REFINITIV

DELTA REPORT

10-Q

REGN - REGENERON PHARMACEUTICALS

10-Q - SEPTEMBER 30, 2024 COMPARED TO 10-Q - JUNE 30, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	1076
CHANGES	203
DELETIONS	327
ADDITIONS	546

REFINITIV

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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2024 September 30, 2024

OR

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

Commission File Number: 000-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

The number of shares outstanding of each of the registrant's classes of common stock as of July 25, 2024 October 23, 2024:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,817,146
Common Stock, $.001 par value	108,417,383 108,072,385

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

Item 1. Financial Statements

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

	June 30,	December 31,		
	September 30,	December 31,		
	2024	2024	2023	2024 2023
ASSETS				
Current assets:				
Cash and cash equivalents				
Cash and cash equivalents				

Cash and cash equivalents	
Marketable securities	
Accounts receivable, net	
Inventories	
Prepaid expenses and other current assets	
Total current assets	
Marketable securities	
Marketable securities	
Marketable securities	
Property, plant, and equipment, net	
Intangible assets, net	
Deferred tax assets	
Other noncurrent assets	
Total assets	
	LIABILITIES AND STOCKHOLDERS' EQUITY
	LIABILITIES AND STOCKHOLDERS' EQUITY
	LIABILITIES AND STOCKHOLDERS' EQUITY
Current liabilities:	
Accounts payable	
Accounts payable	
Accounts payable	
Accrued expenses and other current liabilities	
Deferred revenue	
Total current liabilities	
Long-term debt	
Long-term debt	
Long-term debt	
Finance lease liabilities	
Deferred revenue	
Other noncurrent liabilities	
Total liabilities	
Stockholders' equity:	
Stockholders' equity:	
Stockholders' equity:	
Preferred Stock, par value $.01 per share; 30.0 shares authorized; shares issued and outstanding - none	
Preferred Stock, par value $.01 per share; 30.0 shares authorized; shares issued and outstanding - none	
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 2024 and 2023	
Common Stock, par value $.001 per share; 320.0 shares authorized; shares issued - 134.8 in 2024 and 133.1 in 2023	
Common Stock, par value $.001 per share; 320.0 shares authorized; shares issued - 135.3 in 2024 and 133.1 in 2023	
Additional paid-in capital	
Retained earnings	
Accumulated other comprehensive loss	
Treasury Stock, at cost; 26.4 shares in 2024 and 25.5 shares in 2023	
Accumulated other comprehensive income (loss)	
Treasury Stock, at cost; 27.0 shares in 2024 and 25.5 shares in 2023	
Total stockholders' equity	
Total liabilities and stockholders' equity	
	The accompanying notes are an integral part of the financial statements.
	The accompanying notes are an integral part of the financial statements.
	The accompanying notes are an integral part of the financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,					
	Three Months Ended September 30,		Nine Months Ended September 30,					
	2024	2024	2023	2024	2023	2024	2023	2024	2023
Statements of Operations									
Revenues:									
Revenues:									
Revenues:									
Net product sales									
Net product sales									
Net product sales									
Collaboration revenue									
Other revenue									
	3,547.1								
	3,720.7								
Expenses:									
Expenses:									
Expenses:									
Research and development									
Research and development									
Research and development									
Acquired in-process research and development									
Selling, general, and administrative									
Cost of goods sold									
Cost of collaboration and contract manufacturing									
Other operating expense (income), net									
	2,477.5								
	2,541.2								
Income from operations									
Income from operations									
Income from operations									
Other income (expense):									
Other income (expense):									
Other income (expense):									
Other income (expense), net									
Other income (expense), net									
Other income (expense), net									
Interest expense									
	558.5								
	313.5								
Income before income taxes									
Income before income taxes									
Income before income taxes									

Income tax expense
Income tax expense
Income tax expense
Net income
Net income
Net income
Net income per share - basic
Net income per share - basic
Net income per share - basic
Net income per share - diluted
Weighted average shares outstanding - basic
Weighted average shares outstanding - basic
Weighted average shares outstanding - basic
Weighted average shares outstanding - diluted
Statements of Comprehensive Income
Statements of Comprehensive Income
Statements of Comprehensive Income
Net income
Net income
Net income
Other comprehensive income (loss), net of tax:
Unrealized gain (loss) on debt securities
Unrealized gain (loss) on debt securities
Unrealized gain (loss) on debt securities
Loss on foreign currency translation
Unrealized gain on debt securities
Unrealized gain on debt securities
Unrealized gain on debt securities
Gain (loss) on foreign currency translation
Comprehensive income

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

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

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 Shares	Class A Stock	Common Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity	Class A Stock	Common Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholde Equity
Balance, December 31, 2023															
Balance, December 31, 2023															
Balance, December 31, 2023															

Issuance of Common Stock for equity awards granted under long-term incentive plans
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations
Issuance/distribution of Common Stock for 401(k) Savings Plan
Repurchases of Common Stock
Stock-based compensation charges
Net income
Other comprehensive income, net of tax
Balance, March 31, 2024
Issuance of Common Stock for equity awards granted under long-term incentive plans
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations
Issuance/distribution of Common Stock for 401(k) Savings Plan
Repurchases of Common Stock
Stock-based compensation charges
Net income
Other comprehensive income, net of tax
Balance, June 30, 2024
Issuance of Common Stock for equity awards granted under long-term incentive plans

Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations															
Issuance/distribution of Common Stock for 401(k) Savings Plan															
Repurchases of Common Stock															
Stock-based compensation charges															
Net income															
Other comprehensive income, net of tax															
Balance, September 30, 2024															

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

	Class A Stock Shares	Class A Stock	Common Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity	Class A Stock	Common Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholde Equity
Balance, December 31, 2022															
Balance, December 31, 2022															
Balance, December 31, 2022															
Issuance of Common Stock for equity awards granted under long-term incentive plans															
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations															
Issuance/distribution of Common Stock for 401(k) Savings Plan															
Repurchases of Common Stock															

Stock-based compensation charges	
Net income	
Other comprehensive income, net of tax	
Balance, March 31, 2023	
Issuance of Common Stock for equity awards granted under long-term incentive plans	
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	
Issuance/distribution of Common Stock for 401(k) Savings Plan	
Repurchases of Common Stock	
Stock-based compensation charges	
Net income	
Other comprehensive loss, net of tax	
Balance, June 30, 2023	
Issuance of Common Stock for equity awards granted under long-term incentive plans	
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	
Issuance/distribution of Common Stock for 401(k) Savings Plan	
Repurchases of Common Stock	
Stock-based compensation charges	
Net income	
Other comprehensive income, net of tax	

Balance, September 30, 2023
The accompanying notes are an integral part of the financial statements.
The accompanying notes are an integral part of the financial statements.
The accompanying notes are an integral part of the financial statements.

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

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Cash flows from operating activities:				
Net income				
Net income				
Net income				
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization				
Depreciation and amortization				
Depreciation and amortization				
Stock-based compensation expense				
(Gains) losses on marketable and other securities, net				
Other non-cash items, net				
Deferred income taxes				
Changes in assets and liabilities:				
(Increase) decrease in accounts receivable				
(Increase) decrease in accounts receivable				
(Increase) decrease in accounts receivable				
Increase in accounts receivable				
Increase in accounts receivable				
Increase in accounts receivable				
Increase in inventories				
Increase in prepaid expenses and other assets				
Increase (decrease) in deferred revenue				
Increase in accounts payable, accrued expenses, and other liabilities				
Total adjustments				
Net cash provided by operating activities				
Cash flows from investing activities:				
Cash flows from investing activities:				
Cash flows from investing activities:				
Purchases of marketable and other securities				
Purchases of marketable and other securities				
Purchases of marketable and other securities				
Sales or maturities of marketable and other securities				
Capital expenditures				

Proceeds from sale of property, plant, and equipment	
Payments for Libtayo intangible asset	
Acquisitions, net of cash acquired	
Net cash used in investing activities	
Cash flows from financing activities:	
Cash flows from financing activities:	
Cash flows from financing activities:	
Proceeds from issuance of Common Stock	
Proceeds from issuance of Common Stock	
Proceeds from issuance of Common Stock	
Payments in connection with Common Stock tendered for employee tax obligations	
Repurchases of Common Stock	
Other	
Net cash used in financing activities	
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	
Net decrease in cash, cash equivalents, and restricted cash	
Net decrease in cash, cash equivalents, and restricted cash	
Net decrease in cash, cash equivalents, and restricted cash	
Cash, cash equivalents, and restricted cash at beginning of period	
Cash, cash equivalents, and restricted cash at beginning of period	
Cash, cash equivalents, and restricted cash at beginning of period	
Cash, cash equivalents, and restricted cash at end of period	
Cash, cash equivalents, and restricted cash at end of period	
Cash, cash equivalents, and restricted cash at end of period	
The accompanying notes are an integral part of the financial statements.	
The accompanying notes are an integral part of the financial statements.	
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, 2023 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, 2023.

Recently Issued Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*. The amendments require disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in Accounting Standards Codification 280, *Segment Reporting*.

The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

In December 2023, the FASB issued Accounting Standards Update No. 2023-09, *Income Taxes - Improvements to Income Tax Disclosures*. The amendments require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

2. Product Sales

Net product sales consist of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2024	2023	2024	2023
EYLEA® HD				
EYLEA HD®				
EYLEA®				
Total EYLEA HD and EYLEA				
Libtayo®				
Libtayo				
Total Libtayo				
Praluent®				
Evkeeza®				
Inmazeb®				
	$			

As of June 30, 2024 September 30, 2024 and December 31, 2023, the Company had $3.958 billion $4.142 billion and $3.888 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 six nine months ended June 30, 2024 September 30, 2024 and 2023. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

		Three Months Ended June 30,		Six Months Ended June 30,					
		Three Months Ended September 30,		Nine Months Ended September 30,					
		2024	2024	2023	2024	2023	2024	2023	2024	2023
Besse Medical, a subsidiary of Cencora, Inc.	Besse Medical, a subsidiary of Cencora, Inc.	51 %	51 %	51 %	51 %	Besse Medical, a subsidiary of Cencora, Inc.	51 %	53 %	51 %	52 %
McKesson Corporation	McKesson Corporation	24 %	25 %	24 %	25 %	McKesson Corporation	24 %	24 %	24 %	25 %

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 worldwide 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 June 30, 2024 September 30, 2024, the Company's contingent reimbursement obligation to Sanofi under the collaboration was approximately $2.013 $1.810 billion.

Sanofi leads commercialization activities for products under the collaboration, subject to the Company's right to co-commercialize such products. During the three months ended September 30, 2023, the Company earned the final $50.0 million sales-based milestone from Sanofi upon aggregate annual sales of antibodies outside the United States exceeding $3.0 billion on a rolling twelve-month basis.

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 June 30,		Six Months Ended June 30,		Statement of Operations Classification	Three Months Ended September 30,		Nine Months Ended September 30,	
	(In millions)	2024	2023	2024	2023	(In millions)	2024	2023	2024	2023
Regeneron's share of profits										
Sales-based milestones earned										
Reimbursement for manufacturing of commercial supplies										
Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses										
Reimbursement of commercialization-related expenses										

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

(In millions)	(In millions)	June 30, September 30, 2024	2023	(In millions)	December 31, December 31, 2024	2023
Accounts receivable, net						
Deferred revenue						

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. Within the United States, the Company is responsible for commercialization and retains profits from such sales. 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 June 30,		Six Months Ended June 30,		Statement of Operations Classification	Three Months Ended September 30,		Nine Months Ended September 30,	
	(In millions)	2024	2023	2024	2023	(In millions)	2024	2023	2024	2023
Regeneron's share of profits										
Reimbursement for manufacturing of ex-U.S. commercial supplies										
Regeneron's obligation for its share of Bayer R&D expenses, net of reimbursement of R&D expenses										

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

		June 30,		December 31,	
		September 30,		December 31,	
(In millions)	*(In millions)*	**2024**	**2023**	*(In millions)*	**2024**	**2023**
Accounts receivable, net						
Deferred revenue						

c. Roche

The Company is a party to a collaboration agreement with Roche to develop, manufacture, and distribute the casirivimab and imdevimab antibody cocktail (known as REGEN-COV® in the United States and Ronapreve™ in other countries). Under the terms of the collaboration agreement, the Company has the right to distribute the product in the United States while Roche has the right to distribute the product outside the United States. The parties share gross profits from worldwide sales based on a pre-specified formula, depending on the amount of manufactured product supplied by each party to the market. sales.

