7	18,660.9
Marketable securities	10,285.7	8,900.1
Property, plant, and equipment, net	5,002.3	4,599.7
Intangible assets, net	1,380.9	1,148.6
Deferred tax assets	3,846.7	3,314.1
Other noncurrent assets	1,673.1	1,136.0
Total assets	$ 40,169.4	$ 37,759.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 903.8	$ 789.5
Accrued expenses and other current liabilities	2,975.7	2,527.1
Deferred revenue	545.6	627.7
Total current liabilities	4,425.1	3,944.3
Long-term debt	1,985.5	1,984.4
Finance lease liabilities	720.0	720.0
Deferred revenue	219.2	185.7
Other noncurrent liabilities	1,861.8	1,571.4
Total liabilities	9,211.6	8,405.8
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 2025 and 2024	—	—
Common Stock, par value $.001 per share; 320.0 shares authorized; shares issued - 136.2 in 2025 and 136.0 in 2024	0.1	0.1
Additional paid-in capital	13,787.3	12,855.9
Retained earnings	35,045.8	31,672.9
Accumulated other comprehensive income (loss)	69.0	(7.9)
Treasury Stock, at cost; 32.7 shares in 2025 and 28.2 shares in 2024	(17,944.4)	(15,167.4)
Total stockholders' equity	30,957.8	29,353.6
Total liabilities and stockholders' equity	$ 40,169.4	$ 37,759.4

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,	
	2025	**2024**	**2025**	**2024**
Statements of Operations				
Revenues:				
Net product sales	$ 1,587.7	$ 1,946.4	$ 4,634.3	$ 5,626.3
Collaboration revenue	1,968.4	1,660.1	5,360.3	4,450.9
Other revenue	198.2	114.2	464.0	335.6
	3,754.3	3,720.7	10,458.6	10,412.8
Expenses:				
Research and development	1,475.0	1,271.5	4,224.1	3,719.9
Acquired in-process research and development	83.1	56.2	105.4	87.2
Selling, general, and administrative	657.8	714.4	1,925.0	2,162.2
Cost of goods sold	281.0	262.3	822.1	760.5
Cost of collaboration and contract manufacturing	240.6	228.8	694.0	644.6
Other operating (income) expense, net	(10.0)	8.0	(10.0)	37.9
	2,727.5	2,541.2	7,760.6	7,412.3
Income from operations	1,026.8	1,179.5	2,698.0	3,000.5
Other income (expense):				
Other income (expense), net	755.8	327.3	1,520.6	866.0
Interest expense	(19.3)	(13.8)	(31.6)	(44.7)
	736.5	313.5	1,489.0	821.3
Income before income taxes	1,763.3	1,493.0	4,187.0	3,821.8
Income tax expense	303.3	152.4	526.7	326.9
Net income	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Net income per share - basic	$ 14.09	$ 12.40	$ 34.83	$ 32.36
Net income per share - diluted	$ 13.62	$ 11.54	$ 33.61	$ 30.23
Weighted average shares outstanding - basic	103.6	108.1	105.1	108.0
Weighted average shares outstanding - diluted	107.2	116.2	108.9	115.6
Statements of Comprehensive Income				
Net income	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Other comprehensive income (loss), net of tax:				
Unrealized gain on debt securities	15.7	128.2	75.9	139.6
Gain on foreign currency translation	0.8	1.9	1.0	1.5
Comprehensive income	$ 1,476.5	$ 1,470.7	$ 3,737.2	$ 3,636.0

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

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

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 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	1.8	$ —	136.2	$ 0.1	$13,787.3	$35,045.8	$ 69.0	(32.7)	$(17,944.4)	$ 30,957.8

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

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2023	1.8	$ —	133.1	$ 0.1	$11,354.0	$27,260.3	$ (80.9)	(25.5)	$(12,560.4)	$ 25,973.1
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	1.5	—	672.4	—	—	—	—	672.4
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.4)	—	(335.9)	—	—	—	—	(335.9)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	18.8	—	—	—	1.7	20.5
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.3)	(298.0)	(298.0)
Stock-based compensation charges	—	—	—	—	233.3	—	—	—	—	233.3
Net income	—	—	—	—	—	722.0	—	—	—	722.0
Other comprehensive income, net of tax	—	—	—	—	—	—	3.7	—	—	3.7
Balance, March 31, 2024	1.8	—	134.2	0.1	11,942.6	27,982.3	(77.2)	(25.8)	(12,856.7)	26,991.1
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	1.0	—	436.5	—	—	—	—	436.5
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.4)	—	(311.8)	—	—	—	—	(311.8)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	19.6	—	—	—	2.2	21.8
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.6)	(601.4)	(601.4)
Stock-based compensation charges	—	—	—	—	230.0	—	—	—	—	230.0
Net income	—	—	—	—	—	1,432.3	—	—	—	1,432.3
Other comprehensive income, net of tax	—	—	—	—	—	—	7.3	—	—	7.3
Balance, June 30, 2024	1.8	—	134.8	0.1	12,316.9	29,414.6	(69.9)	(26.4)	(13,455.9)	28,205.8
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	0.6	—	255.7	—	—	—	—	255.7
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.1)	—	(120.2)	—	—	—	—	(120.2)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	20.0	—	—	—	1.8	21.8
Repurchases of Common Stock	—	—	—	—	—	—	—	(0.6)	(738.3)	(738.3)
Stock-based compensation charges	—	—	—	—	230.4	—	—	—	—	230.4
Net income	—	—	—	—	—	1,340.6	—	—	—	1,340.6
Other comprehensive income, net of tax	—	—	—	—	—	—	130.1	—	—	130.1
Balance, September 30, 2024	1.8	$ —	135.3	$ 0.1	$12,702.8	$30,755.2	$ 60.2	(27.0)	$(14,192.4)	$ 29,325.9

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,	
	2025	**2024**
Cash flows from operating activities:		
Net income	$ 3,660.3	$ 3,494.9
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	398.7	356.5
Stock-based compensation expense	744.4	678.4
Gains on marketable and other securities, net	(967.6)	(331.2)
Other, net	(1.4)	(31.9)
Deferred income taxes	(552.9)	(477.1)
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	549.3	(436.2)
Increase in inventories	(277.4)	(502.0)
Increase in prepaid expenses and other assets	(458.1)	(352.2)
(Decrease) increase in deferred revenue	(48.6)	249.0
Increase in accounts payable, accrued expenses, and other liabilities	761.5	509.5
Total adjustments	147.9	(337.2)
Net cash provided by operating activities	3,808.2	3,157.7
Cash flows from investing activities:		
Purchases of marketable and other securities	(8,914.6)	(14,664.5)
Sales or maturities of marketable and other securities	8,991.2	12,445.3
Capital expenditures	(649.7)	(556.3)
Payments for intangible assets	(273.3)	(58.3)
Proceeds from sale of property, plant, and equipment	—	20.1
Acquisitions, net of cash acquired	(3.0)	(5.0)
Net cash used in investing activities	(849.4)	(2,818.7)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	132.4	1,374.4
Payments in connection with Common Stock tendered for employee tax obligations	(12.9)	(775.7)
Repurchases of Common Stock	(2,766.9)	(1,630.3)
Dividends paid	(277.6)	—
Other	(10.3)	(33.4)
Net cash used in financing activities	(2,935.3)	(1,065.0)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	0.6	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	24.1	(726.0)
Cash, cash equivalents, and restricted cash at beginning of period	2,489.0	2,737.8
Cash, cash equivalents, and restricted cash at end of period	$ 2,513.1	$ 2,011.8

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, 2024 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, 2024.

Recently Issued Accounting Standards

Standard/Description	Effective Date	Impact of Adoption on the Company's Financial Statements
ASU 2023-09: In December 2023, the FASB issued amended guidance related to improvements to **income tax disclosures**. The amendments require annually (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction.	January 1, 2025	No significant impact expected
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:

		Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)		2025	2024	2025	2024
EYLEA HD®	U.S.	$ 430.6	$ 392.3	$ 1,130.6	$ 896.5
EYLEA®	U.S.	680.6	1,144.6	2,170.9	3,576.7
Total EYLEA HD and EYLEA	U.S.	1,111.2	1,536.9	3,301.5	4,473.2
Libtayo®	U.S.	219.1	194.5	659.4	536.1
Libtayo	Rest of world	146.1	94.1	367.4	313.8
Total Libtayo	Global	365.2	288.6	1,026.8	849.9
Praluent®	U.S.	67.7	52.9	190.3	179.0
Evkeeza®	U.S.	42.8	32.4	114.9	87.6
Inmazeb®	U.S.	—	35.6	—	36.6
Other products	Global	0.8	—	0.8	—
		$ 1,587.7	$ 1,946.4	$ 4,634.3	$ 5,626.3

As of September 30, 2025 and December 31, 2024, the Company had $3.471 billion and $4.278 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, 2025 and 2024. 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,	
	2025	2024	2025	2024
Customer A	49 %	51 %	51 %	51 %
Customer B	30 %	24 %	26 %	24 %

3. Collaboration, License, and Other Agreements

a. Sanofi

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

Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. The Company is obligated to reimburse Sanofi for 30% to 50% of development expenses that were funded by Sanofi (i.e., "development balance") based on the Company's share of collaboration profits; however, the Company is only required to apply 20% of its share of profits from the collaboration each calendar quarter to reimburse Sanofi for these development expenses. As of September 30, 2025, the Company's contingent reimbursement obligation to Sanofi in connection with the development balance was approximately $905 million.

Sanofi leads commercialization activities for products under the collaboration, subject to the Company's right to co-commercialize such products. The parties equally share profits from sales within the United States. The parties 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).

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, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Regeneron's share of profits	Collaboration revenue	$ 1,455.5	$ 1,088.3	$ 3,755.7	$ 2,880.6
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	$ 161.5	$ 175.1	$ 488.1	$ 438.2
Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses	(R&D expense)	$ (23.5)	$ (7.8)	$ (56.9)	$ (35.5)
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	$ 182.6	$ 169.0	$ 535.8	$ 459.3

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

(In millions)	September 30, 2025	December 31, 2024
Accounts receivable, net	$ 1,493.9	$ 1,216.2
Deferred revenue	$ 423.5	$ 571.7

b. Bayer

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA 8 mg (aflibercept 8 mg) and EYLEA (aflibercept) outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits 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, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Regeneron's share of profits	Collaboration revenue	$ 311.9	$ 367.6	$ 1,012.6	$ 1,054.5
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	$ 32.9	$ 23.2	$ 91.1	$ 67.4
Regeneron's obligation for its share of Bayer R&D expenses, net of reimbursement of R&D expenses	(R&D expense)	$ (3.9)	$ (11.8)	$ (18.9)	$ (35.2)

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

(In millions)	September 30, 2025	December 31, 2024
Accounts receivable, net	$ 363.2	$ 349.9
Deferred revenue	$ 317.0	$ 216.3

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 costs, 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

During the three and nine months ended September 30, 2025, the Company recorded to Acquired IPR&D expense an $80.0 million up-front payment in connection with its license agreement with Hansoh Pharmaceuticals Group Company Limited to acquire development and commercial rights outside mainland China, Hong Kong, and Macau for HS-20094 (a dual GLP-1/GIP receptor agonist currently in Phase 3 clinical development in China).

During the three and nine months ended September 30, 2024, the Company recorded to Acquired IPR&D expense a $45.0 million development milestone in connection with its collaboration agreement with Sonoma Biotherapeutics, Inc.

Other

In June 2025, the Company purchased an FDA Rare Pediatric Disease Priority Review Voucher from a third party for $155.0 million (which was recorded as an indefinite-lived intangible asset).

4. Net Income Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except per share data)	**2025**	**2024**	**2025**	**2024**
Net income - basic and diluted	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Weighted average shares - basic	103.6	108.1	105.1	108.0
Effect of dilutive securities:				
Stock options	1.5	5.3	1.8	5.2
Restricted stock awards and restricted stock units	2.1	2.8	2.0	2.4
Weighted average shares - diluted	107.2	116.2	108.9	115.6
Net income per share - basic	$ 14.09	$ 12.40	$ 34.83	$ 32.36
Net income per share - diluted	$ 13.62	$ 11.54	$ 33.61	$ 30.23

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(Shares in millions)	**2025**	**2024**	**2025**	**2024**
Stock options	6.3	0.1	6.3	1.5
Restricted stock awards and restricted stock units	0.9	—	1.0	—

5. Marketable Securities

Marketable securities as of September 30, 2025 and December 31, 2024 consist of both available-for-sale debt securities of investment grade issuers (see below and Note 6) as well as equity securities of publicly traded companies (see Note 6).