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

				Three Months Ended June 30,		Six Months Ended June 30,			Three Months Ended September 30,		Nine Months Ended September 30,
(In millions)	*(In millions)*	**Statement of Operations Classification**	**Statement of Operations Classification**	**2024**	**2023**	**2024**	**2023**	*(In millions)*	**Statement of Operations Classification**	**2024**	**2023**	**2024**	**2023**
Global gross profit payment from Roche in connection with sales of Ronapreve													
Global gross profits earned in connection with sales of Ronapreve													
Other													

Contract balances in the Company's Balance Sheets in connection with the Roche collaboration were not material as of June 30, 2024 September 30, 2024 and December 31, 2023.

d. Other

In addition to the collaboration and license agreements discussed above, the Company has various other 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 be required to pay, or it may receive, additional amounts contingent upon the occurrence of various future events (e.g., upon the achievement of various development and commercial milestones), which in the aggregate could be significant. The Company may also incur, or get reimbursed for, significant research and development costs.

During the three and six nine months ended June 30, 2024 September 30, 2024, the Company recorded to Acquired in-process research and development expense $23.9 a $45.0 million and $31.0 million, respectively, which primarily related to up-front payments, as well as a premium on equity securities purchased, development milestone in connection with the Company's collaboration and licensing agreements. agreement with Sonoma Biotherapeutics, Inc.

During the six three and nine months ended June 30, 2023 September 30, 2023, the Company recorded to Acquired in-process research and development expense $56.1 a $100.0 million which development milestone in connection with the Company's collaboration agreement with Alnylam Pharmaceuticals, Inc. Acquired in-process research and development expense for the nine months ended September 30, 2023 also included a $45.0 million up-front payment in connection with the Company's collaboration agreement with Sonoma Biotherapeutics, Inc. Sonoma.

4. Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share

includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In millions, except per share data)	**2024**	**2023**	**2024**	**2023**
Net income - basic and diluted	$ 1,432.3	$ 968.4	$ 2,154.3	$ 1,786.2
Weighted average shares - basic	108.1	107.0	108.0	107.0
Effect of dilutive securities:				
Stock options	5.0	4.8	5.1	4.9
Restricted stock awards and restricted stock units	2.3	2.1	2.2	2.0
Weighted average shares - diluted	115.4	113.9	115.3	113.9
Net income per share - basic	$ 13.25	$ 9.05	$ 19.95	$ 16.69
Net income per share - diluted	$ 12.41	$ 8.50	$ 18.68	$ 15.68

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except per share data)	**2024**	**2023**	**2024**	**2023**
Net income - basic and diluted	$ 1,340.6	$ 1,007.8	$ 3,494.9	$ 2,794.0
Weighted average shares - basic	108.1	106.3	108.0	106.8
Effect of dilutive securities:				
Stock options	5.3	4.8	5.2	4.9
Restricted stock awards and restricted stock units	2.8	2.3	2.4	2.0
Weighted average shares - diluted	116.2	113.4	115.6	113.7
Net income per share - basic	$ 12.40	$ 9.48	$ 32.36	$ 26.16
Net income per share - diluted	$ 11.54	$ 8.89	$ 30.23	$ 24.57

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

		Three Months Ended June 30,		Six Months Ended June 30,						
		Three Months Ended September 30,		Nine Months Ended September 30,						
(Shares in millions)	*(Shares in millions)*	**2024**	**2023**	**2024**	**2023**	*(Shares in millions)*	**2024**	**2023**	**2024**	**2023**
Stock options										

5. Marketable Securities

Marketable securities as of June 30, 2024 September 30, 2024 and December 31, 2023 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)	*(In millions)*	**Amortized**	**Unrealized**		**Fair**	*(In millions)*	**Amortized**	**Unrealized**	**Fair**
As of June 30, 2024		**Cost Basis**	**Gains**	**Losses**	**Value**				
As of September 30, 2024		**Cost Basis**	**Gains**	**Losses**	**Value**				

Corporate bonds	
U.S. government and government agency obligations	
Sovereign bonds	
Commercial paper	
Certificates of deposit	
Asset-backed securities	
	$

As of December 31, 2023		
As of December 31, 2023		
As of December 31, 2023		
Corporate bonds		
Corporate bonds		
Corporate bonds		
U.S. government and government agency obligations		
Sovereign bonds		
Commercial paper		
Certificates of deposit		
Asset-backed securities		
		$

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities as of June 30, 2024 September 30, 2024 mature at various dates through June October 2029. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

	June 30,		December 31,		
	September 30,		December 31,		
(In millions)	*(In millions)*	**2024**	**2023**	*(In millions)*	**2024**	**2023**
Maturities within one year						
Maturities after one year through five years						
Maturities after five years						
		$				

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

	Less than 12 Months		**Less than 12 Months**		**12 Months or Greater**		**Total**	**Less than 12 Months**	**12 Months or Greater**	**Total**
(In millions) **As of June 30, 2024**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**				
(In millions) **As of September 30, 2024**	**Fair Value**	**Unrealized Losses**	**Fair Value**	**Unrealized Losses**	**Fair Value**	**Unrealized Losses**				
Corporate bonds										
U.S. government and government agency obligations										
Sovereign bonds										
Commercial paper										
Certificates of deposit										
Asset-backed securities										
	$									

As of December 31, 2023
As of December 31, 2023
As of December 31, 2023
Corporate bonds
Corporate bonds
Corporate bonds
U.S. government and government agency obligations
Sovereign bonds
Commercial paper
Asset-backed securities
$

The unrealized losses on corporate bonds as of June 30, 2024 were primarily driven by increased changes in interest rates. The Company has reviewed its portfolio of available-for-sale debt securities and determined that the decline in fair value below cost did not result from credit-related factors. In addition, the Company does not intend to sell, and it is not more likely than not that the Company will be required to sell, such securities before recovery of their amortized cost bases.

With respect to marketable securities, for the three and six nine months ended June 30, 2024 September 30, 2024 and 2023, amounts reclassified from Accumulated other comprehensive loss income (loss) into Other income (expense), net were related to realized gains/losses on sales of available-for-sale debt securities. For the three and six nine months ended June 30, 2024 September 30, 2024 and 2023, realized gains/losses on sales of marketable securities were not material.

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 June 30, 2024	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents	$ 781.8	$ 94.8	$ 687.0	$ —
Available-for-sale debt securities:	13			
Corporate bonds	7,296.4	—	7,296.4	—
U.S. government and government agency obligations	5,767.5	—	5,767.5	—
Sovereign bonds	53.3	—	53.3	—
Commercial paper	784.9	—	784.9	—
Certificates of deposit	384.3	—	384.3	—
Asset-backed securities	[illegible]	—	[illegible]	—
Equity securities (unrestricted)	[illegible]	—	[illegible]	—
Equity securities (restricted)	82.9	82.9	—	—
Total assets	$ 16,392.5	$ 1,268.6	$ 15,123.9	$ —
Liabilities:				
Contingent consideration	$ 90.4	$ —	$ —	$ 90.4

The Company held certain restricted equity securities as of June 30, 2024 which are subject to transfer restrictions that expire in April 2026.

During the three and six months ended June 30, 2024, the Company recorded $392.5 million and $196.3 million of net unrealized gains, respectively, on equity securities in Other income (expense), net; and during the three and six months ended June 30, 2023, the Company recorded $30.9 million and $195.6 million of net unrealized losses, respectively, on equity securities in Other income (expense), net.

(In millions)		Fair Value Measurements at Reporting Date		
As of September 30, 2024	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents	$ 934.8	$ 517.3	$ 417.5	$ —
Available-for-sale debt securities:				
Corporate bonds	7,767.3	—	7,767.3	—
U.S. government and government agency obligations	5,998.6	—	5,998.6	—
Sovereign bonds	66.9	—	66.9	—
Commercial paper	557.6	—	557.6	—

As of December 31, 2023				
Assets:				
Cash equivalents	$ 928.1	$ 6.4	$ 921.7	$ —
Available-for-sale debt securities:				

Certificates of deposit	6,398.0	—	6,398.0	—
U.S. government and government agency obligations	4,833.4	—	4,833.4	—
Sovereign bonds (unrestricted)	57.2	1,232.1	57.2	—
Commercial paper	636.8	76.1	636.8	—
Certificates of deposit	521.4	1,825.5	521.4	—
Asset-backed securities	87.1	—	87.1	—
Equity securities (unrestricted)	864.5	864.5	—	—
Equity securities (restricted)	112.9	112.9	—	—
Total assets	$ 14,439.4	$ 983.8	$ 13,455.6	$ —
As of December 31, 2023				
Assets:				
Cash equivalents	$ 928.1	$ 6.4	$ 921.7	$ —
Available-for-sale debt securities:				
Certificates of deposit	6,398.0	—	6,398.0	—
U.S. government and government agency obligations	4,833.4	—	4,833.4	—
Sovereign bonds	57.2	—	57.2	—
Commercial paper	636.8	—	636.8	—
Certificates of deposit	521.4	—	521.4	—
Asset-backed securities	87.1	—	87.1	—
Equity securities (unrestricted)	864.5	864.5	—	—
Equity securities (restricted)[a]	112.9	112.9	—	—
Total assets	$ 14,439.4	$ 983.8	$ 13,455.6	$ —
Liabilities:				
Contingent consideration	$ 43.7	$ —	$ —	$ 43.7

[a] Includes equity securities which are subject to transfer restrictions that expire in April 2026

In addition to the investments summarized in the table above, as of June 30, 2024 September 30, 2024 and December 31, 2023, the Company had $196.8 million $159.8 million and $74.3 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets. Also recorded within Other noncurrent assets as of September 30, 2024 were equity investments of $47.0 million which are measured at fair value based on Level 3 inputs; no such investments were held by the Company as of December 31, 2023.

During the three and nine months ended September 30, 2024, the Company recorded $134.5 million and $330.8 million of net unrealized gains, respectively, on equity securities in Other income (expense), net; and during the three and nine months ended September 30, 2023, the Company recorded $100.3 million and $295.9 million of net unrealized losses, respectively, on equity securities in Other income (expense), net. In addition, during the three months ended September 30, 2023, the Company recorded a write-down of $29.0 million in Other income (expense), net related to the Company's investments in private companies.

The fair value of the Company's long-term debt, which was determined based on Level 2 inputs, was estimated to be $1.485 billion $1.577 billion and $1.528 billion as of June 30, 2024 September 30, 2024 and December 31, 2023, respectively.

7. Inventories

Inventories consist of the following:

	June 30,		December 31,	
	September 30,		December 31,	
(In millions)	*(In millions)* **2024**	**2023**	*(In millions)* **2024**	**2023**
Raw materials				
Work-in-process				
Finished goods				
Deferred costs				

	$

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

8. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate was 12.0% 10.2% and 10.6% 9.3% for the three months ended June 30, 2024 September 30, 2024 and 2023, respectively, and 7.5% 8.6% and 8.0% 8.4% for the six nine months ended June 30, 2024 September 30, 2024 and 2023, respectively. The Company's effective tax rate for the three and six nine months ended June 30, 2024 September 30, 2024 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation and income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate partly offset 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 existing uncertain tax positions.

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

9. Stockholders' Equity

In January 2023, the Company's board of directors authorized a share repurchase program to repurchase up to $3.0 billion of the Company's Common Stock. As of September 30, 2024, the Company had repurchased the entire $3.0 billion of its Common Stock it was authorized to repurchase under the program.

In April 2024, the Company's board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of the Company's Common Stock. The share repurchase program permits the Company to make repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Securities Exchange Act) Act of 1934, as amended (the "Exchange Act")), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. Repurchases may be made from time to time at management's discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The program has no time limit and can be discontinued at any time. There can be no assurance as to the timing or number of shares of any repurchases in the future.

In April 2024, the Company's board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of the Company's Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase program described above.

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

		Three Months Ended June 30,		Six Months Ended June 30,					
		Three Months Ended September 30,		Nine Months Ended September 30,					
(In millions)	*(In millions)*	**2024**	**2023**	**2024**	**2023**	*(In millions)*	**2024**	**2023**	**2024**	**2023**
Number of shares										
Total cost of shares										

As of June 30, 2024 September 30, 2024, an aggregate of $3.631 billion $2.893 billion remained available for share repurchases under the programs. April 2024 program.

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:

		June 30,			September 30,
(In millions)	*(In millions)*	**2024**	**2023**	*(In millions)*	**2024**	**2023**
Cash and cash equivalents						
Restricted cash included in Prepaid expenses and other current assets						
Restricted cash included in Other noncurrent assets						
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statements of Cash Flows						

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

Supplemental disclosure of non-cash investing and financing activities

	June 30, September 30,	December 31, December 31,	June 30, September 30,	December 31, December 31,
(In millions)	*(In millions)* **2024**	**2023**	**2022**	*(In millions)* **2024**	**2023**	**2022**
Accrued capital expenditures						
Accrued contingent consideration in connection with acquisitions						

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were is unable to prevail in any 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 accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of June 30, 2024 September 30, 2024 and December 31, 2023, the Company's accruals for loss contingencies were not material. There are certain loss contingencies that the Company deems reasonably possible for which the possible loss or range of possible loss is not estimable at this time.

Proceedings Relating to Praluent (alirocumab) Injection

United States

On May 27, 2022, the Company filed a lawsuit against Amgen Inc. in the United States District Court for the District of Delaware, alleging that, beginning in 2020, Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws. The lawsuit seeks damages for harm caused by the alleged scheme, as well as injunctive relief restraining Amgen from continuing its alleged anticompetitive conduct. On August 1 and 11, 2022, Amgen filed a motion to dismiss the complaint and a motion to stay these proceedings, respectively. On February 10, 2023, the court denied Amgen's motion to stay; and on March 21, 2023, the court denied Amgen's motion to dismiss. 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 May 22, 2024, Amgen filed a motion for summary judgment. A trial An oral hearing on Amgen's motion for summary judgment has been scheduled to begin in November 2024. for November 20, 2024.

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 Technical Board of Appeal (the "TBA") of the European Patent Office (the "EPO"). A trial on the revocation action before the Munich Central Division of the UPC was held on June 4, 2024. On July 16, 2024, 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.

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).

Proceedings Relating to EYLEA (aflibercept) Injection

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

United States

Post-Grant Proceedings Before USPTO

Company Patent(s)	Challenger(s)	Type of Challenge	Date of Challenge	Latest Events/Current Status
U.S. Patent Nos. 9,254,338 (the "'338 Patent") and 9,669,069 (the "'069 Patent")	Mylan Pharmaceuticals Inc., joined by Apotex Inc. and Celltrion	IPR petitions seeking declarations of invalidity	May 5, 2021	On November 9, 2022, the USPTO issued final written decisions finding that the challenged claims of the '338 and '069 Patents are unpatentable and, therefore, invalid. On January 10, 2023, the Company filed notices of appeal of these decisions to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). On July 9, 2024, the Company's appeal was voluntarily dismissed.
U.S. Patent Nos. 10,130,681 (the "'681 Patent") and 10,888,601 (the "'601 Patent")	Mylan, joined by Celltrion ('601 and '681 Patents) and Samsung Bioepis Co., Ltd. ('601 Patent)	IPR petitions seeking declarations of invalidity	July 1, 2022	On January 9, 2024, the USPTO issued final written decisions finding that that the challenged claims of the '681 and '601 Patents are unpatentable and, therefore, invalid. On March 12, 2024, the Company filed notices of appeal of these decisions to the Federal Circuit. On August 20, 2024, the Company's appeal was voluntarily dismissed.
	Samsung Bioepis, joined by Biocon Biologics Inc. ('601 Patent)	IPR petitions seeking declarations of invalidity	January 6, 2023 ('681 Patent) March 26, 2023 ('601 Patent)	On July 19, 2023 and October 20, 2023, the USPTO instituted IPR proceedings concerning the '681 Patent and the '601 Patent, respectively. On June 14, 2024, the USPTO issued a final written decision finding that the challenged claims of the '681 Patent are unpatentable and, therefore, invalid.
U.S. Patent No. 11,253,572 (the "'572 Patent")	Samsung Bioepis	IPR petition seeking declaration of invalidity	April 27, 2023	On November 17, 2023, the USPTO instituted IPR proceedings concerning the '572 Patent. On July 11, 2024, the Company filed a Notice of Disclaimer with the USPTO, disclaiming all claims of the '572 Patent.

U.S. Patent Litigation

On August 2, 2022, the Company filed a patent infringement lawsuit against 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 FDA U.S. Food and Drug Administration ("FDA") approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On April 20, 2023, Mylan filed a motion for summary judgment or partial summary judgment concerning four of the asserted patents. On April 26, 2023, the Company filed a stipulation accepting summary judgment of noninfringement of all asserted claims of the Company's U.S. Patent No. 11,104,715. On June 5, 2023, Biocon, as successor-in-interest to the aflibercept 2 mg biosimilar, was joined as a defendant to the lawsuit. A trial was held from June 12, 2023 through June 23, 2023 concerning certain claims of the '601 Patent, the '572 Patent, and the Company's U.S. Patent No. 11,084,865 (the "'865 Patent"). On December 27, 2023, the court issued a decision finding that (i) the asserted claims of the '865 Patent were valid and infringed by Mylan and Biocon and (ii) the asserted claims of the '601 and '572 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 June 21, 2024, Mylan and Biocon filed a notice of appeal of the court's December 27, 2023 and June 11, 2024 decisions to the Federal Circuit.

On November 8, November 22, and November 29, 2023, respectively, the Company filed patent infringement lawsuits against Celltrion, Samsung Bioepis, and Formycon AG 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 allege that each company has 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 in the United States District Court for the Northern District of West Virginia alleging that Samsung's filing for FDA approval of an aflibercept 2 mg biosimilar infringes certain Company patents. 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. On June 14, June 25, and July 8, 2024, respectively, Samsung Bioepis, Formycon, and Celltrion filed notices of appeal of the court's preliminary injunction decisions to the Federal Circuit. An oral hearing concerning the respective notices of appeal of Samsung Bioepis and Formycon has been scheduled for December 5, 2024.

On January 10, 2024, the Company filed a patent infringement lawsuit against 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 infringes 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 June 7, 2024, the Company filed a motion for a preliminary injunction against Amgen. An oral hearing before the United States District Court for the Northern District of West Virginia has been scheduled was held on August 13, 2024. On September 23, 2024, the court denied the Company's motion for August 13, 2024. a preliminary injunction, and the Company filed (i) a notice of appeal of such decision to the Federal Circuit, (ii) a motion for an immediate administrative stay, and (iii) a motion for a temporary injunction preventing Amgen from launching its aflibercept 2 mg biosimilar during the pendency of such appeal. 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, lifted the administrative stay, and indicated that an expedited oral hearing on the Company's appeal to the Federal Circuit will be held in January 2025.

On August 26, 2024, the Company filed a patent infringement lawsuit against Sandoz Inc. 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 infringes 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 paragraphs.

Europe

Post-Grant Proceedings

Authority/Court	Company Patent(s)	Challenger(s)	Type of Challenge	Date of Challenge	Latest Events/Current Status
EPO	European Patent No. 2,944,306 (the "'306 Patent")	Anonymous parties	Opposition proceedings	October 26 and October 27, 2021	Oral hearing scheduled for November 2024. 2024
EPO	European Patent No. 3,716,992 (the "'992 Patent")	Amgen and three anonymous parties	Opposition proceedings	May 5-10, 5–10, 2023	Oral hearing to be scheduled. scheduled
EPO	European Patent No. 3,384,049 (the "'049 Patent")	Amgen and anonymous parties	Opposition proceedings	April 22-30, 22–30, 2024	Oral hearing to be scheduled.scheduled
German Federal Patent Court	German designation of European Patent No. 2,364,691 (the "'691 Patent")	Samsung Bioepis NL B.V.	Invalidation proceedings	June 22, 2023	Trial has been scheduled to begin in June 2025. 2025
High Court of Justice of England and Wales	United Kingdom designations of the '691 Patent and '306 Patent	Formycon AG and Klinge Biopharma GmbH	Invalidation proceedings and declaration of non-infringement by challengers' aflibercept 2 mg biosimilar	April 18, 2024	Trial has been scheduled to begin in June 2025. 2025
		Amgen	Invalidation proceedings and declaration of non-infringement by challenger's aflibercept 2 mg biosimilar	September 11, 2024	Trial has been scheduled to begin in June 2025
		Samsung Bioepis UK Limited	Invalidation proceedings and declaration of non-infringement by challenger's aflibercept 2 mg biosimilar	October 2, 2024	Trial has been scheduled to begin in June 2025
High Court of Justice of England and Wales	United Kingdom designation of the '992 Patent	Amgen	Invalidation proceedings	May 13, 2024	Stayed pending final resolution of the '992 Patent EPO opposition proceedings listed above. above
District Court of The Hague, the Netherlands	Dutch designation of the '691 Patent and '306 Patent	Samsung Bioepis NL B.V.	Invalidation proceedings	July 17, 2024	Trial for both patents has been scheduled for July 18, 2025.
High Court of Justice of England and Wales	United Kingdom designation of the '992 Patent	Samsung Bioepis UK Limited	Invalidation proceedings	July 24, 2024	Stayed pending final resolution of the '992 Patent EPO opposition proceedings listed above
Judicial Court of Paris	French designation of the '691 Patent and '306 Patent	Formycon AG	Invalidation proceedings and declaration of non-infringement by challenger's aflibercept 2 mg biosimilar	August 19, 2024	Trial to be scheduled. scheduled

Canada

Proceedings against Viatris Canada and BCIL

On March 1, 2024, the Company, Bayer Inc., Bayer Healthcare LLC, BGP Pharma ULC d.b.a. Viatris Canada ("Viatris Canada"), Biosimilar Collaborations Ireland Limited ("BCIL"), and Biocon Biologics Limited entered into a settlement agreement concerning the previously disclosed patent infringement lawsuits. Pursuant to the settlement agreement, each of such lawsuits has been dismissed and BCIL is generally precluded from launching its aflibercept 2 mg biosimilar product in Canada until July 1, 2025.

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. On May 7, 2024 and June 28, 2024, respectively, Amgen filed a summary trial motion with respect to the '510 Patent and a motion to delist the '276 Patent from the Canada Patent Register. Hearings for both motions have A hearing on the motion to delist the '276 Patent has been scheduled for November 2024. A trial for the lawsuits concerning the '510 Patent and the '276 Patent has been scheduled for May-June May–June 2025; and a trial for the lawsuits concerning the '315 Patent and the '193 Patent has been scheduled for August-September August–September 2025.

Proceedings against Celltrion Samsung

On January 15, 2024 August 1, 2024, the Company, Bayer Inc., and Bayer Inc. Healthcare LLC filed patent infringement lawsuits against Celltrion, Inc. Samsung Bioepis Co., Celltrion Healthcare Co, Ltd., Celltrion Pharma Inc., and Celltrion Healthcare Canada Ltd. 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, and the '315 Patent. Patent, and Canadian Patent No. 3,137,326 (the "'326 Patent"). On July 2, 2024 October 28, 2024, the Company, Bayer Inc., Bayer Healthcare LLC, and Celltrion, Inc. Samsung Bioepis Co., Ltd. entered into a settlement agreement concerning these patent infringement lawsuits, pursuant to which each such lawsuit has been will be dismissed and Celltrion is Samsung will generally be precluded from launching its aflibercept 2 mg biosimilar product in Canada until July 1, 2025.

Proceedings against Apotex

On March 6, 2024, the Company, Bayer Inc., and Bayer Healthcare LLC filed patent infringement lawsuits against Apotex 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, and the '315 Patent. On June 21, 2024, the Company, Bayer Inc., Bayer Healthcare LLC, and Apotex Inc. entered into a settlement agreement concerning these patent infringement lawsuits, pursuant to which each such lawsuit has been dismissed and Apotex is generally precluded from launching its aflibercept 2 mg biosimilar product in Canada until July 1, 2025.

South Korea

On October 31, 2022 and December 13, 2022, Samsung Bioepis Co., Ltd. initiated invalidation proceedings before the Intellectual Property Trial and Appeal Board of the Korean Intellectual Property Office against the Company's Korean Patent Nos. 1131429 and 1406811 (the "'811 Patent"), respectively, seeking revocation of each of such patents patent in its entirety.

On January 8, 2024, Set forth below is a summary of patent infringement lawsuits filed by the Company and, as applicable, Bayer Consumer Care AG filed a patent infringement lawsuit against Sam Chun Dang Pharm. Co., Ltd. and OPTUS Pharmaceutical Co., Ltd before the Seoul Central District Court seeking damages based on an

allegation that offering to sell an aflibercept 2 mg biosimilar would infringe one or more claims of the Company's Korean Patent No. 659477 (the "'477 Patent").

On January 10, 2024, the Company and Bayer Consumer Care AG filed a patent infringement lawsuit against Celltrion Inc. before the Seoul Central District Court seeking damages and injunctive relief based on an allegation allegations 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 '477 Patent, the '811 Patent, and Korean Patent No. 2519234 (the "'234 Patent"). Company's patents listed below.