The following tables summarize the Company's investments in available-for-sale debt securities:

(In millions)	Amortized	Unrealized		Fair
As of September 30, 2025	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 9,624.3	$ 78.8	$ (5.4)	$ 9,697.7
U.S. government and government agency obligations	4,691.7	12.1	(0.5)	4,703.3
Commercial paper	445.1	0.2	—	445.3
Certificates of deposit	310.2	0.2	—	310.4
Asset-backed securities	293.8	1.4	—	295.2
Sovereign bonds	69.8	0.5	(0.1)	70.2
	$ 15,434.9	$ 93.2	$ (6.0)	$ 15,522.1
As of December 31, 2024				
Corporate bonds	$ 8,226.9	$ 25.1	$ (31.4)	$ 8,220.6
U.S. government and government agency obligations	4,820.5	3.4	(6.9)	4,817.0
Commercial paper	548.3	0.4	—	548.7
Certificates of deposit	380.6	0.5	—	381.1
Asset-backed securities	279.0	0.6	(0.3)	279.3
Sovereign bonds	82.7	0.1	(0.4)	82.4
	$ 14,338.0	$ 30.1	$ (39.0)	$ 14,329.1

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, 2025 mature at various dates through February 2038. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

(In millions)	September 30, 2025	December 31, 2024
Maturities within one year	$ 5,937.2	$ 6,524.3
Maturities after one year through five years	9,518.9	7,804.8
Maturities after five years	66.0	—
	$ 15,522.1	$ 14,329.1

The following table shows the fair value and gross unrealized losses by category and disaggregated by the length of time that the Company's available-for-sale debt securities have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
(In millions) **As of September 30, 2025**	**Fair Value**	**Unrealized Losses**	**Fair Value**	**Unrealized Losses**	**Fair Value**	**Unrealized Losses**
Corporate bonds	$ 9,300.3	$ (1.5)	$ 397.4	$ (3.9)	$ 9,697.7	$ (5.4)
U.S. government and government agency obligations	4,541.8	(0.4)	161.5	(0.1)	4,703.3	(0.5)
Sovereign bonds	56.0	(0.1)	14.2	—	70.2	(0.1)
	$ 13,898.1	$ (2.0)	$ 573.1	$ (4.0)	$ 14,471.2	$ (6.0)
As of December 31, 2024						
Corporate bonds	$ 7,175.8	$ (14.2)	$ 1,044.8	$ (17.2)	$ 8,220.6	$ (31.4)
U.S. government and government agency obligations	4,675.3	(6.2)	141.7	(0.7)	4,817.0	(6.9)
Asset-backed securities	265.4	(0.3)	13.9	—	279.3	(0.3)
Sovereign bonds	63.3	(0.3)	19.1	(0.1)	82.4	(0.4)
	$ 12,179.8	$ (21.0)	$ 1,219.5	$ (18.0)	$ 13,399.3	$ (39.0)

Amounts reclassified from Accumulated other comprehensive income (loss) into Other income (expense), net, related to realized gains/losses on sales of available-for-sale debt securities; such amounts were not material for the three and nine months ended September 30, 2025 and 2024.

6. Fair Value Measurements

The table below summarizes the Company's assets and liabilities which are measured at fair value on a recurring basis. 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

(In millions)		Fair Value Measurements at Reporting Date		
As of September 30, 2025	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents	$ 1,162.5	$ 378.3	$ 784.2	$ —
Available-for-sale debt securities:				
Corporate bonds	9,697.7	—	9,697.7	—
U.S. government and government agency obligations	4,703.3	—	4,703.3	—
Commercial paper	445.3	—	445.3	—
Certificates of deposit	310.4	—	310.4	—
Asset-backed securities	295.2	—	295.2	—
Sovereign bonds	70.2	—	70.2	—
Equity securities[(a)]	700.8	700.8	—	—
Total assets	$ 17,385.4	$ 1,079.1	$ 16,306.3	$ —
Liabilities:				
Contingent consideration	$ 10.3	$ —	$ —	$ 10.3
As of December 31, 2024				
Assets:				
Cash equivalents	$ 1,452.2	$ 1,264.2	$ 188.0	$ —
Available-for-sale debt securities:				
Corporate bonds	8,220.6	—	8,220.6	—
U.S. government and government agency obligations	4,817.0	—	4,817.0	—
Commercial paper	548.7	—	548.7	—
Certificates of deposit	381.1	—	381.1	—
Asset-backed securities	279.3	—	279.3	—
Sovereign bonds	82.4	—	82.4	—
Equity securities[(a)]	1,095.3	1,095.3	—	—
Total assets	$ 16,876.6	$ 2,359.5	$ 14,517.1	$ —
Liabilities:				
Contingent consideration	$ 52.3	$ —	$ —	$ 52.3

[(a)] Includes equity securities of $63.9 million and $43.2 million as of September 30, 2025 and December 31, 2024, respectively, that are subject to transfer restrictions expiring in April 2026

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

- As of September 30, 2025 and December 31, 2024, $316.8 million and $159.8 million, respectively, of equity securities that do not have a readily determinable fair value. The change in carrying value of such investments was a result of additional purchases.
- As of September 30, 2025 and December 31, 2024, equity securities held through ownership interest in an investment fund of $98.4 million and $52.0 million, respectively, which are measured at fair value based on Level 3 inputs. The change in carrying value was primarily the result of additional investments by the fund.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
Net gains recognized during the period	$ 581.5	$ 134.5	$ 978.1	$ 330.8
Less: Net gains recognized on investments sold during the period	370.9	—	650.4	—
Net unrealized gains recognized on investments still held as of period end date	$ 210.6	$ 134.5	$ 327.7	$ 330.8

The fair value of the Company's long-term debt, which was determined based on Level 2 inputs, was estimated to be $1.568 billion and $1.484 billion as of September 30, 2025 and December 31, 2024, respectively, and the carrying value was $1.986 billion and $1.984 billion as of September 30, 2025 and December 31, 2024, respectively.

7. Inventories

Inventories consist of the following:

(In millions)	September 30, 2025	December 31, 2024
Raw materials	$ 710.0	$ 879.5
Work-in-process	1,565.9	1,342.3
Finished goods	169.7	139.8
Deferred costs	808.8	725.7
	$ 3,254.4	$ 3,087.3

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

8. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. On July 4, 2025, bill H.R. 1, commonly referred to as the "One Big Beautiful Bill Act" or "OBBBA," was signed into law, with certain provisions effective in 2025 and others in 2026. The OBBBA significantly revises U.S. corporate income tax laws by, among other things, restoring the option for immediate expense recognition for U.S.-based research and development expenditures and making permanent the ability to claim first-year bonus depreciation on qualified property. The OBBBA also modifies U.S. taxation on foreign earnings by, among other things, changing the tax rates for global intangible low-taxed income (now known as Net CFC Tested Income) and foreign-derived intangible income (now known as foreign-derived deduction eligible income), modifying the allocation of expenses in calculating foreign tax credits, as well as changing foreign tax credit limitations. As a result of the OBBBA being signed into law, the Company recognized a charge of $44.5 million in the third quarter of 2025 related to the re-measurement of the Company's U.S. net deferred tax assets.

The Company's effective tax rate was 17.2% and 10.2% for the three months ended September 30, 2025 and 2024, respectively, and 12.6% and 8.6% for the nine months ended September 30, 2025 and 2024, respectively. The Company's effective tax rate for the three and nine months ended September 30, 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 federal tax credits for research activities, partially offset by the impact of the OBBBA being signed into law. In addition, the Company's effective tax rate for the nine months ended September 30, 2025 was positively impacted by the release of liabilities for uncertain tax positions recognized upon the effective settlement of the IRS audit of the Company's 2017 and 2018 federal income tax returns in the second quarter of 2025, which reduced the Company's effective tax rate for the nine months ended September 30, 2025 by 1.4%.

The Company's effective tax rate for the three and nine months ended September 30, 2024 was positively impacted, compared to the U.S. federal statutory rate, primarily by income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and stock-based compensation. The Company's effective tax rate for the nine months ended September 30, 2024 was negatively impacted by the remeasurement of uncertain tax positions.

9. Stockholders' Equity

a. Share Repurchase Programs

In January 2023, the Company's board of directors authorized a share repurchase program for up to $3.0 billion of the Company's Common Stock. In each of April 2024 and February 2025, the Company's board of directors authorized an additional share repurchase program for up to $3.0 billion (up to $6.0 billion in the aggregate). 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 and the cost of such shares, which were recorded as Treasury Stock.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
Number of shares	1.1	0.6	4.5	1.5
Total cost of shares	$ 663.0	$ 738.3	$ 2,785.3	$ 1,637.7

As of September 30, 2025, $2.156 billion remained available for share repurchases under the programs.

b. Dividends

In each of the first, second, and third quarters of 2025, the Company's board of directors declared quarterly cash dividends of $0.88 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 2025, the Company's board of directors declared a cash dividend of $0.88 per share on its Common Stock and Class A Stock. The dividend will be payable to the Company's shareholders in December 2025.

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:

	September 30,	
(In millions)	**2025**	**2024**
Cash and cash equivalents	$ 2,506.4	$ 2,011.8
Restricted cash included in Other current assets	6.7	—
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statements of Cash Flows	$ 2,513.1	$ 2,011.8

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

(In millions)	September 30, 2025	December 31, 2024	September 30, 2024	December 31, 2023
Accrued capital expenditures	$ 176.9	$ 151.6	$ 94.0	$ 75.4
Accrued contingent consideration in connection with acquisitions	$ 52.5	$ 62.7	$ 88.0	$ 71.6

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2025	2024	2025	2024
Direct research and development expenses[(a)]	$ 454.3	$ 386.4	$ 1,296.7	$ 1,158.5
Indirect research and development expenses:				
Payroll and benefits	438.3	407.8	1,339.5	1,249.2
Lab supplies and other research and development costs	67.5	63.0	192.4	175.4
Occupancy and other operating costs	166.3	158.7	479.2	434.9
Total indirect research and development expenses	672.1	629.5	2,011.1	1,859.5
Clinical manufacturing costs	381.4	306.6	1,028.8	841.3
Reimbursement of research and development expenses by collaborators	(32.8)	(51.0)	(112.5)	(139.4)
Total research and development expenses	$ 1,475.0	$ 1,271.5	$ 4,224.1	$ 3,719.9

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

12. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company 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. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. 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, 2025 and December 31, 2024, the Company's accruals for loss contingencies were not material. There are certain loss contingencies that the Company deems reasonably possible for which the possible loss or range of possible loss is not estimable at this time.

Proceedings Relating to EYLEA (aflibercept) Injection

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

United States

U.S. Patent Litigation

On August 2, 2022, the Company filed a patent infringement lawsuit against Mylan Pharmaceuticals Inc. ("Mylan"), a wholly-owned subsidiary of Viatris Inc., in the United States District Court for the Northern District of West Virginia alleging that Mylan's filing for U.S. Food and Drug Administration ("FDA") approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On June 5, 2023, Biocon Biologics Inc. ("Biocon"), as successor-in-interest to the aflibercept 2 mg biosimilar, was joined as a defendant to the lawsuit. On December 27, 2023, following a trial, the court issued a decision finding that (i) the asserted claims of the Company's U.S. Patent No. 11,084,865 (the "'865 Patent") were valid and infringed by Mylan and Biocon and (ii) the asserted claims of two other Company patents were infringed by Mylan and Biocon but were invalid as obvious. On June 11, 2024, the court granted the Company's motion for a permanent injunction, enjoining Mylan and Biocon from selling in the United States their aflibercept 2 mg biosimilar until the expiration of the '865 Patent. On April 14, 2025, the parties entered into a settlement agreement, pursuant to which Mylan and Biocon's appeal to the Federal Circuit and all related litigation have been dismissed and Biocon is precluded from launching its aflibercept 2 mg biosimilar until the second half of 2026.

On November 8, November 22, and November 29, 2023, respectively, the Company filed patent infringement lawsuits against Celltrion, Inc. ("Celltrion"), Samsung Bioepis Co., Ltd. ("Samsung Bioepis"), and Formycon AG ("Formycon") in the United States District Court for the Northern District of West Virginia following service on Regeneron of each company's notice of commercial marketing. The lawsuits alleged that each company had infringed certain Company patents, including based on each company's filing for FDA approval of an aflibercept 2 mg biosimilar. On December 27, 2023, the Company filed a second patent infringement lawsuit against Samsung Bioepis. On June 14, June 21, and June 28, 2024, respectively, the court granted the Company's motions for preliminary injunctions against Samsung Bioepis, Formycon, and Celltrion; each of these decisions was affirmed by the Federal Circuit on appeal. On May 23, 2025, Formycon petitioned the district court to revoke the preliminary injunction. On September 28, 2025, the Company and Formycon entered into a settlement agreement, pursuant to which Formycon's motion to revoke the preliminary injunction and all related litigation have been dismissed and Formycon is precluded from launching its aflibercept 2 mg biosimilar until the fourth quarter of 2026. On October 20, 2025, the Company and Celltrion entered into a settlement agreement, pursuant to which all litigation in the United States related to Celltrion's aflibercept 2 mg biosimilar has been dismissed and Celltrion is precluded from launching such biosimilar until December 31, 2026.