On January 16, 2023, the Company filed a patent infringement lawsuit against Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd. before the Seoul Central District Court seeking damages based on an allegation that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would infringe one or more claims of the '477 Patent.

On May 8, 2024, the Company and Bayer Consumer Care AG filed a patent infringement lawsuit against Sam Chun Dang Pharm. Co., Ltd. and OPTUS Pharmaceutical Co., Ltd before the Seoul Central District Court seeking damages and injunctive relief based on an allegation that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would infringe one or more claims of the '811 patent and the '234 Patent.

On May 14, 2024, the Company and Bayer Consumer Care AG filed a patent infringement lawsuit against Samsung Bioepis Co., Ltd., its parent company Samsung Biologics Co., Ltd., and Samil Pharmaceuticals Co., Ltd. before the Seoul Central District Court seeking injunctive relief based on an allegation that the making, constructing, using, or selling of an

aflibercept 2mg biosimilar would infringe one or more claims of the '811 Patent and the '234 Patent.

Company Patent(s)	Defendant(s)	Relief Sought	Date of Action
Korean Patent No. 659477 (the "'477 Patent")	Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd.	Damages	January 16, 2023
	Sam Chun Dang Pharm. Co., Ltd. and OPTUS Pharmaceutical Co., Ltd	Damages	January 8, 2024
'477 Patent, '811 Patent, and Korean Patent No. 2519234 (the "'234 Patent")	Celltrion Inc.	Damages and injunctive relief	January 10, 2024
'811 Patent and '234 Patent	Sam Chun Dang Pharm. Co., Ltd. and OPTUS Pharmaceutical Co., Ltd	Damages and injunctive relief	May 8, 2024
	Samsung Bioepis Co., Ltd., its parent company Samsung Biologics Co., Ltd., and Samil Pharmaceuticals Co., Ltd	Injunctive relief	May 14, 2024
'811 Patent	Samsung Bioepis Co., Ltd., its parent company Samsung Biologics Co., Ltd., and Samil Pharmaceuticals Co., Ltd.	Injunctive relief	July 30, 2024
	Celltrion Inc. and Kukje Pharmaceuticals, Inc.	Injunctive relief	July 30, 2024

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

On June 19, 2020, Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") filed a patent infringement lawsuit (as amended on August 2, 2021) in the U.S. District Court for the Northern District of New York asserting claims of Novartis's U.S. Patent No. 9,220,631 (the "'631 Patent") and seeking preliminary and permanent injunctions to prevent the Company from continuing to infringe the '631 Patent. Novartis also seeks a judgment of patent infringement of the '631 Patent, monetary damages (together with interest), an order of willful infringement of the '631 Patent (which would allow the court in its discretion to award damages up to three times the amount assessed), costs and expenses of the lawsuits, and attorneys' fees. On November 7, 2022, the Company and Novartis entered into a stipulation staying the lawsuit in light of the decision in the IPR proceeding discussed below.

On July 16, 2020, the Company initiated two IPR petitions in the USPTO seeking a declaration of invalidity of the '631 Patent on two separate grounds. On October 26, 2021, the USPTO issued a decision instituting the IPR proceeding. An oral hearing was held on July 21, 2022. On October 25, 2022, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a final written decision invalidating all claims of the '631 Patent. On December 23, 2022, Novartis filed a notice of appeal of the PTAB's decision to the Federal Circuit. An oral hearing has been scheduled for was held on August 6, 2024. On September 23, 2024, the Federal Circuit affirmed the PTAB's decision invalidating all claims of the '631 Patent.

On July 17, 2020, the Company filed an antitrust lawsuit against Novartis and Vetter Pharma International Gmbh ("Vetter") in the United States District Court for the Southern District of New York seeking a declaration that the '631 Patent is unenforceable and a judgment that the defendants' conduct violates Sections 1 and 2 of the Sherman Antitrust Act of 1890, as amended (the "Sherman Antitrust Act"). The Company is also seeking injunctive relief and treble damages. On September 4, 2020, Novartis filed, and Vetter moved to join, a motion to dismiss the complaint, to transfer the lawsuit to the Northern District of New York, or to stay the lawsuit; and on October 19, 2020, Novartis filed, and Vetter moved to join, a second motion to dismiss the complaint on different grounds. On January 25, 2021, the Company filed an amended complaint seeking a

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

Proceedings Relating to REGEN-COV (casirivimab and imdevimab)

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit (as amended on April 8, 2021 and December 12, 2022) against the Company in the United States District Court for the Southern District of New York, asserting infringement of U.S. Patent No. 10,221,221 (the "'221 Patent"). Allele seeks a judgment of patent infringement of the '221 Patent, an award of monetary damages (together with interest), an order of willful infringement of the '221 Patent (which

would allow the court in its discretion to award damages up to three times the amount assessed), costs and expenses of the lawsuit, and attorneys' fees. On July 16, 2021, the Company filed a motion to dismiss the complaint, which motion was denied on March 2, 2022. On September 18, 2023, the parties entered into a stipulation that narrowed the case to (i) whether any safe harbor defense under federal law applies to Regeneron's use of the invention covered, based on the court's claim construction, by the '221 Patent; (ii) damages for any use by Regeneron found to not be covered by such safe harbor defense; and (iii) whether any use referred to in clause (ii) above was willful. On October 4, 2024, the court granted Allele's motion for summary judgment and found that the safe harbor defense under federal law does not apply to Regeneron's use of the invention covered, based on the court's claim construction, by the '221 Patent. A trial date has not yet been scheduled.

Department of Justice Matters

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST®, and ZALTRAP®); and certain other related documents and communications. On June 24, 2020, the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint in the U.S. District Court for the District of Massachusetts alleging violations of the federal Anti-Kickback Statute, and asserting causes of action under the federal False Claims Act and state law (the "June 2020 Civil Complaint"). On August 24, 2020, the Company filed a motion to dismiss the June 2020 Civil Complaint in its entirety. On December 4, 2020, the court denied the motion to dismiss. On December 28, 2022, the U.S. Attorney's Office for the District of Massachusetts filed a motion for partial summary judgment. On January 31, 2023, the Company filed a motion for summary judgment. An oral hearing on the parties' respective motions for summary judgment was held on July 21, 2023. 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; and on December 11, 2023, the U.S. Court of Appeals for the First Circuit certified for appeal (i.e., accepted for review) the court's September 27, 2023 order. An oral hearing concerning the appeal to the U.S. Court of Appeals for the First Circuit was held on July 22, 2024.

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 granted and denied in part denied 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. A trial has been scheduled for April 2025. On July 31, 2024 and August 15, 2024, respectively, the District Court granted the Company's second motion to dismiss the amended

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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.

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 of 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 states 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 has been scheduled for December 16, 2024.

California Department of Insurance Subpoena

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

Proceedings Initiated by Other Payors

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.

Proceedings Relating to Shareholder Derivative Complaint

On June 29, 2021, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former members of the Company's board of directors and certain current and former executive officers of the Company as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties in relation to the allegations in the 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others:

- *the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation 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 our late-stage product candidates 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;*
- *competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; 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 on the commercial success of Regeneron's Products and Regeneron's Product Candidates;*
- *our ability to manufacture and manage supply chains for multiple products and product candidates;*
- *the ability of our collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates;*
- *the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid;*
- *coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors;*
- *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 (such as the COVID-19 pandemic) on our business; and*
- *risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings described further in Note 11 to our Condensed Consolidated Financial Statements included in this report), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 11 to our Condensed Consolidated Financial Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition.*

These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from

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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, hematologic conditions, infectious diseases, and rare diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to advance as an integrated, multi-product biotechnology company that provides patients and medical professionals with important medicines for preventing and treating human diseases.

Selected financial information is summarized as follows:

		Three Months Ended June 30,		Six Months Ended June 30,						
		Three Months Ended September 30,		Nine Months Ended September 30,						
(In millions, except per share data)	*(In millions, except per share data)*	**2024**	**2023**	**2024**	**2023**	*(In millions, except per share data)*	**2024**	**2023**	**2024**	**2023**
Revenues										
Net income										

Net income per share - diluted

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

Products

Products that have received marketing approval are summarized in the table below. 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® HD (aflibercept) Injection 8 mg[(a)]	Wet age-related macular degeneration ("wAMD")	a	a	a
	Diabetic macular edema ("DME")	a	a	a
	Diabetic retinopathy ("DR")	a		
EYLEA® (aflibercept) Injection[(a)]	wAMD	a	a	a
	DME	a	a	a
	DR	a		
	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")	a	a	a
	Myopic choroidal neovascularization ("mCNV")		a	a
	Neovascular glaucoma ("NVG")			a
	Retinopathy of prematurity ("ROP")	a	a	a
Dupixent® (dupilumab) Injection[(b)]	Atopic dermatitis (in adults, adolescents, and pediatrics aged 6 months and older)	a	a	a
	Asthma (in adults and adolescents)	a	a	a

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
Dupixent (dupilumab) Injection[b] *(continued)*	Asthma (in pediatrics 6–11 years of age)	a	a	
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP") (in adults)	a	a	a
	CRSwNP (in adolescents)	a		
	Chronic obstructive pulmonary disease ("COPD")	a	a	
	Eosinophilic esophagitis ("EoE") (in adults and adolescents)	a	a	
	EoE (in pediatrics 1–11 years of age)	a		
	Prurigo nodularis	a	a	a
	Chronic spontaneous urticaria ("CSU") (in adults and adolescents)			a
Libtayo® (cemiplimab) Injection	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	a	a	
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	a	a	
	Metastatic or locally advanced basal cell carcinoma ("BCC")	a	a	
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	a	a	
	Metastatic or recurrent second-line cervical cancer		a	a
Praluent® (alirocumab) Injection[c]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	a	a	
	HeFH in pediatrics and adolescents (8–17 years of age)	a	a	
	Cardiovascular risk reduction in patients with established cardiovascular disease	a	a	
	Homozygous familial hypercholesterolemia ("HoFH")	a		
Kevzara® (sarilumab) Injection[b]	Rheumatoid arthritis ("RA")	a	a	a
	Polymyalgia rheumatica ("PMR")	a		
	Polyarticular juvenile idiopathic arthritis ("pJIA")	a		
REGEN-COV®[d]	COVID-19		a	a
Evkeeza® (evinacumab) Injection[e]	HoFH (in adults, adolescents, and pediatrics)	a	a	a
Ordspono™ (odronextamab)	Follicular lymphoma ("FL")		a	
	Diffuse large B-cell lymphoma ("DLBCL")		a	
Inmazeb® (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by *Zaire ebolavirus*	a		
Veopoz® (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in adults, adolescents, and pediatrics aged 1 year and older)	a		
ARCALYST® (rilonacept) Injection[f]	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	a		
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults, adolescents, and pediatrics)	a		

Product *(continued)*	Disease	Territory U.S.	EU	Japan
ARCALYST (rilonacept) Injection(f) *(continued)*	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults, adolescents, and pediatrics)	a		
	Recurrent pericarditis (in adults and adolescents)	a		
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion(g)	Metastatic colorectal cancer ("mCRC")	a	a	a

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 solely 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) In collaboration with Roche. Product is known as REGEN-COV in the United States and Ronapreve™ in other countries.

(e) The Company is solely responsible for the development and commercialization of Evkeeza in the United States and Ultragenyx is responsible for the development and commercialization of Evkeeza outside the United States.

(f) Kiniksa is solely responsible for the development and commercialization of ARCALYST.

(g) Sanofi is solely 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 June 30, / Three Months Ended September 30,												
		2024												
		2024												
		2024			2023			% Change		2023			% Change	
(In millions)	*(In millions)*	U.S.	ROW(g)	Total	U.S.	ROW	Total		(Total Sales)	*(In millions)*	U.S.		ROW(g)	
EYLEA HD and EYLEA(a)	EYLEA HD and EYLEA(a)	$1,534.7	$ $ 907.8	$ $2,442.5	$ $1,500.1	$ $ 886.3	$ $2,386.4	2	2 %	EYLEA HD and EYLEA(a)	$1,536.9	$	$ 931.7	$
Dupixent(b)	Dupixent(b)	$2,610.2	$ $ 946.2	$ $3,556.4	$ $2,105.2	$ $ 684.2	$ $2,789.4	27	27 %	Dupixent(b)	$2,824.7	$	$ 992.5	$
Libtayo(c)	Libtayo(c)	$ 182.4	$ $ 115.0	$ $ 297.4	$ $ 130.2	$ $ 79.8	$ $ 210.0	42	42 %	Libtayo(c)	$ 194.5	$	$ 94.1	$
Praluent(d)	Praluent(d)	$ 56.1	$ $ 135.8	$ $ 191.9	$ $ 40.5	$ $ 99.8	$ $ 140.3	37	37 %	Praluent(d)	$ 52.9	$	$ 138.5	$
Kevzara(b)	Kevzara(b)	$ 65.1	$ $ 44.6	$ $ 109.7	$ $ 56.9	$ $ 42.6	$ $ 99.5	10	10 %	Kevzara(b)	$ 72.7	$	$ 47.4	$
REGEN-COV(e)	REGEN-COV(e)	$ —	$ $ 1.1	$ $ 1.1	$ $ —	$ $ —	$ $ —	*	*	REGEN-COV(e)	$ —	$	$ 1.2	$
Other products(f)	Other products(f)	$ 30.9	$ $ 20.8	$ $ 51.7	$ $ 22.5	$ $ 16.9	$ $ 39.4	31	31 %	Other products(f)	$ 68.2	$	$ 23.2	$
		Six Months Ended June 30,												

Six Months Ended June 30,

Six Months Ended June 30,

Nine Months Ended September 30,

Nine Months Ended September 30,

Nine Months Ended September 30,

2024

2024

		2024			2023			% Change			2023		% Change
(In millions)	*(In millions)*	U.S.	ROW	Total	U.S.	ROW	Total		(Total Sales)	*(In millions)*	U.S.		ROW
EYLEA HD and EYLEA(a)	EYLEA HD and EYLEA(a)	$2,936.3	$ $1,757.2	$ $4,693.5	$ $2,933.9	$ $1,733.4	$ $4,667.3	1	1 %	EYLEA HD and EYLEA(a)	$4,473.2	$	$2,688.9 $
Dupixent(b)	Dupixent(b)	$4,828.2	$ $1,805.0	$ $6,633.2	$ $4,003.3	$ $1,271.1	$ $5,274.4	26	26 %	Dupixent(b)	$7,652.9	$	$2,797.5 $
Libtayo(c)	Libtayo(c)	$ 341.6	$ $ 219.7	$ $ 561.3	$ $ 239.9	$ $ 152.7	$ $ 392.6	43	43 %	Libtayo(c)	$ 536.1	$	$ 313.8 $
Praluent(d)	Praluent(d)	$ 126.1	$ $ 267.1	$ $ 393.2	$ $ 80.7	$ $ 205.5	$ $ 286.2	37	37 %	Praluent(d)	$ 179.0	$	$ 405.6 $
Kevzara(b)	Kevzara(b)	$ 115.1	$ $ 88.7	$ $ 203.8	$ $ 96.1	$ $ 81.9	$ $ 178.0	14	14 %	Kevzara(b)	$ 187.8	$	$ 136.1 $
REGEN-COV(e)	REGEN-COV(e)	$ —	$ $ 2.3	$ $ 2.3	$ $ —	$ $ 613.2	$ $ 613.2	(100	(100 %)	REGEN-COV(e)	$ —	$	$ 3.5 $
Other products(f)	Other products(f)	$ 56.2	$ $ 38.5	$ $ 94.7	$ $ 40.6	$ $ 33.4	$ $ 74.0	28	28 %	Other products(f)	$ 124.4	$	$ 61.7 $

* Percentage not meaningful

* Percentage not meaningful

* Percentage not meaningful

(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.

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]	2024 Events to Date	Select Upcoming Milestones
Ophthalmology					
EYLEA HD (aflibercept) 8 mg[a]		–RVO	–Two-year data for wAMD and DME (U.S.)	–Approved by European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") for wAMD and DME –Pre-filled syringe approved by European Medicines Agency ("EMA") –Presented positive three-year data from extension study of Phase 3 DME trial at American Academy of Ophthalmology ("AAO") Annual Meeting	–Initiate Report results from Phase 3 QUASAR study in RVO (second half (fourth quarter 2024) to enable global regulatory submissions –U.S. Food and Drug Administration ("FDA") submission –FDA decision on supplemental Biologics License Application ("sBLA") with two-year data for wAMD and DME (first half 2025)
Pozelimab[f] (REGN3918) *Antibody to C5*		–Geographic atrophy, cemdisiran combination[f]			–Initiate Phase 3 study in combination with cemdisiran in geographic atrophy (second half 2024)
Immunology & Inflammation					
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*	–Ulcerative colitis –Eosinophilic gastroenteritis (Phase 2/3)	–Asthma in pediatrics (2–5 years of age) –Bullous pemphigoid[c] –CSU –Chronic pruritus of unknown origin ("CPUO")	–EoE in pediatrics (1–11 years of age) (EU) –CRSwNP in adolescents (U.S.) –COPD with type 2 inflammatory phenotype (U.S. and Japan) (Japan) –CSU in adults and adolescents (EU) (U.S. and EU)	–Approved by FDA for CRSwNP in adolescents –Approved by FDA for EoE in pediatrics (1–11 years of age) –EMA's Committee for Medicinal Products for Human Use ("CHMP") adopted positive opinion for EoE in pediatrics (1–11 years of age) –Results from Phase 3 trial in pediatrics (1–11 years of age) with EoE published in *New England Journal of Medicine* ("*NEJM*") –Approved by MHLW for CSU in adults and adolescents –Approved by EC for uncontrolled COPD characterized by raised blood eosinophils –Reported that Phase 3 NOTUS trial in COPD with evidence of type 2 inflammation met its primary	–EC decision on regulatory submission for EoE in pediatrics (second half (fourth quarter 2024) –FDA decision on sBLA for CRSwNP in adolescents (target action date of September 15, 2024) –FDA decision on sBLA for COPD with type 2 inflammatory phenotype (target action date of September 27, 2024) – and EC decision on regulatory submission for CSU in adults and adolescents (first half 2025) –Report results from ongoing Phase 3 trial in CSU (in biologic-naïve patients) Submit sBLA for bullous pemphigoid (fourth quarter 2024) –Report results from Phase 3 trial in bullous pemphigoid (second half 2024)

		inflammation met its primary and key secondary endpoints; results presented at 2024 American Thoracic Society International Conference and published in *NEJM*

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*				–Approved by MHLW for CSU in adults and adolescents –Reported that second Phase 3 trial in CSU in biologic-naïve patients met its primary and key secondary endpoints –Approved by FDA, extended by three months target action date of its priority review of sBLA EC, and National Medical Products Administration ("NMPA") in China for uncontrolled COPD and an eosinophilic phenotype –Reported that Phase 3 NOTUS trial in COPD with evidence of type 2 inflammatory phenotype inflammation met its primary and key secondary endpoints; results presented at 2024 American Thoracic Society International Conference and published in *NEJM* –Reported that Phase 3 trial in bullous pemphigoid met its primary and all key secondary endpoints –Reported that first Phase 3 trial in CPUO did not achieve statistical significance in its primary itch responder endpoint	
Kevzara (sarilumab)[b] *Antibody to IL-6R*	–Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)		–PMR (EU) –pJIA (EU)	–Approved by FDA for pJIA –EMA's CHMP adopted positive opinion for PMR	–EC decision on regulatory submission for PMR (second half (fourth quarter 2024) –EC decision on regulatory submission for pJIA (first half 2025)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 Events to Date	Select Upcoming Milestones
Itepekimab[b] (REGN3500) *Antibody to IL-33*	–Non-cystic fibrosis bronchiectasis ("NCFB")	–COPD[e]			–Report results from Phase 3 study in COPD (second half 2025)
REGN5713-5714-5715 *Multi-antibody therapy to Bet v 1*		–Birch allergy			
Solid Organ Oncology					
Libtayo (cemiplimab)[g] *Antibody to PD-1*	–Neoadjuvant CSCC –First-line NSCLC, BNT116[f] combination –Neoadjuvant NSCLC –Neoadjuvant hepatocellular carcinoma ("HCC")	–Adjuvant CSCC	–First-line NSCLC, monotherapy and chemotherapy combination (Japan)	–Presented positive five-year survival data from Phase 3 NSCLC monotherapy trial at IASLC 2024 World Conference on Lung Cancer	–Conduct interim analysis from Phase 3 study in adjuvant CSCC (second half (fourth quarter 2024) –Submit MHLW decision on regulatory application in Japan submission for NSCLC, monotherapy and chemotherapy combination (second half 2024) 2025)
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–First-line advanced NSCLC (Phase 2/3) –Perioperative NSCLC –Perioperative melanoma (Phase 2/3)	–First-line metastatic melanoma[e] –First-line adjuvant Adjuvant melanoma –First-line metastatic melanoma versus the combination of relatlimab and nivolumab		–Presented positive two-year data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at European Society for Medical Oncology ("ESMO") Annual Meeting	–Initiate Phase 2 study (in combination with Libtayo) in perioperative first-line metastatic head and neck squamous cell carcinoma (2025) –Report results from Phase 3 study in first-line metastatic melanoma (2025) –Report initial data from Phase 2/3 study in first-line advanced NSCLC (fourth quarter 2024)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 Events to Date	Select Upcoming Milestones
Vidutolimod *Immune activator targeting TLR9*				–Company discontinued Phase 2 study due to drug supply	
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*	–Platinum-resistant ovarian cancer				
Nezastomig (REGN5678) *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors			–Presented positive results from dose escalation portion of Phase 1/2 trial (in combination with Libtayo) in advanced solid tumors at American Society of Clinical Oncology ("ASCO") 2024 Annual Meeting	
Hematology					
Pozelimab[f] (REGN3918) *Antibody to C5*		–Myasthenia gravis, cemdisiran combination[c][i] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][i]			
Odronextamab[m] (REGN1979) *Bispecific antibody targeting CD20 and CD3*	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–Follicular lymphoma ("FL") –Diffuse large B-cell lymphoma ("DLBCL")	–Relapsed/refractory FL and DLBCL (EU)	–FDA issued Complete Response Letters ("CRLs") for BLA for relapsed/refractory FL and DLBCL due to enrollment status of confirmatory Phase 3 trials –European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") adopted positive opinion for relapsed/refractory FL and DLBCL	–EC decision on Marketing Authorization Application ("MAA") for relapsed/refractory FL and DLBCL (second half 2024)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 Events to Date	Select Upcoming Milestones
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors			–Presented positive results from dose escalation portion of Phase 1/2 trial (in combination with Libtayo) in advanced solid tumors at American Society of Clinical Oncology ("ASCO") 2024 Annual Meeting	
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]			
Ordspono (odronextamab)[m] *Bispecific antibody targeting CD20 and CD3*	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–FL –DLBCL		–FDA issued Complete Response Letters ("CRLs") for BLA for relapsed/refractory FL and DLBCL due to enrollment status of confirmatory Phase 3 trials –Approved by EC for relapsed/refractory FL and DLBCL	
Linvoseltamab[f] (REGN5458) *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma (pivotal study)[c][e] –Earlier (pre-malignant) multiple myeloma –Monoclonal gammopathy of undetermined significance ("MGUS") –Light chain amyloidosis ("ALA")	–Multiple myeloma[c][e]	–Relapsed/refractory multiple myeloma (U.S. (EU)	–FDA issued CRL for BLA for relapsed/refractory multiple myeloma due to findings resulting from an inspection at third-party fill/finish manufacturer	–FDA and EC decisions on regulatory applications for relapsed/refractory multiple myeloma pending resolution of a third-party fill/finish manufacturing issue

Clinical Program *(n)* *(continued)*	Phase 2	Phase 3	Regulatory Review and EU) (h)	2024 Events to Date	Select Upcoming Milestones
Linvoseltamab(f) (REGN5458) *(continued)*				–Presented 14-month median follow-up data from pivotal Phase 1/2 trial in multiple myeloma at European Hematology Association ("EHA") Congress 2024 and published these data in *Journal of Clinical Oncology*	–FDA decision on BLA (target action date of August 22, 2024) and EC decision on MAA (first half 2025) for relapsed/refractory multiple myeloma
NTLA-2001 Nexiguran ziclumeran (NTLA-2001)(j) *TTR gene knockout using CRISPR/Cas9*		–Transthyretin amyloidosis(c) with cardiomyopathy ("ATTR-CM")			
REGN9933 *Antibody to Factor XI*	–Thrombosis				–Report top-line results from Phase 2 study in thrombosis (second half (fourth quarter 2024)
REGN7508 *Antibody to Factor XI*	–Thrombosis				–Report top-line results from Phase 2 study in thrombosis (fourth quarter 2024)
REGN7257 *Antibody to IL2Rg*	–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)			–Report results from Phase 3 study in FOP (second half 2025)
Trevogrumab(f) (REGN1033) *Antibody to myostatin (GDF8)*	–Obesity(o) (n)				–Complete enrollment in Phase 2 study in obesity (fourth quarter 2024)
Mibavademab(f)(p) (o) (REGN4461) *Agonist antibody to leptin receptor ("LEPR")*	–Generalized lipodystrophy(d)(e)				
REGN5381 *Agonist antibody to NPR1*	–Heart failure				
Rapirosiran (ALN-HSD)(k) *RNAi therapeutic targeting HSD17B13*	–Nonalcoholic Metabolic dysfunction-associated steatohepatitis ("NASH" MASH")				

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 did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on sales of the product, if any.