On January 10, 2024, the Company filed a patent infringement lawsuit against Amgen Inc. ("Amgen") in the United States District Court for the Central District of California alleging that Amgen's filing for FDA approval of an aflibercept 2 mg biosimilar infringed certain Company patents. On April 11, 2024, the United States Judicial Panel on Multidistrict Litigation granted the Company's motion to transfer this lawsuit to the United States District Court for the Northern District of West Virginia for coordinated and consolidated pretrial proceedings with the lawsuits described in the preceding paragraph. On September 23, 2024, the court denied the Company's motion for a preliminary injunction; and on September 25, 2024, the Federal Circuit issued an administrative stay pending its review of the Company's temporary injunction motion. On October 22, 2024, the Federal Circuit denied the Company's temporary injunction motion and lifted the administrative stay. On March 14, 2025, the Federal Circuit affirmed the district court's preliminary injunction decision. 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 alleging that Amgen's continued commercialization of its aflibercept 2 mg biosimilar infringes the Company's U.S. Patent No. 12,331,099.

On August 26, 2024, the Company filed a patent infringement lawsuit against Sandoz Inc. ("Sandoz") in the United States District Court for the District of New Jersey alleging that Sandoz's filing for FDA approval of an aflibercept 2 mg biosimilar infringed certain Company patents. On September 12, 2024, the United States Judicial Panel on Multidistrict Litigation granted the Company's motion to transfer this lawsuit to the United States District Court for the Northern District of West Virginia for coordinated and consolidated pretrial proceedings with the lawsuits described in the preceding two paragraphs. On July 11, 2025, the Company filed a motion for a preliminary injunction against Sandoz based on the '865 Patent. On September 8, 2025, the Company and Sandoz entered into a settlement agreement, pursuant to which the Company's preliminary injunction motion and all related litigation have been dismissed and Sandoz is precluded from launching its aflibercept 2 mg biosimilar until the fourth quarter of 2026.

Post-Grant Proceedings Before the USPTO

On November 20, 2024, November 29, 2024, and January 15, 2025, Samsung Bioepis, Formycon, and Celltrion, respectively, filed *inter partes* review ("IPR") petitions in the USPTO against the '865 Patent, each seeking a declaration that the '865 Patent is invalid. On June 6, 2025, the USPTO denied institution of Samsung and Formycon's respective IPR petitions, and on June 25, 2025, the USPTO denied institution of Celltrion's IPR petition.

On July 14, 2025, Fresenius Kabi SwissBioSim GmbH filed IPR petitions in the USPTO against the '865 Patent and U.S. Patent No. 10,828,345 (the "'345 Patent"), seeking a declaration that the '865 Patent and '345 Patent are invalid.

Europe

EPO Post-Grant Proceedings

Various parties, including Amgen and other, anonymous parties, are seeking revocation of 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") 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. On March 11, 2025, the Company appealed the OD's decision. On October 22, 2025, following an oral hearing, the OD upheld the validity of the '992 Patent's claims in amended form. An oral hearing concerning the '049 Patent has been scheduled for December 2025.

Country-Specific Proceedings

Various parties, including Samsung Bioepis and Formycon and/or their affiliated entities, are seeking revocation of the '306 Patent, the '992 Patent, and the Company's European Patent No. 2,364,691 (the "'691 Patent") and/or a declaration that its aflibercept 2 mg biosimilar would not infringe these patents in several European national courts (including those in Belgium, France, Germany, Italy, the Netherlands, and the United Kingdom). In certain of these proceedings, the Company has filed a preemptive counterclaim for infringement of one or more of such patents. In the United Kingdom, following trials held in June 2025, the High Court of England and Wales issued a decision in October 2025 that found that Formycon and Samsung Bioepis's aflibercept 2 mg biosimilar products do not infringe the '691 and '306 Patents; upheld the '691 Patent as valid; and invalidated the '306 Patent. Proceedings in the United Kingdom concerning the '992 Patent are stayed pending resolution of the EPO proceedings concerning this patent. In Germany, following a June 2025 trial concerning the revocation proceeding brought by Samsung Bioepis, the German Federal Patent Court upheld the '691 Patent as valid. In addition, in October 2025, the Munich Regional Court issued a decision that found that Formycon's aflibercept biosimilar product infringes the '691 Patent and granted the Company's motion for a permanent injunction, enjoining Formycon from selling its aflibercept 2 mg biosimilar in Germany and several other EU countries (including Spain and the Netherlands) until the expiration of the '691 Patent. In the Netherlands, following a trial held in July 2025, the District Court of the Hague issued a decision in October 2025 that upheld the '691 and '306 Patents as valid; found that Samsung Bioepis's aflibercept 2 mg biosimilar product infringes the '691 and '306 Patents; and granted the Company's request for a permanent injunction, enjoining Samsung Bioepis from selling its aflibercept 2 mg biosimilar in the Netherlands until the expiration of the '691 and '306 Patents.

The Company has commenced proceedings in Belgium against various parties, including Amgen, Celltrion, Sterigenics (Petit-Rechain) NV, and Sandoz GmbH, for infringement of the Company's European Patent No. 1,183,353 (as extended by Supplementary Protection Certificate 2013C/029).

Canada

Proceedings against Amgen Canada

On May 9, 2023, Amgen Canada Inc. ("Amgen Canada") filed invalidation proceedings against the Company in the Federal Court of Canada seeking revocation of the Company's Canadian Patent Nos. 2,654,510 (the "'510 Patent") and 3,007,276 (the "'276 Patent"). On September 14, 2023, the Company, Bayer Inc., and Bayer Healthcare LLC filed patent infringement lawsuits against Amgen Canada in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of Bayer Healthcare LLC's Canadian Patent No. 2,970,315 (the "'315 Patent"). On September 14, 2023, the Company and Bayer Inc. filed three separate patent infringement lawsuits against Amgen Canada in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of the Company's Canadian Patent Nos. 3,129,193 (the "'193 Patent"), 2,965,495 (the "'495 Patent"), and 2,906,768 (the "'768 Patent"), respectively. On October 11, 2023, the Company, Bayer Inc., and Bayer Healthcare LLC filed two separate patent infringement lawsuits against Amgen Canada in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of the Company's '510 Patent and '276 Patent, respectively. A trial concerning the '510 Patent and the '276 Patent was held in May–

June 2025. On August 15, 2025, the Company, Bayer Inc., Bayer Healthcare LLC, and Amgen Canada entered into a settlement agreement concerning these patent infringement lawsuits, pursuant to which each such lawsuit has been dismissed. As a result of the settlement agreement, the Company, Bayer Inc., and Bayer Healthcare LLC are no longer seeking a declaration that Amgen Canada's aflibercept 2 mg biosimilar infringes the patents referenced in this paragraph.

Proceedings against Sandoz

On January 24, 2025, the Company, Bayer Inc., and Bayer Healthcare LLC filed patent infringement lawsuits against Sandoz Canada Inc. in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of the '510 Patent, the '276 Patent, the '495 Patent, the '768 Patent, the '193 Patent, the '315 Patent, and Canadian Patent No. 3,137,326 (the "'326 Patent"). On August 15, 2025, the Company, Bayer Inc., Bayer Healthcare LLC, and Sandoz Canada Inc. entered into a settlement agreement concerning these patent infringement lawsuits, pursuant to which each such lawsuit has been dismissed. As a result of the settlement agreement, the Company, Bayer Inc., and Bayer Healthcare LLC are no longer seeking a declaration that Sandoz Canada Inc.'s aflibercept 2 mg biosimilar infringes the patents referenced in this paragraph.

South Korea

On December 13, 2022, Samsung Bioepis initiated invalidation proceedings before the Intellectual Property Trial and Appeal Board of the Korean Intellectual Property Office ("KIPO") against the Company's Korean Patent No. 1406811 (the "'811 Patent"), seeking revocation of the '811 Patent in its entirety. On October 23, 2024, the KIPO maintained the '811 Patent as valid; Samsung Bioepis has appealed that decision.

The Company and, as applicable, Bayer Consumer Care AG, have also filed patent infringement lawsuits in the Seoul Central District Court against various parties including Samsung Bioepis and its parent company Samsung Biologics Co., Ltd. (collectively, "Samsung"), Sam Chun Dang Pharm. Co., Ltd. and OPTUS Pharmaceutical Co., Ltd., and Celltrion. These lawsuits seek damages and/or injunctive relief and allege that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar by the relevant defendant(s) would infringe one or more claims of the '811 Patent and/or the Company's Korean Patent Nos. 659477 (the "'477 Patent") and 2519234 (the "'234 Patent"). On February 7, 2025, the Seoul Central District Court granted the Company's preliminary injunction request against Samsung on the basis of the '811 Patent; Samsung has appealed that decision. The preliminary injunction against Samsung prohibits Samsung from manufacturing and selling its aflibercept 2 mg biosimilar in South Korea. Also on February 7, 2025, the Seoul Central District Court denied Regeneron's preliminary injunction request against Celltrion; Regeneron has appealed that decision.

Australia

On June 4, 2025, the Company, Bayer Consumer Care AG, and Bayer Australia filed a patent infringement lawsuit against Sandoz Pty Ltd. and a request for a preliminary injunction in the Federal Court of Australia alleging that the importing, selling, supplying, or otherwise disposing of an aflibercept 2 mg biosimilar would infringe one or more claims of the Company's Australian Patent No. 2012205599. On September 3, 2025, the court denied the Company's request for a preliminary injunction, and this ruling has been appealed.

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 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 of 1890, as amended, 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 Southern District of New York, which motion was granted on December 5, 2024.

Proceedings Relating to Praluent (alirocumab) Injection

United States

On May 27, 2022, the Company filed a lawsuit against Amgen in the United States District Court for the District of Delaware, alleging that, beginning in 2020, Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws. The lawsuit seeks damages for harm caused by the alleged scheme, as well as injunctive relief restraining Amgen from continuing its alleged anticompetitive conduct. On February 10, 2023, the court denied Amgen's motion to stay these proceedings; and on March 21, 2023, the court denied Amgen's motion to dismiss the complaint. On August 28, 2023, the Company filed an amended complaint in this matter; and, as part of its response, on September 20, 2023, Amgen filed a counterclaim alleging that the Company engaged in unfair business practices in violation of state law. On April 10, 2025, the court denied Amgen's motion for summary judgment. 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.

Europe

On June 1, 2023, Sanofi filed an action in the Munich Central Division of the Unified Patent Court (the "UPC") seeking revocation of Amgen's European Patent No. 3,666,797 (the "'797 Patent"). The '797 Patent is a divisional patent of European Patent No. 2,215,124 (the "'124 Patent") (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '124 Patent), which was previously invalidated by the Technical Board of Appeal of the EPO. On July 16, 2024, following a trial, the Munich Central Division of the UPC issued a decision revoking the '797 Patent in its entirety. On September 16, 2024, Amgen appealed the decision of the Munich Central Division of the UPC to the Court of Appeal of the UPC. An oral hearing before the Court of Appeal of the UPC was held in August 2025.

Also on June 1, 2023, Amgen filed a lawsuit against the Company and certain of Sanofi's affiliated entities in the Munich Local Division of the UPC alleging infringement of the '797 Patent. The lawsuit seeks, among other things, a permanent injunction in several countries in Europe and monetary damages. On July 29, 2024, the Munich Local Division of the UPC ordered a stay of the infringement lawsuit in light of the decision of the Munich Central Division of the UPC to revoke the '797 Patent in its entirety (discussed above).

The Company and Sanofi are also seeking revocation of the '797 Patent at the EPO. On April 3, 2025, the OD upheld the '797 Patent as valid. The Company and Sanofi have appealed this decision to the Technical Board of Appeal of the EPO. An oral hearing before the Technical Board of Appeal of the EPO has been scheduled for April 2026.

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.

In September 2019, the Company and Regeneron Healthcare Solutions, Inc., a wholly-owned subsidiary of the Company, each received a civil investigative demand ("CID") from the U.S. Department of Justice pursuant to the federal False Claims Act relating to remuneration paid to physicians in the form of consulting fees, advisory boards, speaker fees, and payment or reimbursement for travel and entertainment allegedly in violation of the federal Anti-Kickback Statute. The CIDs relate to EYLEA, Praluent, Dupixent, ZALTRAP, ARCALYST, and Kevzara and cover the period from January 2015 to the present. On June 3, 2021, the United States District Court for the Central District of California unsealed a qui tam complaint filed against the Company, Regeneron Healthcare Solutions, Inc., and Sanofi-Aventis U.S. LLC by two qui tam plaintiffs (known as relators) purportedly on behalf of the United States and various states (the "State Plaintiffs"), asserting causes of action under the federal False Claims Act and state law. Also on June 3, 2021, the United States and the State Plaintiffs notified the court of their decision to decline to intervene in the case. On October 29, 2021, the qui tam plaintiffs filed an amended complaint in this

matter. On January 14, 2022, the Company filed a motion to dismiss the amended complaint in its entirety. On July 25, 2023, the court 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 has been scheduled for November 18, 2025.