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

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

(i) 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 sales milestones.

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

(n) Company is seeking accelerated approval in the United States

(o)Studied in combination with semaglutide with and without garetosmab

(p) (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.

Additional Information - Clinical Development Programs

Dupixent (dupilumab) Linvoseltamab

In May August 2024, the FDA extended by three months issued a CRL for the target action date of its priority review of the sBLA BLA for Dupixent as an add-on maintenance treatment linvoseltamab in certain adult patients with uncontrolled COPD. The FDA had requested additional analyses on the efficacy of Dupixent in the BOREAS and NOTUS pivotal trials. Based on the submission of these analyses, the agency determined that this additional information constituted a major amendment to the sBLA and extended the target action date accordingly. The revised target action date is September 27, 2024.

Linvoseltamab

During its review of the linvoseltamab BLA for relapsed/refractory multiple myeloma the FDA informed us that the third-party fill/finish provider for linvoseltamab had unresolved has progressed after at least three prior therapies. The sole approvability issue identified is related to findings from a pre-approval inspection for another company's product candidate, which is to be filled on the same manufacturing line as linvoseltamab. Although this at a third-party fill/finish provider communicated to us and the FDA that they believe these findings have been successfully remediated, the FDA has indicated that a re-inspection manufacturer. Resolution of this issue will be required before these issues are considered resolved for both FDA and any new products filled on this line can be approved, including linvoseltamab. Therefore, we believe EC regulatory approvals.

Dupixent

In September 2024, the Company and Sanofi announced that any potential FDA approval the first Phase 3 trial (Study A) of the linvoseltamab BLA will be delayed beyond the August 22, 2024 target action date. Dupixent in adults with uncontrolled and severe CPUO did not achieve statistical significance in its primary itch responder endpoint (despite favorable numerical improvements), but showed nominally significant improvements in all other itch endpoints. The FDA has not informed us Dupixent Phase 3 program in CPUO consists of any approvability issues for linvoseltamab related Study A and Study B. Study B is planned to safety, efficacy, or the status of our confirmatory initiate as a subsequent pivotal trial.

Early-Stage Clinical Development Updates

In 2024, a Phase 1 study of linvoseltamab, in combination with dupilumab, in severe food allergy was initiated.

A Phase 1/2 study of DB-OTO, an AAV-based gene therapy, in children with profound genetic hearing loss due to mutations of the otoferlin gene is ongoing. In May 2024, the Company we presented updated data from the Phase 1/2 trial at the American Society of Gene and Cell Therapy ("ASGCT") annual conference and announced that DB-OTO improved hearing to normal levels in one child and that initial hearing improvements were observed in a second child. Additionally, the FDA granted DB-OTO Regenerative Medicine Advanced Therapy ("RMAT") designation.

In 2024, a Phase 1 combination cohort of nezastomig and REGN4336 (bispecific antibody targeting PSMA and CD3) in metastatic castration-resistant prostate cancer was initiated.

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 collaboration, 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 worldwide 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 June 30, 2024 September 30, 2024, the total amount of our contingent reimbursement obligation to Sanofi (i.e., "development balance") in connection with such development expenses was approximately $2.013 $1.810 billion.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-commercialize such products on a country-by-country basis. We co-commercialize Dupixent in the United States and in certain countries outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi equally share profits 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 ("CNS"), in addition to a select number of targets expressed in the liver. During 2023, we paid a $100.0 million development milestone to Alnylam upon the achievement of specified proof-of-principle criteria for a CNS program (ALN-APP) and Alnylam is eligible to receive an additional $100.0 million clinical proof-of-principle milestone in connection with an eye program.

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.

During the second quarter of 2024, we elected to no longer co-develop ALN-APP pursuant to a co-development/co-commercialization collaboration agreement; as a result, Alnylam retains the right to develop and commercialize such product and we will receive a royalty on sales (if any).

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. NTLA-2001, which is in clinical development, is subject to a co-development and co-commercialization arrangement pursuant to which Intellia will lead development and commercialization activities and the parties share an agreed-upon percentage of development expenses and profits (if commercialized). In addition, we also have non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products.

In September 2023, we expanded the license and collaboration agreement to develop additional *in vivo* CRISPR-based gene editing therapies focused on neurological and muscular diseases. Intellia will lead the design of the editing methodology, we will lead the design of the targeted viral vector delivery approach, and the parties share costs equally. Each company will have the opportunity to lead potential development and commercialization of product candidates for one 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.

In addition, in October 2023, we elected to extend the period for selecting targets under the license and collaboration agreement for an additional two years until April 2026; as a result, we made a $30.0 million extension payment to Intellia.

In March 2024, Intellia elected to opt-out of further development activities pursuant to the Factor IX co-development and co-commercialization agreement; as a result, we retain the right to develop and commercialize products directed to Factor IX, and Intellia will be entitled to receive milestone payments and royalties on sales (if any).

Decibel

In 2017, we entered into an agreement with Decibel Therapeutics, Inc. to discover and develop new potential therapeutics to protect, repair and restore hearing (including DB-OTO, which is currently in clinical development, and preclinical programs for GJB2-related and stereocilin-related hearing loss).

In August 2023, we acquired Decibel by paying $101.3 million in cash (or $4.00 per share of Decibel common stock). In addition, Decibel shareholders received one non-tradeable contingent value right ("CVR") per share of Decibel common stock, entitling them to receive up to an additional $3.50 per share in cash upon achievement of certain development milestones for DB-OTO within specified time periods.

In July During the third quarter of 2024, a development milestone contemplated by the CVRs was achieved, and, as a result, we became obligated to pay paid $55.1 million to the holders of the CVRs. The holders of the CVRs may will be entitled to receive an additional $42.0 million if an additional milestone contemplated by the CVRs is achieved.

2seventy bio

In 2018, we entered into a collaboration agreement with bluebird bio, Inc. (which subsequently spun out 2seventy bio, Inc. in 2021) to research, develop, and commercialize novel cell therapy approaches to address cancer.

In April 2024, we acquired full development and commercialization rights to 2seventy bio's oncology and autoimmune preclinical and clinical stage cell therapy pipeline. Under the terms of the agreement, we made a $5.0 million up-front payment, and have assumed ongoing program, infrastructure, and personnel costs related to the product candidates acquired. We are

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obligated to pay 2seventy bio a regulatory milestone upon the first major market approval of the first approved product; and, with respect to any approved product, a low single-digit percent royalty on sales. In addition, we separately entered into sublease agreements for a portion of 2seventy bio's facilities.

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 EYLEA HD, EYLEA, 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. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such products and whether or when they may become profitable.

Corporate Information

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

We make available free of charge on or through our Internet website (*http://www.regeneron.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC").

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

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

Results of Operations

Net Income

	Three Months Ended June 30,	Six Months Ended June 30,
	Three Months Ended September 30,	**Nine Months Ended September 30,**

(In millions, except per share data)	(In millions, except per share data)	2024	2023	2024	2023	(In millions, except per share data)	2024	2023	2024	2023
Revenues										
Operating expenses										
Income from operations										
Other income (expense)										
Income before income taxes										
Income tax expense										
Net income										
Net income per share - diluted										
Net income per share - diluted										
Net income per share - diluted										

36 40

Revenues

	Three Months Ended June 30,			Three Months Ended September 30,								
(In millions)												
(In millions)												
(In millions)	2024	2023	$ Change	2024	2023	$ Change	2024	2023	$ Change	2024	2023	$ Change
Net product sales:												
EYLEA HD - U.S.												
EYLEA HD - U.S.												
EYLEA HD - U.S.												
EYLEA - U.S.												
Total EYLEA HD and EYLEA - U.S.												
Libtayo - U.S.												
Libtayo - ROW												
Total Libtayo - Global												
Praluent - U.S.												
Evkeeza - U.S.												
Inmazeb - Global												
Total net product sales												
Collaboration revenue:												
Collaboration revenue:												
Collaboration revenue:												
Sanofi												
Sanofi												
Sanofi												
Bayer												
Roche												
Other												
Other revenue												
Total revenues												

Net Product Sales

Total EYLEA HD and EYLEA net product sales in the U.S. increased for the three and six nine months ended June 30, 2024, September 30, 2024 compared to the same periods in 2023. EYLEA HD was approved by the FDA in August 2023 and EYLEA HD net product sales for the three and six nine months ended June 30, 2024 September 30, 2024 were

driven by the transition of patients from other anti-VEGF products, including EYLEA, to EYLEA HD, as well as new patients naïve to anti-VEGF therapy. Net product sales of EYLEA in the United States decreased for the three and six nine months ended June 30, 2024, September 30, 2024 were adversely impacted by a lower net selling price compared to the same periods in 2023, primarily due to (i) 2023. In addition, for the aforementioned approval and transition of certain patients to three months ended September 30, 2024 total EYLEA HD and (ii) other market dynamics that resulted in EYLEA net product sales were favorably impacted by approximately $40 million as a result of higher wholesaler inventory levels for EYLEA HD at the end of the third quarter of 2024 compared to the end of the second quarter of 2024, partially offset by lower volumes and a lower net selling price. wholesaler inventory levels for EYLEA.

Collaboration Revenue

Sanofi Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2024	2023	2024	2023
Regeneron's share of profits				
Sales-based milestones earned				
Reimbursement for manufacturing of commercial supplies[a]				
Total Sanofi collaboration revenue				

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

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

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

Global net product sales of Dupixent and Kevzara are recorded by Sanofi, 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 June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2024	2023	2024	2023
Dupixent and Kevzara net product sales				
Regeneron's share of collaboration profits in connection with commercialization of antibodies				
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation				
Regeneron's share of profits				
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales				
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales				
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales	27%	26%	25%	28%

The increase in our share of profits for the three and six nine months ended June 30, 2024 September 30, 2024, compared to the same periods in 2023, was driven by higher profits associated with Dupixent sales.

During the three months ended September 30, 2023, the Company earned the final $50.0 million sales-based milestone from Sanofi upon aggregate annual sales of antibodies outside the United States exceeding $3.0 billion on a rolling twelve-month basis.

Bayer Collaboration Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2024	2023	2024	2023
Regeneron's share of profits				
Reimbursement for manufacturing of ex-U.S. commercial supplies[(a)]				
Total Bayer collaboration revenue				

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

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

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

Bayer records net product sales of EYLEA 8 mg and EYLEA outside the United States. 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 June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2024	2023	2024	2023
EYLEA 8 mg and EYLEA net product sales outside the United States				
Regeneron's share of collaboration profit from sales outside the United States				
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation				
Regeneron's share of profits				
Regeneron's share of profits as a percentage of EYLEA 8 mg and EYLEA net product sales outside the United States				
Regeneron's share of profits as a percentage of EYLEA 8 mg and EYLEA net product sales outside the United States				
Regeneron's share of profits as a percentage of EYLEA 8 mg and EYLEA net product sales outside the United States	38	42	39%	39%

Roche Collaboration Revenue

	Three Months Ended June 30,	Six Months Ended June 30,
	Three Months Ended September 30,	Nine Months Ended September 30,

(In millions)	(In millions)	2024	2023	2024	2023	(In millions)	2024	2023	2024	2023
Global gross profit payment from Roche in connection with sales of Ronapreve										
Global gross profits earned in connection with sales of Ronapreve										
Other										
Total Roche collaboration revenue										

Roche distributes and records net product sales of Ronapreve outside the United States, and the parties share gross profits from sales. Net product sales of Ronapreve outside the United States declined as a result of new variants of the SARS-CoV-2 virus emerging that are not susceptible to the treatment.

Expenses

	Three Months Ended June 30,			Three Months Ended September 30,								
(In millions, except headcount data)												
(In millions, except headcount data)												
(In millions, except headcount data)	2024	2023	Change	2024	2023	Change	2024	2023	Change	2024	2023	Change
Research and development[(a)]												
Acquired in-process research and development												
Selling, general, and administrative[(a)]												
Cost of goods sold												
Cost of collaboration and contract manufacturing[(b)]												
Other operating expense (income), net												
Total operating expenses												
Average headcount												
Average headcount												
Average headcount												

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

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

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

(b) Includes costs incurred in connection with producing commercial drug supplies for collaborators and others

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

Operating expenses included stock-based compensation of $223.2 million $225.1 million and $202.0 million $203.9 million for the three months ended June 30, 2024 September 30, 2024 and 2023, respectively, and $453.3 million $678.4 million and $440.7 million $644.6 million for the six nine months ended June 30, 2024 September 30, 2024 and 2023, respectively. Stock-based compensation expense relates to equity awards granted under our long-term incentive plans.

Research and Development Expenses

The following table summarizes our 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.

	Three Months Ended June 30,			Three Months Ended September 30,								
(In millions)												
(In millions)												
(In millions)	2024	2023*	$ Change	2024	2023*	$ Change	2024	2023*	$ Change	2024	2023*	$ Change
Direct research and development expenses:												
Fianlimab												
Fianlimab												
Fianlimab												
Ordspono (odronextamab)												
Dupixent (dupilumab)												
Odronextamab												
EYLEA HD (aflibercept) 8 mg												
Linvoseltamab												
Itepekimab												
Linvoseltamab												
Libtayo (cemiplimab)												
Pozelimab												
Other product candidates in clinical development and other research programs												
Total direct research and development expenses												
Indirect research and development expenses:												
Indirect research and development expenses:												
Indirect research and development expenses:												
Payroll and benefits												
Payroll and benefits												
Payroll and benefits												
Lab supplies and other research and development costs												
Occupancy and other operating costs												
Total indirect research and development expenses												
Clinical manufacturing costs												
Clinical manufacturing costs												
Clinical manufacturing costs												
Reimbursement of research and development expenses by collaborators												
Reimbursement of research and development expenses by collaborators												
Reimbursement of research and development expenses by collaborators												
Total research and development expenses												
Total research and development expenses												
Total research and development expenses												

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

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

* 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 $122.4 million $123.7 million and $109.1 million $107.4 million for the three months ended June 30, 2024 September 30, 2024 and 2023, respectively, and $245.4 million $369.1 million and $248.6 million $356.0 million for the six nine months ended June 30, 2024 September 30, 2024 and 2023, 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")

Acquired IPR&D for the three and six nine months ended June 30, 2024 primarily September 30, 2024 included up-front payments, as well as a premium on equity securities purchased, $45.0 million development milestone in connection with our collaboration and licensing agreements. agreement with Sonoma Biotherapeutics, Inc.

Acquired IPR&D for the six three and nine months ended June 30, 2023 September 30, 2023 included a $100.0 million development milestone in connection with our collaboration agreement with Alnylam Pharmaceuticals, Inc. The nine months ended September 30, 2023 also included a $45.0 million up-front payment in connection with our collaboration agreement with Sonoma Biotherapeutics, Inc. Sonoma.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased for the three and six nine months ended June 30, 2024 September 30, 2024, compared to the same periods in 2023, due to higher commercialization-related expenses to support our launch of EYLEA HD and higher headcount and headcount-related costs partly related to our international commercial expansion. Selling, general, and administrative expenses also included stock-based compensation expense of $82.6 million $83.1 million and $73.3 million $74.4 million for the three months ended June 30, 2024 September 30, 2024 and 2023, respectively, and $168.8 million $251.9 million and $150.1 million $224.5 million for the six nine months ended June 30, 2024 September 30, 2024 and 2023, respectively.

Cost of Goods Sold

Cost of goods sold increased for the three and six nine months ended June 30, 2024 September 30, 2024, compared to the same periods in 2023, primarily due to higher start-up costs for our Rensselaer, New York fill/finish facility.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing decreased for the six months ended June 30, 2024, compared to the same period in 2023, partly due to the recognition of lower Dupixent manufacturing costs as a result of the transition to a higher-yielding manufacturing process.

Other Operating Expense (Income)

Other operating expense (income), net, reflected charges of $14.6 million $8.0 million and $29.9 million, $37.9 million for the three and six nine months ended June 30, 2024 September 30, 2024, respectively, 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)

Other income (expense) consists of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2024	2023	2024	2023
Unrealized gains (losses) on equity securities, net				
Interest income				
Other				
Other income (expense), net				
Interest expense				
Total other income (expense)				

41 45

Income Taxes

	Three Months Ended June 30,	Six Months Ended June 30,

		Three Months Ended September 30,		Nine Months Ended September 30,					
(In millions, except effective tax rate)	*(In millions, except effective tax rate)*	2024	2023	2024	2023	*(In millions, except effective tax rate)*	2024	2023	2024	2023
Income tax expense	Income tax expense	$ 195.8	$ 114.5	$ 174.5	$ 154.7	Income tax expense	$ 152.4	$ 103.0	$ 326.9	$ 257.7
Effective tax rate	Effective tax rate	12.0 %	10.6 %	7.5 %	8.0 %	Effective tax rate	10.2 %	9.3 %	8.6 %	8.4 %

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

Certain countries in which we have operations, including Ireland, have adopted legislation influenced by the Organization for Economic Co-operation and Development ("OECD") Global Anti-Base Erosion Model Rules ("Pillar Two") framework, including a minimum tax rate of 15%. The adoption of the Pillar Two framework did not have a material impact on our effective tax rate for the three and six nine months ended June 30, 2024 September 30, 2024. It is uncertain whether the United States will enact legislation to adopt the Pillar Two framework. We continue to evaluate additional guidance released by the OECD, along with the pending legislative adoption by additional individual countries.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

	June 30, September 30,					
(In millions)						
(In millions)						
(In millions)	2024	2023	$ Change	2024	2023	$ Change
Financial assets:						
Cash and cash equivalents						
Cash and cash equivalents						
Cash and cash equivalents						
Marketable securities - current						
Marketable securities - noncurrent						
	$					
Working capital:						
Working capital:						
Working capital:						
Current assets						
Current assets						
Current assets						
Current liabilities						
	$					
Borrowings and finance lease liabilities:						
Borrowings and finance lease liabilities:						
Borrowings and finance lease liabilities:						
Long-term debt						
Long-term debt						
Long-term debt						
Finance lease liabilities						

As of June 30, 2024 September 30, 2024, we also had borrowing availability of $750.0 million under a revolving credit facility.

Sources and Uses of Cash for the Six Nine Months Ended June 30, 2024 September 30, 2024 and 2023

	Six Months Ended June 30, Nine Months Ended September 30,					
(In millions)						
(In millions)						
(In millions)	2024	2023	$ Change	2024	2023	$ Change

Cash flows provided by operating activities	
Cash flows used in investing activities	
Cash flows used in financing activities	

Cash Flows from Investing Activities

Capital expenditures for the six nine months ended June 30, 2024 September 30, 2024 included costs incurred in connection with the expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown, New Tarrytown, New York location, as well as costs associated

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with the expansion of our manufacturing facilities in Rensselaer, New York (including the fill/finish facility). In addition, in September 2024, we acquired a 1,100,000 square foot facility in Saratoga Springs, New York. We expect to incur

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capital expenditures of $750 million $700 million to $820 million $740 million for the full year of 2024 primarily in connection with the continued expansion of our facilities in Tarrytown and Rensselaer (including the fill/finish facility).

Payments for the Libtayo intangible asset of $58.3 million and $121.8 million $145.7 million for the six nine months ended June 30, 2024 September 30, 2024 and 2023, respectively, were related to contingent consideration in connection with our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide.

Cash Flows from Financing Activities

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $1.120 billion $1.374 billion for the six nine months ended June 30, 2024 September 30, 2024, compared to $575.9 million $844.5 million for the six nine months ended June 30, 2023 September 30, 2023. In addition, payments in connection with Common Stock tendered for employee tax obligations were $655.5 million $775.7 million for the six nine months ended June 30, 2024 September 30, 2024, compared to $113.1 million $242.5 million for the six nine months ended June 30, 2023 September 30, 2023. For information related to repurchases of Common Stock, see "*Share Repurchase Programs*" section below.

Share Repurchase Programs

In January 2023, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock. As of September 30, 2024, the Company had repurchased the entire $3.0 billion of its Common Stock it was authorized to repurchase under the program.

In April 2024, our board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. The share repurchase program permits the Company to make repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. Repurchases may be made from time to time at management's discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The program has no time limit and can be discontinued at any time. There can be no assurance as to the timing or number of shares of any repurchases in the future.

In April 2024, our board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase program described above.

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

	Six Months Ended June 30,			Nine Months Ended September 30,		
(In millions)	*(In millions)*	**2024**	**2023**	*(In millions)*	**2024**	**2023**
Number of shares						
Total cost of shares						

As of June 30, 2024 September 30, 2024, an aggregate of $3.631 billion $2.893 billion remained available for share repurchases under the programs. April 2024 program.

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, 2023 (filed February 5, 2024). There have been no material changes to critical accounting estimates during the six nine months ended June 30, 2024 September 30, 2024.

Future Impact of Recently Issued Accounting Standards

See Note 1 to our Condensed Consolidated Financial Statements for a summary 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, 2023 (filed February 5, 2024). There have been no material changes to our market risks or to our management of such risks as of June 30, 2024 September 30, 2024.

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")) Act), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2024 September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information called for by this item is incorporated herein by reference to the information set forth in Note 11 to our Condensed Consolidated Financial Statements included in this report.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors. For purposes of this section (as well as this report in general), references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees; and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), unless otherwise stated or required by the context. In this section, we first provide a summary of the more significant risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Summary of Risk Factors

As noted above, we are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in this "Risk Factors" section. Please carefully consider all of the information in this Form 10-Q, including the full set of risks set forth in this "Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding Regeneron.

Commercialization Risks

- We are substantially dependent on the success of EYLEA, EYLEA HD, and Dupixent.
- Sales of our products are dependent on the availability and extent of coverage and reimbursement from third-party payors, including private payors and government programs such as Medicare and Medicaid.
- Product reimbursement and coverage policies and practices could change due to various factors such as drug price control measures that have been or may be enacted or introduced in the United States by various federal and state authorities.
- The commercial success of our products is subject to significant competition from products or product candidates that may be superior to, or more established or cost effective than, our products or product candidates.
- We and our collaborators on which we rely to commercialize some of our marketed products may be unable to continue to successfully commercialize or co-commercialize our products, both in 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, including EYLEA and EYLEA HD. 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' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales.

Other Regulatory and Litigation Risks

- If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.
- Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines.
- We face risks from the improper conduct of our employees, agents, contractors, or collaborators, including those relating to potential non-compliance with relevant laws and regulations such as the Foreign Corrupt Practices Act and the U.K. Bribery Act.
- Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials.
- Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

- Tax liabilities and risks associated with our operations outside 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 (such as the COVID-19 pandemic) 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 our ophthalmology portfolio, which consists of EYLEA and, since its August 2023 FDA approval, 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 six nine months ended June 30, 2024 September 30, 2024 and 2023, our aggregate EYLEA HD and EYLEA net product sales in the United States represented 44% 43% and 46% of our total revenues, respectively. For the six nine months ended June 30, 2024 September 30, 2024, EYLEA HD U.S. net product sales represented 17% 20% of our aggregate EYLEA HD and EYLEA U.S. net product sales. If we are successful in commercializing 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 six nine months ended June 30, 2024 September 30, 2024, EYLEA U.S. net product sales declined by 18% 21% and 17% 18%, respectively, compared to the same periods in 2023. In the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) expired on May 18, 2024. See "Risks Related to Intellectual Property and Market Exclusivity - *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*" below. As of the date of this report, three Several biosimilar versions of EYLEA had have been approved by the FDA. While no FDA, and one such biosimilar product has been launched is expected to launch in the United States to date, we face in the risk of lower near future. EYLEA and/or EYLEA HD net product sales when these or other recorded by us are likely to be negatively impacted by biosimilar versions of EYLEA are brought to market commercialized 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 increase in the future when 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. The degree to

which EYLEA HD net product sales may offset any further potential decrease in EYLEA net product sales, resulting from the factors discussed above or otherwise, is uncertain.

In addition, we are substantially dependent on our share of profits from the commercialization of Dupixent under our Antibody Collaboration with Sanofi. If we or Sanofi were to experience any difficulty with the commercialization of Dupixent or if we or Sanofi are unable to maintain current marketing approvals of Dupixent, we may experience a reduction in revenue and our business, prospects, operating results, and financial condition may be materially harmed.

If we or our collaborators are unable to continue to successfully commercialize our products, our business, prospects, operating results, and financial condition will be materially harmed.