In June 2021, the Company received a CID from the U.S. Department of Justice pursuant to the federal False Claims Act. The CID states that the investigation concerns allegations that the Company (i) violated the False Claims Act by paying kickbacks to distributors and ophthalmology practices to induce purchase of EYLEA, including through discounts, rebates, credit card fees, free units of EYLEA, and inventory management systems; and (ii) inflated reimbursement rates for EYLEA by excluding applicable discounts, rebates, and benefits from the average sales price reported to the Centers for Medicare & Medicaid Services. The CID covers the period from January 2011 through June 2021. On November 29, 2023, the U.S. Department of Justice informed the Company that it had filed a notice of partial intervention in this matter. On March 28, 2024, the Department of Justice and the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint intervention (the "March 2024 Civil Complaint") in the U.S. District Court for the District of Massachusetts asserting causes of action under the federal False Claims Act and a claim for unjust enrichment. Also on March 28, 2024, the U.S. District Court for the District of Massachusetts unsealed a qui tam complaint against the Company, AmerisourceBergen, and Besse Medical by two qui tam plaintiffs (known as relators) 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. 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 U.S. District Court for the District of Massachusetts asserting causes of action under various state laws. On July 18, 2024, the Company filed a motion to dismiss the March 2024 Civil Complaint and the June 2024 Civil Complaint. An oral hearing on the Company's motion to dismiss was held on December 16, 2024. On April 29, 2025, the court denied the Company's motion to dismiss. On May 27, 2025, the Company filed its answers to the March 2024 Civil Complaint and the June 2024 Civil Complaint. On June 17, 2025, the court granted a motion by the States of Maine, Nebraska, Ohio, Oregon, and Wyoming to intervene in the action. On June 18, 2025, those states filed a consolidated complaint asserting causes of action under their respective state laws (the "June 2025 Civil Complaint"). On July 23, 2025, the Company filed its answer and counterclaims to the June 2025 Civil Complaint. On August 14, 2025, the Company moved to amend its answer and assert counterclaims to the March 2024 Civil Complaint and June 2024 Civil Complaint.

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 "Department of Justice Matters" above. These lawsuits were filed by UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "UHC") and Humana Inc. ("Humana") in the United States District Court for the Southern District of New York on December 17, 2020 and July 22, 2021, respectively; and by Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively, "BCBS"), Medical Mutual of Ohio ("MMO"), Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey ("Horizon"), and Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund ("Local 464A") in the U.S. District Court for the District of Massachusetts on December 20, 2021, February 23, 2022, April 4, 2022, and June 17, 2022, respectively. These lawsuits allege causes of action under state law and the federal Racketeer Influenced and Corrupt Organizations Act ("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 United States District Court for the Southern District of New York pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts 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 "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.

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 New York 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 "Department of Justice Matters" above. The complaint seeks an award of damages allegedly sustained by the Company; an order requiring Regeneron to take all necessary actions to reform and improve its corporate governance and internal procedures; disgorgement from the individual defendants of all profits and benefits obtained by them resulting from their sales of Regeneron stock; and costs and disbursements of the action, including attorneys' fees. On July 28, 2021, the defendants filed a notice of removal, removing the case from the New York Supreme Court to the U.S. District Court for the Southern District of New York. On September 23, 2021, the plaintiff moved to remand the case to the New York Supreme Court. Also on September 23, 2021, the individual defendants moved to dismiss the complaint in its entirety. On December 19, 2022, the U.S. District Court for the Southern District of New York denied the plaintiff's motion to remand the case and granted a motion to stay the case pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts 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.

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

On January 16 and January 22, 2025, purported shareholders filed two separate shareholder derivative complaints in the U.S. District Court for the Southern District of New York 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 each 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 "Department of Justice Matters" above. The complaints also each 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 each 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. On June 3, 2025, the court consolidated the two separate shareholder derivative complaints pursuant to a joint stipulation by the parties.

On June 6, 2025, two purported shareholders filed separate shareholder derivative complaints in the New York 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. These complaints make similar allegations to the 2025 derivative complaints referenced above. On June 16, 2025, the Company filed notices of removal, removing both of the newly filed actions from the New York Supreme Court to the U.S. District Court for the Southern District of New York. On July 16, 2025, the purported shareholders each filed a motion to remand their respective actions back to the New York Supreme Court.

On July 30, 2025, a purported shareholder filed another shareholder derivative complaint in the U.S. District Court for the Southern District of New York 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. This complaint makes similar allegations to the 2025 derivative complaints referenced above.

On September 2, 2025, a purported shareholder filed another shareholder derivative complaint in the New York 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. This complaint makes similar allegations to the 2025 derivative complaints referenced above. On September 11, 2025, the Company filed a notice of removal, removing this action from the New York Supreme Court to the U.S. District Court for the Southern District of New York. On October 14, 2025, the purported shareholder filed a motion to remand the action back to the New York Supreme Court.

Shareholder Derivative Complaint – Director Compensation

On July 22, 2025, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current non-employee members of our board of directors, and the co-Chairs of our board of directors (who also serve as our President and Chief Executive Officer and our 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. On September 25, 2025, the Company filed a motion to dismiss the complaint.

Class Action Civil Complaint

On January 7, 2025 (as amended on September 8, 2025), a purported shareholder filed a putative class action civil complaint, on behalf of himself and all others similarly situated, in the U.S. District Court for the Southern District of New York against the Company and certain current and former executive officers of the Company. The 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 "Department of Justice Matters" above. On July 10, 2025, the court appointed a lead plaintiff and lead counsel for the action.

Sanofi Litigation

On November 18, 2024, the Company filed a lawsuit (as amended on December 20, 2024) in the United States District Court for the Southern District of New York against Sanofi and certain of its affiliated entities. The lawsuit alleges 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 seeks a declaratory judgment, injunctive relief, damages, and other relief. On July 3, 2025, Sanofi filed a motion to dismiss the complaint.

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 drugs and product candidates 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") (including biosimilar versions of Regeneron's Products);*
- *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;*
- *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, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance;*
- *the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated;*
- *the impact of public health outbreaks, epidemics, or pandemics 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 other parties and pending or future litigation 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except per share data)	**2025**	**2024**	**2025**	**2024**
Revenues	$ 3,754.3	$ 3,720.7	$ 10,458.6	$ 10,412.8
Net income	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Net income per share - diluted	$ 13.62	$ 11.54	$ 33.61	$ 30.23

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.

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

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
Dupixent® (dupilumab) Injection[b]	Atopic dermatitis (in adults, adolescents, and pediatrics aged 6 months and older)	✔	✔	✔
	Asthma (in adults and adolescents)	✔	✔	✔
	Asthma (in pediatrics 6–11 years of age)	✔	✔	
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP") (in adults)	✔	✔	✔
	CRSwNP (in adolescents)	✔		
	Chronic obstructive pulmonary disease ("COPD")	✔	✔	✔
	Eosinophilic esophagitis ("EoE") (in adults, adolescents, and pediatrics aged 1 year and older)	✔	✔	
	Prurigo nodularis	✔	✔	✔
	Chronic spontaneous urticaria ("CSU") (in adults and adolescents)	✔		✔
	Bullous pemphigoid	✔		
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]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✔	✔	
	HeFH in pediatrics and adolescents (8–17 years of age)	✔	✔	
	Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔	
	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	✔	✔	
Inmazeb® (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by *Zaire ebolavirus*	✔		
Veopoz® (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in adults, adolescents, and pediatrics aged 1 year and older)	✔		

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
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,						
	2025			2024			% Change
(In millions)	U.S.	ROW[f]	Total	U.S.	ROW	Total	(Total Sales)
EYLEA HD[a]	$ 430.6	$ 232.4	$ 663.0	$ 392.3	$ 75.2	$ 467.5	42%
EYLEA[a]	$ 680.6	$ 621.4	$ 1,302.0	$ 1,144.6	$ 856.5	$ 2,001.1	(35%)
Total EYLEA HD and EYLEA	$ 1,111.2	$ 853.8	$ 1,965.0	$ 1,536.9	$ 931.7	$ 2,468.6	(20%)
Dupixent[b]	$ 3,618.8	$ 1,238.2	$ 4,857.0	$ 2,824.7	$ 992.5	$ 3,817.2	27%
Libtayo[c]	$ 219.1	$ 146.1	$ 365.2	$ 194.5	$ 94.1	$ 288.6	27%
Praluent[d]	$ 67.7	$ 148.0	$ 215.7	$ 52.9	$ 138.5	$ 191.4	13%
Kevzara[b]	$ 102.9	$ 51.1	$ 154.0	$ 72.7	$ 47.4	$ 120.1	28%
Other products[e]	$ 43.9	$ 28.0	$ 71.9	$ 68.2	$ 24.4	$ 92.6	(22%)

	Nine Months Ended September 30,						
	2025			2024			% Change
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA HD[a]	$ 1,130.6	$ 620.5	$ 1,751.1	$ 896.5	$ 149.5	$ 1,046.0	67%
EYLEA[a]	$ 2,170.9	$ 2,068.8	$ 4,239.7	$ 3,576.7	$ 2,539.4	$ 6,116.1	(31%)
Total EYLEA HD and EYLEA	$ 3,301.5	$ 2,689.3	$ 5,990.8	$ 4,473.2	$ 2,688.9	$ 7,162.1	(16%)
Dupixent[b]	$ 9,453.2	$ 3,414.0	$ 12,867.2	$ 7,652.9	$ 2,797.5	$ 10,450.4	23%
Libtayo[c]	$ 659.4	$ 367.4	$ 1,026.8	$ 536.1	$ 313.8	$ 849.9	21%
Praluent[d]	$ 190.3	$ 440.7	$ 631.0	$ 179.0	$ 405.6	$ 584.6	8%
Kevzara[b]	$ 271.4	$ 151.2	$ 422.6	$ 187.8	$ 136.1	$ 323.9	30%
Other products[e]	$ 117.1	$ 81.5	$ 198.6	$ 124.4	$ 65.2	$ 189.6	5%

[a] 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.

[b] 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.

[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, which are being developed by us and/or our collaborators, are summarized in the table below.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes to drug pricing and reimbursement regulations and requirements, and changes in the competitive landscape affecting a product candidate. The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results.

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

Clinical Program	Phase 2	Phase 3	Regulatory Review[h]	2025 Events to Date	Select Upcoming Milestones
Ophthalmology					
EYLEA HD (aflibercept) 8 mg[a]		–RVO	–RVO (U.S., EU, and Japan) –Every 4-week dosing regimen for approved indications (U.S.)	–Presented positive three-year data from extension study of Phase 3 wAMD trial at Angiogenesis, Exudation, and Degeneration ("Angiogenesis") 2025 annual meeting –Presented positive data from Phase 3 QUASAR trial in RVO at Angiogenesis 2025 annual meeting –FDA issued Complete Response Letters ("CRLs") for sBLA for addition of extended dosing intervals and for regulatory application for pre-filled syringe –Approved by European Commission ("EC") for extended dosing intervals up to 6 months (24 weeks) in wAMD and DME	–U.S. Food and Drug Administration ("FDA") decision on supplemental Biologics License Application ("sBLA") for RVO (November 2025)[r] –FDA decision on sBLA for every 4-week dosing regimen (November 2025)[r]
Pozelimab[f] **(REGN3918)** *Antibody to C5*		–Geographic atrophy, cemdisiran combination[l][q]			
Immunology & Inflammation					
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*		–Asthma in pediatrics (2–5 years of age) –Chronic pruritus of unknown origin ("CPUO") –Lichen simplex chronicus	–Asthma in pediatrics (6–11 years of age) (Japan) –CSU in adults and adolescents (EU)	–Approved by Japan's Ministry of Health, Labour and Welfare ("MHLW") for COPD –Approved by FDA for CSU in adults and adolescents	–EC decision on regulatory submission for CSU in adults and adolescents (fourth quarter 2025) –EC decision on regulatory submission for bullous pemphigoid (first half 2026)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2025 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*			–CSU in pediatrics (2–11 years of age) (U.S. and EU) –Bullous pemphigoid (EU and Japan) –Allergic fungal rhinosinusitis ("AFRS")	– European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") adopted positive opinion for CSU in adults and adolescents –Presented positive data from Phase 2/3 bullous pemphigoid trial at 2025 American Academy of Dermatology ("AAD") Annual Meeting –Approved by FDA for bullous pemphigoid	
Kevzara (sarilumab)[b] *Antibody to IL-6R*	–Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)			–Approved by EC for pJIA	
Itepekimab[b] (REGN3500) *Antibody to IL-33*	–Non-cystic fibrosis bronchiectasis ("NCFB") –Chronic rhinosinusitis without nasal polyposis ("CRSsNP")	–COPD[e] –CRSwNP		–Reported that Phase 3 trial (AERIFY-1) in COPD met its primary endpoint; second Phase 3 trial (AERIFY-2) did not meet same primary endpoint	
REGN5713-5715 *Multi-antibody therapy to Bet v 1*		–Birch allergy		–Reported that Phase 3 trial in birch allergy met its primary and key secondary endpoints	–Initiate additional Phase 3 study in birch allergy (fourth quarter 2025)
REGN1908-1909[f] *Multi-antibody therapy to Fel d 1*		–Cat allergy		–Reported that Phase 3 trial in cat allergy met its primary and key secondary endpoints	–Initiate additional Phase 3 study in cat allergy (first half 2026)
Solid Organ Oncology					
Libtayo (cemiplimab)[g] *Antibody to PD-1*	–Neoadjuvant CSCC –First-line NSCLC, BNT116[i] combination –Neoadjuvant NSCLC	–Early-stage CSCC (intralesional)	–Adjuvant CSCC (EU)	–Approved by FDA for adjuvant CSCC –EMA's CHMP adopted positive opinion for adjuvant CSCC	–EC decision on regulatory submission for adjuvant CSCC (fourth quarter 2025)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2025 Events to Date	Select Upcoming Milestones
Libtayo (cemiplimab)[g] *(continued)*	–Neoadjuvant hepatocellular carcinoma ("HCC")			–Reported positive data from Phase 3 trial in adjuvant CSCC; results presented at 2025 American Society of Clinical Oncology ("ASCO") Annual Meeting and published in *New England Journal of Medicine ("NEJM")* –Approved by MHLW for NSCLC, monotherapy and chemotherapy combination –Reported positive five-year follow-up data from Phase 3 trial in combination with chemotherapy for NSCLC; results presented at IASLC 2025 World Conference on Lung Cancer ("WCLC")	
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–First-line advanced NSCLC (Phase 2/3) –Perioperative NSCLC –Perioperative melanoma	–First-line metastatic melanoma[e] –Adjuvant melanoma		–Based on pre-planned interim analysis of two Phase 2/3 studies in first-line advanced NSCLC, Phase 2 portion of the studies will continue unchanged	–Report results from Phase 3 study versus pembrolizumab in first-line metastatic melanoma (first half 2026) –Report data from Phase 2/3 studies in first-line advanced NSCLC (first half 2026) –Initiate Phase 2 study (in combination with Libtayo) in first-line metastatic head and neck squamous cell carcinoma (first half 2026)
Vidutolimod *Immune activator targeting TLR9*					
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*	–Ovarian cancer			–Presented additional data from Phase 2 study in platinum-resistant ovarian cancer at European Society for Medical Oncology ("ESMO") 2025 Meeting	

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2025 Events to Date	Select Upcoming Milestones
REGN5668[p] *Bispecific antibody targeting MUC16 and CD28*	–Ovarian cancer				
Nezastomig (REGN5678) *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer			–Reported additional data from study in prostate cancer at American Association for Cancer Research ("AACR") Annual Meeting	
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors				–Report additional data from study in solid tumors (first half 2026)
Davutamig (REGN5093) *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC				
Hematology					
Pozelimab[f] (REGN3918) *Antibody to C5*		–Myasthenia gravis, cemdisiran combination[c][l] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][l]		–Reported that Phase 3 cemdisiran combination trial in myasthenia gravis met its primary and key secondary endpoints	
Cemdisiran[l] *siRNA therapeutic targeting C5*		–Myasthenia gravis[c]		–Reported that Phase 3 trial in myasthenia gravis met its primary and key secondary endpoints	–Submit New Drug Application ("NDA") for myasthenia gravis (first quarter 2026), pending discussions with FDA
Ordspono (odronextamab) *Bispecific antibody targeting CD20 and CD3*	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–FL[c][e] (multiple lines and settings) –DLBCL[c][e] (multiple lines and settings)		–FDA issued CRL for BLA for relapsed/refractory FL	
Lynozyfic (linvoseltamab)[r] *Bispecific antibody targeting BCMA and CD3*	–Earlier (pre-malignant) multiple myeloma –Monoclonal gammopathy of undetermined significance ("MGUS")	–Multiple myeloma[c][e] (multiple lines and settings)		–Approved by FDA and EC for relapsed/refractory multiple myeloma –Completed enrollment in Phase 3 confirmatory trial (LINKER-MM3) in relapsed/refractory multiple myeloma	

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2025 Events to Date	Select Upcoming Milestones
Lynozyfic (linvoseltamab)[f] *(continued)*	–Light chain amyloidosis ("ALA") (Phase 1/2)				
Nexiguran ziclumeran (Nex-z, NTLA-2001)[j] *TTR gene knockout using CRISPR/Cas9*		–Transthyretin amyloidosis with cardiomyopathy ("ATTR-CM")[c][m] –Hereditary transthyretin amyloidosis with polyneuropathy ("ATTRv-PN")[c][m]		–Intellia temporarily paused dosing and screening in Phase 3 ATTR-CM and ATTRv-PN trials due to a Grade 4 adverse event involving the liver	
REGN9933 *Antibody to Factor XI (A2 domain)*	–Thrombosis				–Initiate Phase 3 studies (first half 2026)
REGN7508 *Antibody to Factor XI (catalytic domain)*	–Thrombosis	–Venous thromboembolism after total knee replacement surgery			–Initiate additional Phase 3 studies (first half 2026)
REGN7257 *Antibody to IL2Rg*				–Discontinued study in aplastic anemia	
REGN7999 *Antibody to TMPRSS6*	–Iron overload in beta-thalassemia				
Internal Medicine/Genetic Medicines					
Garetosmab[f] **(REGN2477)** *Antibody to Activin A*		–Fibrodysplasia ossificans progressiva ("FOP")[c][d][e]		–Reported that Phase 3 trial in FOP met its primary endpoint	–Submit BLA for FOP (fourth quarter 2025)
Trevogrumab[f] **(REGN1033)** *Antibody to myostatin (GDF8)*	–Obesity[n]			–Reported 26-week results from Phase 2 study in obesity	
Mibavademab[f][o] **(REGN4461)** *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[c][d][e]			
REGN5381 *Agonist antibody to NPR1*				–Discontinued Phase 2 studies in heart failure and uncontrolled hypertension	

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2025 Events to Date	Select Upcoming Milestones
REGN7544 *Antagonist antibody to NPR1*	–Postural orthostatic tachycardia syndrome ("POTS") –Sepsis-induced hypotension				
Rapirosiran (ALN-HSD)[k] *RNAi therapeutic targeting HSD17B13*	–Metabolic dysfunction-associated steatohepatitis ("MASH")				
DB-OTO *AAV-based gene therapy*	–Hearing deficit due to variants of the otoferlin gene[c][e][m] (Phase 1/2) (pivotal study)			–Presented updated data from Phase 1/2 trial and published in *NEJM* –FDA granted Commissioner's National Priority Voucher	–Submit BLA for hearing deficit due to variants of the otoferlin gene (fourth quarter 2025)

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

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

[c] FDA granted Orphan Drug designation

[d] FDA granted Breakthrough Therapy designation

[e] FDA granted Fast Track designation

[f] Sanofi is entitled to receive royalties on sales of the product, if any

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

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

[l] Under the terms of our license agreement for cemdisiran, Alnylam is entitled to receive royalties on sales (if any), as well as milestone payments

[m] FDA granted Regenerative Medicine Advanced Therapy ("RMAT") designation

[n] Studied in combination with semaglutide with and without 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

[q] Geographic atrophy also studied with cemdisiran monotherapy

[r] Refer to "Additional Information - Clinical Development Programs - EYLEA HD" for further details

Additional Information - Clinical Development Programs

EYLEA HD

In August 2025, the FDA extended the target action dates for the Company's FDA applications for EYLEA HD (pre-filled syringe, every-four-week dosing, and for the treatment of RVO). The delay resulted from observations from a July 2025 FDA general site inspection (not specific to EYLEA HD) at Catalent Indiana, LLC ("Catalent"), part of Novo Nordisk A/S, the manufacturing filler in the EYLEA HD BLA. The FDA extended the review periods after determining that the information submitted by the manufacturing filler in August 2025 to address the observations constituted a major amendment to each regulatory application.

In October 2025, the Company was notified by Catalent that they received an official action indicated ("OAI") letter from the FDA citing unresolved issues related to a July 2025 FDA general site inspection. On October 27, 2025, the FDA issued a CRL for the pre-filled syringe sBLA. The sole approvability issue cited in the CRL relates to unresolved inspection findings at Catalent. The Company is planning to submit by January 2026 an application to include a new pre-filled syringe manufacturing filler in the EYLEA HD BLA.

In addition, the Company has submitted an application to include an additional vial filler, should this be needed for approval of every-four-week dosing and RVO label enhancements, with an FDA decision regarding this new vial filler expected by late December 2025.

Itepekimab

In May 2025, the Company and Sanofi announced that a Phase 3 trial, AERIFY-1, in adults who were former smokers with inadequately controlled COPD met the primary endpoint of significantly reducing moderate or severe acute exacerbations by 27% compared to placebo at week 52, a clinically meaningful benefit. A second Phase 3 trial, AERIFY-2, did not meet the same primary endpoint, although a benefit was seen earlier in the trial. The safety profile of itepekimab observed in the Phase 3 trials was consistent with prior clinical trials. The Company and Sanofi are evaluating next steps.

Fianlimab

In April 2025, a pre-planned interim analysis was conducted on two ongoing Phase 2/3 studies evaluating the combination of fianlimab and cemiplimab in first-line advanced NSCLC. Due to limited follow-up, the Phase 2 portion of the studies will continue unchanged until additional data are available. The next analyses for these studies are expected in the first half of 2026, at which time a decision whether to advance to Phase 3 is expected to be made. No new safety signals were observed in either study.

Ordspono (odronextamab)

On July 30, 2025, the FDA issued a CRL for the BLA for odronextamab in relapsed/refractory follicular lymphoma after two or more lines of systemic therapy, which was also impacted by the Catalent Indiana LLC site inspection (as described in the "EYLEA HD" section above).

Collaboration, License, and Other Agreements

Sanofi

We are collaborating with Sanofi on the global development and commercialization of Dupixent, Kevzara, and itepekimab (the "Antibody Collaboration"). Under the terms of the Antibody Collaboration, Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30% to 50% of development expenses that were funded by Sanofi based on our share of collaboration profits; however, we are only required to apply 20% of our share of profits from the collaboration each calendar quarter to reimburse Sanofi for these development expenses. As of September 30, 2025, the total amount of our contingent reimbursement obligation to Sanofi (i.e., "development balance") in connection with such development expenses was approximately $905 million.

Under our collaboration agreement, Sanofi records product sales for commercialized products, 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 supply certain commercial bulk product to Sanofi. 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).

Bayer

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

We are obligated to reimburse Bayer for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer at a faster rate.

Within the United States, we retain exclusive commercialization rights and are entitled to all profits from such sales.

Alnylam

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.

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 agreement or a license agreement. The initial target nomination and discovery period of five years has been automatically extended until the earlier of seven years from the effective date of the collaboration or the achievement of certain milestones (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee of $300.0 million.

We have also entered into various license agreements with Alnylam, with us as the licensee, including for cemdisiran (a small interfering RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway) as a monotherapy and for a combination consisting of cemdisiran and pozelimab.

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 have 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 be entitled to 25% of any profits.

Hansoh

In July 2025, our license agreement with Hansoh Pharmaceuticals Group Company Limited to acquire development and commercial rights outside of mainland China, Hong Kong, and Macau for HS-20094 (a dual GLP-1/GIP receptor agonist currently in Phase 3 clinical development in China) became effective. In-licensing a late-stage GLP-1/GIP agonist enables us to study combinations with our products and product candidates in order to address muscle loss and potentially other comorbidities of obesity, such as cardiovascular diseases, diabetes, and liver conditions. 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 a low double-digit royalty on sales.

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 which are not reimbursed by collaborators are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of our marketed products. Our financial results may fluctuate from

quarter to quarter and will depend on, among other factors, the net sales of our products; the scope and progress of our research and development efforts; the timing of certain expenses; the continuation of our collaborations, in particular with Sanofi and Bayer, including our share of collaboration profits from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators; and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. 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,	
(In millions, except per share data)	**2025**	**2024**	**2025**	**2024**
Revenues	$ 3,754.3	$ 3,720.7	$ 10,458.6	$ 10,412.8
Operating expenses	2,727.5	2,541.2	7,760.6	7,412.3
Income from operations	1,026.8	1,179.5	2,698.0	3,000.5
Other income (expense)	736.5	313.5	1,489.0	821.3
Income before income taxes	1,763.3	1,493.0	4,187.0	3,821.8
Income tax expense	303.3	152.4	526.7	326.9
Net income	$ 1,460.0	$ 1,340.6	$ 3,660.3	$ 3,494.9
Net income per share - diluted	$ 13.62	$ 11.54	$ 33.61	$ 30.23

Revenues

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2025**	**2024**	**$ Change**	**2025**	**2024**	**$ Change**
Net product sales:						
EYLEA HD - U.S.	$ 430.6	$ 392.3	$ 38.3	$ 1,130.6	$ 896.5	$ 234.1
EYLEA - U.S.	680.6	1,144.6	(464.0)	2,170.9	3,576.7	(1,405.8)
Total EYLEA HD and EYLEA - U.S.	1,111.2	1,536.9	(425.7)	3,301.5	4,473.2	(1,171.7)
Libtayo - U.S.	219.1	194.5	24.6	659.4	536.1	123.3
Libtayo - ROW	146.1	94.1	52.0	367.4	313.8	53.6
Total Libtayo - Global	365.2	288.6	76.6	1,026.8	849.9	176.9
Praluent - U.S.	67.7	52.9	14.8	190.3	179.0	11.3
Evkeeza - U.S.	42.8	32.4	10.4	114.9	87.6	27.3
Inmazeb - U.S.	—	35.6	(35.6)	—	36.6	(36.6)
Other products - Global	0.8	—	0.8	0.8	—	0.8
Total net product sales	$ 1,587.7	$ 1,946.4	$ (358.7)	$ 4,634.3	$ 5,626.3	$ (992.0)
Collaboration revenue:						
Sanofi	$ 1,617.0	$ 1,263.4	$ 353.6	$ 4,243.8	$ 3,318.8	$ 925.0
Bayer	344.8	390.8	(46.0)	1,103.7	1,121.9	(18.2)
Other	6.6	5.9	0.7	12.8	10.2	2.6
Other revenue	198.2	114.2	84.0	464.0	335.6	128.4
Total revenues	$ 3,754.3	$ 3,720.7	$ 33.6	$ 10,458.6	$ 10,412.8	$ 45.8

Net Product Sales

Net product sales of EYLEA HD increased for the three and nine months ended September 30, 2025, compared to the same periods in 2024, due to higher sales volumes, partly offset by a lower net selling price.

Net product sales of EYLEA for the three and nine months ended September 30, 2025, compared to the same periods in 2024, were negatively impacted by (i) lower sales volumes as a result of continued competitive pressures (as described below), loss in market share to compounded bevacizumab due to patient affordability constraints, and the continued transition of patients to EYLEA HD, and (ii) a lower net selling price.

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 the success of EYLEA, EYLEA HD, and Dupixent*" and "*The commercial success of our products and product candidates is subject to significant competition* - Marketed Products." In addition, if independent not-for-profit patient assistance funds that provide 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.

Collaboration Revenue

Sanofi Collaboration Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
Regeneron's share of profits	$ 1,455.5	$ 1,088.3	$ 3,755.7	$ 2,880.6
Reimbursement for manufacturing of commercial supplies[(a)]	161.5	175.1	488.1	438.2
Total Sanofi collaboration revenue	$ 1,617.0	$ 1,263.4	$ 4,243.8	$ 3,318.8

[(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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
Dupixent and Kevzara net product sales	$ 5,011.0	$ 3,937.3	$ 13,289.8	$ 10,774.3
Regeneron's share of collaboration profits in connection with commercialization of antibodies	$ 1,723.6	$ 1,263.4	$ 4,400.5	$ 3,338.5
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation[(a)]	(268.1)	(175.1)	(644.8)	(457.9)
Regeneron's share of profits	$ 1,455.5	$ 1,088.3	$ 3,755.7	$ 2,880.6
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales	29%	28%	28%	27%

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

The increase in our share of profits for the three and nine months ended September 30, 2025, compared to the same periods in 2024, was driven by higher profits associated with an increase in Dupixent sales.

Bayer Collaboration Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
Regeneron's share of profits	$ 311.9	$ 367.6	$ 1,012.6	$ 1,054.5
Reimbursement for manufacturing of commercial supplies[(a)]	32.9	23.2	91.1	67.4
Total Bayer collaboration revenue	$ 344.8	$ 390.8	$ 1,103.7	$ 1,121.9

[(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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
EYLEA 8 mg and EYLEA net product sales outside the United States	$ 853.8	$ 931.7	$ 2,689.3	$ 2,688.9
Regeneron's share of collaboration profit from sales outside the United States	$ 328.0	$ 384.2	$ 1,061.5	$ 1,103.7
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation[(a)]	(16.1)	(16.6)	(48.9)	(49.2)
Regeneron's share of profits	$ 311.9	$ 367.6	$ 1,012.6	$ 1,054.5
Regeneron's share of profits as a percentage of EYLEA 8 mg and EYLEA net product sales outside the United States	37%	39%	38%	39%

[(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, 2025, compared to the same periods in 2024, was driven by lower profits associated with a decrease in EYLEA sales outside the United States.

Other Revenue

Other revenue increased for the three and nine months ended September 30, 2025, compared to the same periods in 2024. Other revenue included royalties and share of profits earned in connection with license agreements of $165.4 million and $90.7 million for the three months ended September 30, 2025 and 2024, respectively, and $353.0 million and $207.5 million for the nine months ended September 30, 2025 and 2024, respectively.

Operating Expenses

(In millions, except headcount data)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Research and development[(a)]	$ 1,475.0	$ 1,271.5	$ 203.5	$ 4,224.1	$ 3,719.9	$ 504.2
Acquired in-process research and development	83.1	56.2	26.9	105.4	87.2	18.2
Selling, general, and administrative[(a)]	657.8	714.4	(56.6)	1,925.0	2,162.2	(237.2)
Cost of goods sold	281.0	262.3	18.7	822.1	760.5	61.6
Cost of collaboration and contract manufacturing[(b)]	240.6	228.8	11.8	694.0	644.6	49.4
Other operating (income) expense, net	(10.0)	8.0	(18.0)	(10.0)	37.9	(47.9)
Total operating expenses	$ 2,727.5	$ 2,541.2	$ 186.3	$ 7,760.6	$ 7,412.3	$ 348.3
Average headcount	15,301	14,642	659	15,222	14,165	1,057

[(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 $237.0 million and $225.1 million for the three months ended September 30, 2025 and 2024, respectively, and $744.4 million and $678.4 million for the nine months ended September 30, 2025 and 2024, 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 and product development activities, including costs related to preclinical research activities, clinical trials, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse. Indirect research and development expenses have not been allocated directly to each program, and primarily consist of costs to compensate personnel, overhead and infrastructure costs to maintain our facilities, and other costs related to activities that benefit multiple projects. Clinical manufacturing costs primarily consist of costs to manufacture bulk drug product for clinical development purposes as well as related drug filling, packaging, and labeling costs. Clinical manufacturing costs also 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, 2025	Three Months Ended September 30, 2024*	$ Change	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024*	$ Change
Direct research and development expenses:						
Fianlimab	$ 55.8	$ 53.4	$ 2.4	$ 155.3	$ 168.4	$ (13.1)
Ordspono (odronextamab)	50.1	33.8	16.3	119.1	94.1	25.0
Lynozyfic (linvoseltamab)	32.8	25.4	7.4	118.1	111.8	6.3
Itepekimab	28.1	24.2	3.9	90.9	67.8	23.1
Dupixent (dupilumab)	27.6	31.3	(3.7)	81.1	96.4	(15.3)
EYLEA HD (aflibercept) 8 mg	21.1	28.9	(7.8)	73.9	76.0	(2.1)
Libtayo (cemiplimab)	18.0	17.9	0.1	57.3	60.7	(3.4)
Trevogrumab	17.9	6.4	11.5	57.0	18.7	38.3
Pozelimab	16.5	17.6	(1.1)	45.6	49.3	(3.7)
Other product candidates in clinical development and other research programs	186.4	147.5	38.9	498.4	415.3	83.1
Total direct research and development expenses	454.3	386.4	67.9	1,296.7	1,158.5	138.2
Indirect research and development expenses:						
Payroll and benefits	438.3	407.8	30.5	1,339.5	1,249.2	90.3
Lab supplies and other research and development costs	67.5	63.0	4.5	192.4	175.4	17.0
Occupancy and other operating costs	166.3	158.7	7.6	479.2	434.9	44.3
Total indirect research and development expenses	672.1	629.5	42.6	2,011.1	1,859.5	151.6
Clinical manufacturing costs	381.4	306.6	74.8	1,028.8	841.3	187.5
Reimbursement of research and development expenses by collaborators	(32.8)	(51.0)	18.2	(112.5)	(139.4)	26.9
Total research and development expenses	$ 1,475.0	$ 1,271.5	$ 203.5	$ 4,224.1	$ 3,719.9	$ 504.2

* 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 $125.1 million and $123.7 million for the three months ended September 30, 2025 and 2024, respectively, and $405.1 million and $369.1 million for the nine months ended September 30, 2025 and 2024, 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 three and 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.

Acquired IPR&D expenses for the three and nine months ended September 30, 2024 included a $45.0 million development milestone in connection with our collaboration agreement with Sonoma Biotherapeutics, Inc.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses decreased for the three and nine months ended September 30, 2025, compared to the same periods in 2024, primarily due to lower charitable contributions to an independent not-for-profit patient assistance organization. Selling, general, and administrative expenses included stock-based compensation expense of $92.0 million and $83.1 million for the three months ended September 30, 2025 and 2024, respectively, and $279.0 million and $251.9 million for the nine months ended September 30, 2025 and 2024, respectively.

Cost of Goods Sold

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except gross margin on net product sales)	**2025**	**2024**	**2025**	**2024**
Cost of goods sold	$ 281.0	$ 262.3	$ 822.1	$ 760.5
Gross margin on net product sales[(a)]	82%	87%	82%	86%

[(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 three and nine months ended September 30, 2025, compared to the same periods in 2024, partly due to ongoing investments to support our manufacturing operations. In addition, gross margin on net product sales decreased due to higher amortization expense associated with our Libtayo intangible asset as each quarter we record additions to the intangible asset related to royalties due to Sanofi.

Other Operating (Income) Expense

Other operating (income) expense, net, for the nine months ended September 30, 2024 reflected a charge of $37.9 million related to the increase in the estimated fair value of the contingent consideration liability recognized in connection with our 2023 acquisition of Decibel Therapeutics, Inc.

Other Income (Expense)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2025**	**2024**	**2025**	**2024**
Gains on marketable and other securities, net	$ 577.7	$ 134.7	$ 967.6	$ 331.2
Interest income	175.1	187.4	523.5	528.3
Other	3.0	5.2	29.5	6.5
Other income (expense), net	755.8	327.3	1,520.6	866.0
Interest expense	(19.3)	(13.8)	(31.6)	(44.7)
Total other income (expense)	$ 736.5	$ 313.5	$ 1,489.0	$ 821.3

Income Taxes

(In millions, except effective tax rate)	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Income tax expense	$ 303.3	$ 152.4	$ 526.7	$ 326.9
Effective tax rate	17.2%	10.2%	12.6%	8.6%

On July 4, 2025, bill H.R. 1, commonly referred to as the "One Big Beautiful Bill Act" or "OBBBA," was signed into law, with certain provisions effective in 2025 and others in 2026. The OBBBA significantly revises U.S. corporate income tax laws by, among other things, restoring the option for immediate expense recognition for U.S.-based research and development expenditures and making permanent the ability to claim first-year bonus depreciation on qualified property. The OBBBA also modifies U.S. taxation on foreign earnings by, among other things, changing the tax rates for global intangible low-taxed income (now known as Net CFC Tested Income) and foreign-derived intangible income (now known as foreign-derived deduction eligible income), modifying the allocation of expenses in calculating foreign tax credits, as well as changing foreign tax credit limitations. As a result of the OBBBA being signed into law, we recognized a charge of $44.5 million in the third quarter of 2025 related to the re-measurement of our U.S. net deferred tax assets.

Our effective tax rate for the three and nine months ended September 30, 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 federal tax credits for research activities, partially offset by the impact of the OBBBA being signed into law. In addition, our effective tax rate for the nine months ended September 30, 2025 was positively impacted by the release of liabilities for uncertain tax positions recognized upon the effective settlement of the IRS audit of our 2017 and 2018 federal income tax returns in the second quarter of 2025, which reduced our effective tax rate for the nine months ended September 30, 2025 by 1.4%.

The increase in our effective tax rate for the three and nine months ended September 30, 2025, compared to the same periods in 2024, was primarily impacted by the net change in uncertain tax positions, as well as lower tax benefits from less stock option exercises and the enactment of the OBBBA.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	September 30, 2025	December 31, 2024	$ Change
Financial assets:			
Cash and cash equivalents	$ 2,506.4	$ 2,488.2	$ 18.2
Marketable securities - current	5,937.2	6,524.3	(587.1)
Marketable securities - noncurrent	10,285.7	8,900.1	1,385.6
	$ 18,729.3	$ 17,912.6	$ 816.7
Working capital:			
Current assets	$ 17,980.7	$ 18,660.9	$ (680.2)
Current liabilities	4,425.1	3,944.3	480.8
	$ 13,555.6	$ 14,716.6	$ (1,161.0)
Borrowings and finance lease liabilities:			
Long-term debt	$ 1,985.5	$ 1,984.4	$ 1.1
Finance lease liabilities	$ 720.0	$ 720.0	$ —

As of September 30, 2025, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Nine Months Ended September 30, 2025 and 2024

	Nine Months Ended September 30,		
(In millions)	**2025**	**2024**	**$ Change**
Cash flows provided by (used in):			
Operating activities	$ 3,808.2	$ 3,157.7	$ 650.5
Investing activities	$ (849.4)	$ (2,818.7)	$ 1,969.3
Financing activities	$ (2,935.3)	$ (1,065.0)	$ (1,870.3)

Cash Flows from Investing Activities

Capital expenditures for the nine months ended September 30, 2025 included costs incurred in connection with the expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown, New York corporate headquarters. We expect to incur capital expenditures of $850 million to $890 million for the full year of 2025.

Payments for intangible assets for the nine months ended September 30, 2025 included $155.0 million related to our purchase of an FDA Rare Pediatric Disease Priority Review Voucher from a third party in the second quarter of 2025.

Cash Flows from Financing Activities

Share Repurchase Programs

In each of April 2024 and February 2025, our board of directors authorized an additional share repurchase program for up to $3.0 billion of our Common Stock (up to $6.0 billion in the aggregate). The programs have no time limit and can be discontinued at any time. As of September 30, 2025, $2.156 billion remained available for share repurchases under the programs.

Dividends

In each of the first, second, and third quarters of 2025, our board of directors declared quarterly cash dividends of $0.88 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 2025, our board of directors declared a cash dividend of $0.88 per share on our Common Stock and Class A Stock. The dividend will be payable on December 5, 2025 to our shareholders of record as of November 20, 2025.

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, 2024 (filed February 5, 2025). There have been no material changes to critical accounting estimates during the nine months ended September 30, 2025.

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, 2024 (filed February 5, 2025). There have been no material changes to our market risks or to our management of such risks as of September 30, 2025.

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, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors. For purposes of this section (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 the success of EYLEA, EYLEA HD, 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 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.
- 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 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 a potential regulatory approval, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes.
- Expanding our manufacturing capacity and establishing fill/finish capabilities 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 would 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 and 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 the success of EYLEA, EYLEA HD, and Dupixent.

We are substantially dependent on the success of EYLEA and EYLEA HD. EYLEA net product sales have historically represented a substantial portion of our revenues, and we expect that there will continue to be a concentration of our net sales from the net product sales of EYLEA HD and EYLEA. For the nine months ended September 30, 2025 and 2024, our aggregate EYLEA HD and EYLEA net product sales in the United States represented 32% and 43% of our total revenues, respectively. For the nine months ended September 30, 2025, EYLEA HD U.S. net product sales represented 34% of our aggregate EYLEA HD and EYLEA U.S. net product sales. As we further commercialize EYLEA HD, we expect that our dependence on EYLEA HD will grow relative to our historical dependence on EYLEA. 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, if EYLEA net product sales experience a sustained decline in or outside the United States without an offset from EYLEA HD net product sales, 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 and EYLEA HD 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 the three and nine months ended September 30, 2025, EYLEA U.S. net product sales declined by 41% and 39%, respectively, compared to the corresponding periods in 2024 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 (i.e., the period during which no biosimilar product can be approved by the FDA) in May 2024, several biosimilar versions of EYLEA have been approved by the FDA, and one such product has 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, which may have a material adverse impact on our results of operations. In addition, we expect that competition for EYLEA 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, which may negatively

impact the amount of collaboration revenue we earn from Bayer. While we expect certain regulatory decisions relevant to further commercialization of EYLEA HD 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" and further 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 any such milestones will be achieved in the currently anticipated time frame or at all and, if achieved, that they will help accelerate the ongoing launch and further commercialization of EYLEA HD. 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 Antibody Collaboration with Sanofi. For the nine months ended September 30, 2025 and 2024, Sanofi collaboration revenue (most of which is attributable to our share of profits from the commercialization of Dupixent) represented 41% and 32% 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);
- 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 and EYLEA HD, 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 (particularly those launched recently, such as EYLEA HD) seen in a broader patient group (i.e., real-world use);
- the effect of existing and new healthcare laws and regulations currently being considered or implemented in the United States and globally, including measures requiring the U.S. government in the future to negotiate the prices of certain drugs and price reporting and other disclosure requirements and the potential impact of such requirements on physician prescribing practices and payor coverage;
- serious complications or side effects in connection with the use of our marketed products, as discussed under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below;
- maintaining and successfully monitoring commercial manufacturing arrangements for our marketed products with third parties who perform fill/finish 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 pharmaceutical manufacturing facilities;

- our ability to meet the demand for commercial supplies of our marketed products;
- the outcome of the pending proceedings relating to EYLEA (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 for the products' currently approved indications 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' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies (such as those required under an accelerated approval by the FDA or other similar type of approval), or for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.*"), 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 and EYLEA HD) 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 three and nine months ended September 30, 2025, as further described under Part I, Item 2. "Management's

Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations." 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 most of our product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply, and regulatory review of such products. Given cost sensitivities in many 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 the Centers for Medicare & Medicaid Services ("CMS"). There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage, as discussed further below) of our current and future marketed products, which may have a material adverse effect on our business.

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 controls on the profitability of the company placing the medicinal product 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 establish sufficient commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected,*" we 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 (including those necessary for our successful commercialization and co-commercialization of Libtayo and Dupixent, respectively).

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. Starting in 2023 and 2026, the government is authorized to select Part D and Part B drugs, respectively, for inclusion in the Medicare Drug Price Negotiation Program, with established prices to go into effect for selected Part D drugs in 2026 and for selected Part B drugs in 2028, in each case absent certain disqualifying events.
- *Medicare Inflation Based Rebates*. The IRA includes measures 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.

The full extent to which the policy changes described above will ultimately impact reimbursement levels of our marketed products, including those covered under Medicare Part B (such as EYLEA and EYLEA HD), or our product candidates that may be covered under Medicare Part B or Medicare Part D in the future, is currently unclear. In addition, the current U.S. administration is pursuing other measures to reduce the cost of drugs in the United States. For example, a recent 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 (commonly referred to as "most-favored-nation" ("MFN") pricing). On July 31, 2025, as a follow-up to this executive order, President Trump sent a letter to several pharmaceutical companies (including Regeneron) requesting that within the next 60 days they, among other matters, provide their existing drugs at MFN rates to Medicaid patients, guarantee MFN pricing for newly launched drugs, and provide for direct-to-consumer and direct-to-business distribution models for high-volume, high-rebate prescription drugs. In addition, a prior executive order 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. It is currently unclear how and to what extent these measures may be implemented and what impact any such implementation would have on our Company.

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 impact the availability 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.

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 and EYLEA HD. EYLEA and EYLEA HD face significant competition in the marketplace. For example, each of EYLEA and EYLEA HD 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 Biogen 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) (launched in the United States in the fourth quarter of 2024). 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 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, 2024 (filed February 5, 2025)). Ophthalmologists are also using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, bevacizumab, for the treatment of certain of EYLEA's and EYLEA HD's respective indications, and we are aware of another company developing an ophthalmic formulation of such product that has been approved in the EU. In DME (and, in the case of EYLEA, also RVO), EYLEA and EYLEA HD 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's and EYLEA HD'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, 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 approved by the FDA in August 2023 for the treatment of wAMD, DME, and DR 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 and relative timing of our commercial launch and 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 antibodies against other targets, including OX40(L), that may compete with Dupixent in atopic dermatitis and other indications (including asthma and/or prurigo nodularis). In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or thymic stromal lymphopoietin ("TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP, EoE, COPD, and CSU where approved. There are several other potentially competitive products in development that may compete with Dupixent in asthma, COPD, and potential future indications, including antibodies against the IL-33 ligand or receptor. Dupixent also faces 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 Unloxcyt™ (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 also significant actual and potential future competition for other products marketed or otherwise commercialized by us and/or our collaborators under our collaboration agreements with them. For example, 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.

Product Candidates

Our *VelocImmune*® technology, other antibody generation technologies, and late-stage and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies, including antibody generation technologies and other approaches such as RNAi, chimeric antigen receptor T cell (CAR-T cell), and gene therapy technologies. For example, we are aware of other pharmaceutical and biotechnology companies actively engaged in the research and development of antibody-based 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 biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects. 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 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. As described in Note 12 to our Condensed Consolidated Financial Statements included in this report, we have sued Sanofi and certain of its affiliated entities (the "Antibody Collaboration Litigation") alleging that the defendants breached certain provisions of the agreement governing the Antibody Collaboration (the "Collaboration Agreement"). These provisions concern 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. It is not possible to determine what impact (if any) the Antibody Collaboration Litigation may have on the Antibody Collaboration and our business relationship with Sanofi, or whether we will be successful in the Antibody Collaboration Litigation.

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,*" a recent executive order has 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. 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 the nine months ended September 30, 2025 and 2024, our product sales to two distributor customers accounted on a combined basis for 77% and 75% of our total gross product revenue, respectively. We expect significant distributor customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of these products will depend, in part, on the extent to which our distributor customers are able to provide adequate distribution of these products to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these 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 establish sufficient commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected.

While we have made progress with establishing commercial capabilities in certain jurisdictions outside the United States in connection with our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide pursuant to the 2022 Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA") and the exercise of our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, 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 products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.

We cannot sell or market products without regulatory approval or other authorization. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products (or are materially delayed in doing so), the value of our Company and our business, prospects, operating results, and financial condition may be materially harmed.

In the United States, we (which, for purposes of this risk factor, includes our collaborators, unless otherwise stated or required by the context) must obtain and maintain approval from the FDA for each drug we intend to sell. We must obtain and maintain similar regulatory approvals from comparable foreign regulatory authorities in order to sell drugs outside the United States. Obtaining FDA or comparable foreign regulatory authority approval for a new drug or indication is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval for 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, depending on what the FDA considers necessary for the safe use of the drug. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies 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 more resources. It is also possible that 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 our applications for approval. For example, in October 2023, the FDA issued a CRL for the sBLA for Dupixent in CSU stating that additional efficacy data are 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 to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of or product labeling updates for such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. The FDA has the explicit authority to require post-marketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved 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 countries 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 includes standard review and priority review. While the FDA has performance goals that provide for action on 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 the recently announced and any future reductions of staffing or other resources at the FDA, as discussed further below).

The functioning of the FDA has been in the past and may in the future be 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, 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 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. If legislation, administrative action, or changes in policy 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 the recent reductions in communication and policymaking roles) may negatively impact the transparency of agency actions, lead to modifications in FDA approval requirements, 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 past (including the shutdown that started on October 1, 2025 and continues as of the date of this report) and certain regulatory agencies, such as the FDA, had to furlough employees and stop some of their activities. A prolonged government shutdown (including prolonged continuation of the current 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, or priority review, where available, that serve to expedite drug development and/or review, and we may also seek similar designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits, and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by the FDA or other regulatory agencies. Even if obtained, such designations may not result in faster development processes, reviews, or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meets the conditions for a beneficial regulatory designation (including due to factors beyond our control, such as intervening competitive developments) or decide that the time period for FDA review or approval will not be shortened. 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 BLA is submitted to the FDA and also states that the FDA may require that a confirmatory trial for a particular oncology product candidate be well underway, if not fully enrolled, by the time of the accelerated approval action. Application of this guidance 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, thus delaying any potential FDA approval. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Additional Information - Clinical Development Programs - Ordspono (odronextamab)" regarding the current status of the FDA's review of this program.

The FDA and comparable foreign regulatory authorities enforce Good Clinical Practice requirements ("GCPs") and other regulations and legal requirements through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This and similar instances of non-compliance with GCPs could result in non-approval of our product candidates by the FDA or foreign regulatory authorities such as the EC, or we or the FDA or such other regulatory authorities may decide to conduct additional inspections or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA and such comparable foreign regulatory authorities require that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. Additionally, manufacturers of biological products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to any commitments made in the applicable BLA. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, 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 biologic 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 any potential FDA approval of odronextamab in this indication; and the October 2025 CRL concerning the Company's regulatory application for the EYLEA HD pre-filled syringe (as described in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Additional Information - Clinical Development Programs - EYLEA HD"), which has delayed further any 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 BLA or foreign equivalent is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA or foreign equivalent must also submit new or supplemental applications and obtain FDA 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 countries 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 of drugs, and commercial sale and distribution of drugs in countries 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 include all of the risks associated with FDA approval as well as country specific regulations. We and our collaborators must maintain regulatory compliance for the products we or they commercialize in countries 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 may have less experience and where our regulatory capabilities may be more limited; for example, this is now the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) due to the transition under the A&R IO LCA discussed above. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process

for that product candidate in another country or region. Foreign regulatory authorities may ask for additional data in order to begin a clinical study, including Phase 3 clinical trials required to submit a Marketing Authorization Application ("MAA") in the EU. In addition, such authorities often have the authority to require post-approval studies, such as a post-authorization safety study ("PASS") and/or 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 countries outside the United States before we can market that product or any other product in those countries.

Furthermore, we are subject to extensive pharmacovigilance reporting and other pharmacovigilance requirements, which may differ in the numerous countries in which we conduct clinical trials or commercialize a product. Failure to comply with any such requirements may result in the premature closure of the clinical trials and other enforcement actions by the relevant regulatory authorities. For example, if we do not manage to retain a Qualified Person Responsible for Pharmacovigilance ("QPPV"), to maintain a Pharmacovigilance System Master File ("PSMF"), or to comply with other pharmacovigilance obligations in the European Economic Area ("EEA"), we may be at risk of our clinical trials being closed prematurely, our marketing authorization being suspended, and we may be subject to other enforcement actions by the national competent authorities of the EEA or the EC.

Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy; the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates); difficulty in enrolling and maintaining subjects in a clinical trial; clinical trial design that may not make it possible to enroll or retain a sufficient number of patients to achieve a statistically significant result or the desired level of statistical significance for the endpoint in question; lack of sufficient supplies of the product candidate or comparator drug; and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to Good Laboratory Practice requirements ("GLPs") or GCPs. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Additionally, conducting clinical trials in countries outside the United States presents additional risks, including political and economic risks that are not present in the United States, such as armed conflict and economic embargoes or boycotts. For example, we and our collaborators are currently conducting and may in the future conduct or initiate clinical trials with sites in Russia, Ukraine, and/or Israel. While we currently do not expect the Russia-Ukraine or Hamas-Israel armed conflict 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 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, some of our products and product candidates (such as Libtayo) are studied in combination with agents and treatments developed by us or our collaborators. There may be additional risks and unforeseen safety issues resulting from such combined administration, any of which may materially adversely impact clinical development of these product candidates and our ability to obtain regulatory approval.

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

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

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our Company, have suffered significant setbacks in clinical trials, even after promising results had been obtained in earlier trials. For example, in May 2025, we and Sanofi announced that one of two Phase 3 trials evaluating itepekimab in adults who were former smokers with inadequately controlled COPD did not meet its primary endpoint, as further described under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Additional Information - Clinical Development Programs." In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness and/or safety concerns, and clinical trials evaluating our product candidates have failed to meet the relevant endpoints. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. If concerns arise about the safety of a product candidate or non-compliance with the protocol or applicable regulatory requirements, the FDA or other regulatory authorities can delay or suspend a clinical trial by placing it on a full or partial "clinical hold" pending receipt of additional data or the satisfaction of other conditions. A clinical hold may require us to spend significant resources to address the underlying causes of the clinical hold and may result in a delay in the clinical program, which may be significant. In addition, if we are not able to successfully address such underlying causes or our response is not deemed adequate to lift the clinical hold, the clinical program may have to be terminated. 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 of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these

conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive 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.

With respect to EYLEA and EYLEA HD, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully commercialize EYLEA and EYLEA HD. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like aflibercept (such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and retinal vasculitis), which can cause injury to the eye and other complications. The side effects previously reported for aflibercept include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. 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 may yield different outcomes or patient experiences. In addition, commercialization of EYLEA and EYLEA HD or our other products and potential future commercialization of our product candidates may be impacted by actions of third parties on which we rely, such as manufacturers of syringes or other devices used in the administration of our products. These and other complications or issues or side effects could harm further development and/or commercialization of EYLEA and EYLEA HD.

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 Dupixent and Libtayo safety profiles (as applicable) or that regulatory approval of Dupixent or Libtayo (as applicable) in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include severe allergic reactions, eye problems (including eye pain or changes in vision), joint aches and pain, parasitic (helminth) infections, facial rash or redness, and inflammation of blood vessels in the skin; and the side effects previously reported for Libtayo include certain immune-mediated adverse reactions that may occur in any organ system or tissue, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea. These and other complications or side effects could harm further development and/or commercialization of Dupixent and Libtayo (as applicable).

There also are risks inherent in subcutaneous injections (which are used for administering most of our antibody-based products and product candidates), such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. In addition, there are risks inherent in intravenous administration (which are used for some of our antibody-based products and product candidates), such as infusion-related reactions (including nausea, pyrexia, rash, and dyspnea). These and other complications or side effects could harm further development and/or commercialization of our antibody-based products and product candidates utilizing this method of administration.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody-based product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Many of our products are intended to be used and, if approved, our product candidates may be used in combination with drug-delivery devices, which may result in additional regulatory, commercialization, and other risks.

Many of our products are used and some of our products and product candidates may be used, if approved, in combination with a drug-delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. For example, in the United States and the EU, EYLEA is approved in the 2mg pre-filled syringe; 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 EYLEA HD pre-filled syringe, which has delayed further any potential FDA approval of the EYLEA HD pre-filled syringe. The timing of any potential resolution of the approvability issue cited in the CRL or any potential FDA approval of the EYLEA HD pre-filled syringe is uncertain. 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 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. For

example, certain of our U.S. patents (including those pertaining to our key products, such as EYLEA and EYLEA HD) 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 (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. 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 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 United States Patent and Trademark Office (the "USPTO"), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions or our ability to obtain, maintain, and enforce our intellectual property rights. Any such changes could also affect the value of our intellectual property or narrow the scope of our patents. We cannot be certain that our intellectual property rights related to any current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such change or other rulemaking.

Additionally, the United States' and other government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. Further, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patent holders from the United States without consent or compensation. Consequently, we 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, 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 versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "*If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed,*" the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic, biosimilar, and/or interchangeable versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act ("PPACA"), there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened if, for example, the PPACA is amended. A number of jurisdictions outside 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 biosimilar competition has exacerbated the risk of loss of innovators' market exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. 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 an EYLEA biosimilar has 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 recently 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 has 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 in recent years included, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products 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 as required by regulatory authorities. In addition, we may need to develop or acquire additional manufacturing capabilities to the extent we or our collaborators pursue the development of drugs generated by means other than our existing "Trap" or *VelociSuite*® technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill/finish activities. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that 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 REGEN-COV.

Third-party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, the manufacturing facilities of our collaborators or contract manufacturers, or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborators' 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.

Many of our products and product candidates are very difficult to manufacture. As our products and most of our product candidates are biologics, they require processing steps that are more difficult than those required for many other chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us or our collaborators in a timely manner), 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 conflict between Russia and Ukraine). 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 if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted. 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. Recently, 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, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition. 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, 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 products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.*" 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. 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. The current U.S. administration, HHS, and FDA have recently announced an initiative intended to ensure transparency and accuracy in DTC prescription drug advertisements through a series of reforms that are expected to include FDA rulemaking, additional enforcement action, and expanded regulatory oversight of social media promotional activities. Failure to comply with applicable FDA requirements and restrictions in the area of 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 that could have a significant commercial

impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. Any such failures could also cause significant reputational harm. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition to FDA and related regulatory requirements, we are subject to 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.

As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any "transfers of value" made to U.S. licensed physicians and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Information provided by companies is aggregated and posted annually on an "Open Payments" website, which is managed by CMS, the agency responsible for implementing these disclosure requirements. Applicable manufacturers also are required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. We also have similar reporting obligations in other countries based on laws, regulations, and/or industry trade association requirements.

We continue to dedicate significant resources to comply with these requirements. 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 Veterans 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, 2024 (filed February 5, 2025) 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. In September 2024, CMS modified the regulations governing the Medicaid Drug Rebate Program, which could further increase our costs and the complexity of compliance, impact rebate liabilities, and be time-consuming to implement. 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 restrict 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 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 and co-commercialization capabilities in certain jurisdictions outside the United States) are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the 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, in April 2023, the European Commission published a proposal to replace the current pharmaceutical legislative framework in the EU. While it is uncertain whether such proposal will be adopted in its current form, there may ultimately be a number of changes to the current regulatory framework in the EU, including a reduction of the data protection and market exclusivity periods provided thereby.

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 (including prolonged continuation of the current 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 products is costly, time-consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.*"

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 certain jurisdictions outside the United States in connection with our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide pursuant to the A&R IO LCA; and we perform co-commercialization activities under the Antibody Collaboration related to Dupixent in certain jurisdictions outside the United States. Consequently, we are, and will continue to be, subject to risks related to operating in 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 or Hamas-Israel armed conflict;
- 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 the those countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

We 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.

The United States has recently imposed significant tariffs on imports from other countries, including a baseline tariff of 10% on imports into the United States and higher tariffs on multiple designated countries, such as "reciprocal" tariffs at varying rates. Such tariffs have prompted retaliatory measures from several countries, which may further escalate. Certain of these tariffs have been subsequently paused or modified, and the situation remains fluid. While pharmaceutical products are currently excluded from the baseline and "reciprocal" tariffs imposed by the United States, such tariffs still apply to the raw materials and other products necessary for the manufacture and formulation of our marketed products and product candidates. In addition, the U.S. Department of Commerce has initiated an investigation under Section 232 of the Trade Expansion Act of 1962, as amended, to determine the effects of importing pharmaceuticals and pharmaceutical ingredients on national security. This investigation may lead to the imposition of tariffs on pharmaceutical imports, consistent with the current U.S. administration's stated policy objective of reshoring pharmaceutical manufacturing to the United States. Further, the United States and the EU recently announced the framework of a trade agreement that is expected to impose a 15% tariff on most imports from the EU, including pharmaceutical products. However, the details of this trade agreement remain uncertain, including whether and to what extent such agreement may be impacted by the results of the Section 232 investigation.

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 recently approved OBBBA (as discussed further in Note 8 to our Condensed Consolidated Financial Statements included in this report), 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 Regulations ("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. Furthermore, negative posts or comments about us or our products in social media 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 artificial intelligence ("AI")-based solutions in various facets of our 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. 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. 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. With respect to the products and product candidates that we are co-developing with Sanofi under our Antibody Collaboration (currently consisting of Dupixent, Kevzara, and itepekimab), Sanofi initially funds a significant portion of development expenses incurred in connection with the development of these products and product candidates. In addition, we rely on Sanofi to lead much of the clinical development efforts, assist with or lead efforts to obtain and maintain regulatory approvals, and lead the commercialization efforts for these products and product candidates.

If Sanofi terminates the Antibody Collaboration or fails to comply with its 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 it is co-developing and/or co-commercializing with us, our ability to develop, manufacture, and commercialize these products and product candidates may be adversely affected. As described in Note 12 to our Condensed Consolidated Financial Statements included in this report, we have commenced the Antibody Collaboration Litigation against Sanofi and certain of its affiliated entities. It is not possible to determine what impact (if any) the Antibody Collaboration Litigation may have on the Antibody Collaboration and our business relationship with Sanofi, or whether we will be successful in the Antibody Collaboration Litigation. 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 establish sufficient commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Antibody Collaboration may create substantial new and additional risks to the successful development and commercialization of the products and product candidates subject to such collaborations, 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 establish sufficient commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA 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 and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers and other key members of our senior management team. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of Leonard S. Schleifer, M.D., Ph.D., our 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. 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.

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, 2025, we had an aggregate of $2.706 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. For example, as previously reported, the amount of our share of profits we earned in connection with commercialization of antibodies outside the United States was adversely impacted in 2022 by the U.S. dollar strengthening against foreign currencies, including the Japanese yen and the euro.

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

As of September 30, 2025, we had $2.506 billion in cash and cash equivalents and $16.223 billion in marketable securities (including $700.8 million in equity securities). Our investments consist primarily of debt securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

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) 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 January 2025, a putative class action civil complaint was filed against the Company and certain current and former executive officers 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, 2025, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 31.9% 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, 2025. 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 February 2025, our board of directors authorized our most recent share repurchase program to repurchase up to $3.0 billion of our Common Stock (of which $2.156 billion remained available as of September 30, 2025). In February 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, 2025, holders of Class A Stock held 14.9% 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, 2025:

- our current executive officers and directors beneficially owned 5.4% 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, 2025, 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, 2025; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 31.9% 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, 2025. In addition, these five shareholders plus our Chief Executive Officer held approximately 40.3% 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, 2025.

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 June 2025, will be phased out beginning in 2026 and result 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, 2025. 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)*
7/1/2025–7/31/2025	509,949	$ 551.95	509,944	$ 2,532.1
8/1/2025–8/31/2025	280,477	$ 573.15	280,470	$ 2,371.4
9/1/2025–9/30/2025	382,586	$ 569.96	377,153	$ 2,156.4
Total[(a)]	1,173,012		1,167,567	

[(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, 2025, 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

Exhibit Number	Description
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, 2025 and December 31, 2024; (ii) the registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2025 and 2024; (iii) the registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2025 and 2024; (iv) the registrant's Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2025 and 2024; 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).

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 28, 2025

By: /s/ Christopher Fenimore

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

Exhibit 31.1

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

I, Leonard S. Schleifer, certify that:

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

Date: October 28, 2025

/s/ Leonard S. Schleifer

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

Exhibit 31.2

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

I, 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 28, 2025

/s/ Christopher Fenimore

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

Exhibit 32

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2025 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 28, 2025

/s/ Christopher Fenimore
Christopher Fenimore
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
October 28, 2025