We expect that the degree of commercial success of our marketed products will continue to depend on many factors, including the following (as applicable):

- effectiveness of the commercial strategy in and outside the United States for the marketing of our products, including pricing strategy;

- sufficient coverage of, and reimbursement for, our marketed products by third-party payors, including Medicare and Medicaid in the United States and other government and private payors in the United States and foreign jurisdictions, as well as U.S. and foreign payor restrictions on eligible patient populations and the reimbursement process (including drug price control measures that have been or may be enacted or introduced in the United States by various federal and state authorities);
- our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development; 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 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 11 to our Condensed Consolidated Financial Statements included in this report), as well as other risks relating to our marketed products and product candidates associated with intellectual property of other parties and pending or future litigation relating thereto (as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below);
- the outcome of the pending government proceedings and investigations and other matters described in Note 11 to our Condensed Consolidated Financial Statements included in this report (including the civil 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 where such products are approved. 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' 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 from third-party payors.

Sales of our marketed products in the United States are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies ("PBMs"), and government programs such as Medicare and Medicaid. Sales of our marketed products in other countries are also dependent, in large part, on complex coverage and reimbursement mechanisms and programs in those countries.

Our future revenues and profitability will be adversely affected in a material manner if such third-party payors do not adequately defray or reimburse the cost of our marketed products. If these entities do not provide coverage and reimbursement with respect to our marketed products or provide an insufficient level of coverage and reimbursement, such

products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payors cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payors more expensive for patients. Third-party payors may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and most of our product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply, and regulatory review of such products. Given cost sensitivities in many 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. 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 Libtayo, Dupixent, and any other products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected,*" we will need to manage these and other commercialization-related risks in order for us to successfully develop sufficient commercial capabilities outside the United States (including those necessary for our successful commercialization and co-commercialization of Libtayo and Dupixent, respectively).

Changes to product reimbursement and coverage policies and practices may materially harm 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. Some states have also enacted or are considering legislation to control the prices and reimbursement of prescription drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional 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 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, exceeds 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.

While enacted into law, it is currently unclear the The 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. future, is currently unclear.

At the state level, legislatures are becoming increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints,

discounts, restrictions on certain product access, and price and marketing cost disclosure and transparency measures. In some cases, these measures are designed to encourage importation from other countries and bulk purchasing. A reduction in the availability or extent of reimbursement from U.S. government programs (including as a result of the legislation, proposals, initiatives, and developments described above) could have a material adverse effect on the sales of EYLEA, EYLEA HD, or our other 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

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our competitors, regardless of their size, may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with other pharmaceutical or biotechnology companies. There is significant actual and potential future competition for each of our marketed products.

EYLEA and 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 biosimilar versions of Lucentis commercialized in the United States by Biogen Inc. and Sandoz Group AG. In addition, biosimilar versions of EYLEA have been approved both in and outside the United States. These include Amgen's Pavblu™ (aflibercept-ayyh), which is expected to launch in the United States in the near future. We expect that biosimilar competition for EYLEA will increase in the future when additional biosimilar versions of EYLEA are launched in additional countries (such as the United States), States and other countries, the timing of which will depend on, among other factors, the outcome of the pending patent litigation proceedings described in Note 11 to our Condensed Consolidated Financial Statements and the expiration of the patents protecting EYLEA (including those set forth under Part I - Item 1. "Business - Patents, Trademarks, and Trade Secrets" of Regeneron's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (filed February 5, 2024)). 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. In addition, we are aware of several other companies developing biosimilar versions of EYLEA, EYLEA HD, and/or other approved anti-VEGF treatments. Other potentially competitive products in development include products for use in combination with EYLEA and/or other anti-VEGF treatments, small-molecule tyrosine kinase inhibitors, gene therapies, and other eye-drop formulations, devices, and oral therapies. There also is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, even though ZALTRAP has not been manufactured and formulated for use in intravitreal injections. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye.

EYLEA HD was approved by the FDA in August 2023 for the treatment of wAMD, DME, and DR. As a newly approved product, EYLEA HD has entered the highly competitive environment described above. Our success in commercializing EYLEA HD will 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 or the method of administration), the safety and efficacy of EYLEA HD seen in a broader patient group (i.e., real-world use), the extent of payor coverage and reimbursement, 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. In atopic dermatitis, there are topical and 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 prurigo nodularis and in development for atopic dermatitis. In addition, a number of companies are developing antibodies against other targets, including IL-4Ra, IL-13Ra1, and/or OX40(L), that may compete with Dupixent in atopic dermatitis and other indications (including asthma and/or prurigo nodularis), as applicable. . In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or thymic stromal lymphopoietin ("TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP, EoE, and EoE. COPD. There are several other potentially competitive products in development that may compete with Dupixent in asthma, as well as COPD, and potential future indications, including

indications, including antibodies against the IL-33 ligand. 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), and AstraZeneca's Imfinzi® (durvalumab).

Other marketed products. There is also significant actual and potential future competition for other products marketed or otherwise commercialized by us and/or our collaborators under our collaboration agreements with them. For example, there are several companies that are marketing and/or developing antibodies or other molecules (such as small interfering RNA molecules, or siRNAs) against PCSK9, ANGPTL3 and IL-6 and/or IL-6R, which currently (or, for product candidates in development, may in the future if approved) compete with 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 products against targets that are also the targets of our early- and late-stage product candidates. We are also aware of other companies developing or marketing small molecules or other treatments that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our product candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

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

While we have established our own sales and marketing organization for EYLEA 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 will continue to rely in considerable part on Sanofi's sales and marketing organization in such jurisdictions.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. 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 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 or losses from the commercialization of these products under the relevant collaboration agreements and, therefore, our results of operations) may be reduced if the applicable product is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or otherwise alter the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions, (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA HD and EYLEA outside the United States is the responsibility of Bayer. Similarly, under our Antibody Collaboration with Sanofi, pricing and reimbursement for the products commercialized or co-commercialized thereunder outside the United States are the responsibility of Sanofi. Prices for our marketed products in jurisdictions outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United States. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations.

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

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

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

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

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

We sell our marketed products for which we record net product sales in the United States to several distributors and specialty pharmacies, as applicable (collectively, "distributor customers"), which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the six nine months ended June 30, 2024 September 30, 2024 and 2023, our product sales to two distributor customers accounted on a combined basis for 75% and 76% 77% 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

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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 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 Libtayo, Dupixent, and any other products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and have not yet fully established an organization for the sales, marketing, and distribution of marketed products outside the United States. We are in the process of establishing these capabilities outside the United States for Libtayo in connection with our 2022 entry into an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA") in 2022 whereby, all rights to develop, following a defined transition period, the Company will exclusively commercialize and manufacture Libtayo will be transferred exclusively to our Company, on a worldwide basis, over the course of a defined transition period. basis. In addition to fully establishing these commercial capabilities by the end of the transition period, we will also need to obtain and/or maintain regulatory approvals and secure pricing and reimbursement for Libtayo in many jurisdictions outside the United States (including Europe and Japan). Further, following the exercise of our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, we have established certain co-commercialization capabilities for Dupixent in

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

In order to commercialize or co-commercialize any products outside the United States beyond what we have done so far, we must build our sales, marketing, distribution, regulatory, managerial, and other capabilities in the relevant markets or make arrangements with third parties to perform these services, any of which will likely be expensive and time consuming and could delay product launch or the co-commercialization of a product in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop full commercial capabilities outside the United States (particularly as it relates to Libtayo, for which we plan to expand our global commercialization footprint as noted above) within an acceptable time frame, without incurring substantial expenses, or at all. These and other difficulties relating to commercializing our products outside the United States may harm our business, prospects, operating results, and financial condition.

Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products

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 any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. Additionally, in the United States, the FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that

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the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various

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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. While we recently reported results from an ongoing a confirmatory Phase 3 clinical trial of Dupixent in CSU (in biologic-naïve patients) are expected in late 2024, , there can be no assurance that such data will ultimately result in FDA or other regulatory approval. In addition, in April 2024, during its review As another example of our sBLA this type of risk, the FDA's request for Dupixent in COPD with type 2 inflammatory phenotype, the FDA requested that we provide additional analyses regarding sub-populations from the BOREAS and NOTUS pivotal studies. Following our submission of these additional analyses, the FDA determined that the additional information provided constituted a major amendment of the sBLA, thereby extending studies delayed by three months the target action date FDA's September 2024 approval of its review of the our sBLA for Dupixent in as an add-on maintenance treatment of adults with inadequately controlled COPD (from June 27, 2024 to September 27, 2024) pursuant to the applicable regulations. and an eosinophilic phenotype.

In certain instances (such as when we use a biomarker-based test to identify and enroll specific patients in a clinical trial), regulatory approval of a companion diagnostic to our therapeutic product candidate may be required as a condition to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of or product labeling updates for such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. The FDA has the explicit authority to require post-marketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies.

Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products. Obligations equivalent in scope, but which can vary widely in application, apply in 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 may be delayed because the FDA requests additional information or for other reasons, including those beyond our control. For example, in 2022, an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe delayed by nearly two months the FDA's approval of our sBLA for the combination treatment of Libtayo with chemotherapy in NSCLC.

If we believe we meet eligibility requirements, we may apply for various regulatory incentives in the United States, such as breakthrough therapy designation, fast track designation, accelerated approval, or priority review, where available, that serve to expedite drug development and/or review, and we may also seek similar designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits, and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by the FDA or other regulatory agencies. Even if obtained, such designations may not result in faster development processes, reviews, or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meets the conditions for a beneficial regulatory designation (including due to factors beyond our control, such as intervening competitive developments) or decide that the time period for FDA review or approval will not be shortened. 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

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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.

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 present a be challenging environment 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. For example, in June 2023, the FDA issued a CRL concerning the Company's BLA for EYLEA HD for the treatment of wAMD, DME, and DR due to unresolved observations resulting from an inspection at a third-party fill/finish provider, which resulted in a delay of the FDA approval of EYLEA HD by nearly two months. See also Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview – Additional Information - Clinical Development Programs – Linvoseltamab." Similarly, in August 2024, the FDA issued a CRL concerning the Company's BLA for linvoseltamab in relapsed/refractory multiple myeloma due to findings from a pre-approval inspection at a third-party fill/finish provider for another company's product candidate. For additional information, see "Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product*

candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales." Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

We are also subject to ongoing requirements imposed by the FDA and comparable foreign regulatory authorities governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping, and reporting of safety and other post-marketing information. The holder of an approved BLA or foreign equivalent is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA or foreign equivalent must also submit new or supplemental applications and obtain FDA 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; this will be the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) once we complete the full transition from Sanofi pursuant to 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

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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 MAA in the EU. In addition, such authorities often have the authority to require post-approval studies, such as a post-authorization safety study

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("PASS") and/or post-authorization efficacy study ("PAES"), which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in 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 the FDA's Good Laboratory Practice requirements ("GLPs") or GCPs. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

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

Many of our clinical trials are conducted under the oversight of 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 clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after

investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

With respect to EYLEA and 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 to successfully commercialize 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. EYLEA HD is being studied in patients with RVO, as shown in the table under Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview - Programs in Clinical Development." There is no guarantee that regulatory approval of EYLEA HD in this indication will be successfully obtained. 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 regulatory approval of Dupixent or Libtayo (as applicable) in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include hypersensitivity reactions, eye problems (including conjunctivitis and keratitis), injection-site reactions, eye and eyelid inflammation, cold sores, oropharyngeal pain, eosinophilia, insomnia, toothache, gastritis, joint pain (arthralgia), parasitic (helminth) infections, and facial rash or redness; and the side effects previously reported for Libtayo include certain immune-mediated adverse reactions that may occur in any organ system or tissue, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea. These and other complications or side effects could harm further development and/or commercialization of Dupixent and Libtayo (as applicable).

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

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 EYLEA HD may in the future be approved in the 8mg pre-filled syringe. The success of our products and product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application and the additional risks resulting from a product candidate's designation as a combination

product discussed below, our product candidates used with such drug-delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. The FDA review process and criteria for such applications are not well established, which could also lead to

delays in the approval process. In addition, some of these drug-delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply and manufacture the devices; to conduct the studies and prepare related documentation required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. In addition, other parties may allege that our drug-delivery devices infringe patents or other intellectual property rights. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as described in Note 11 to our Condensed Consolidated Financial Statements. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our Company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product or product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply and manufacture these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic, or device. The determination whether a product is a combination product or two separately regulated products is made by the FDA on a case-by-case basis. Although a single marketing application is generally sufficient for the approval, clearance, or licensure of a combination product, the FDA may determine that separate marketing applications are necessary. In addition, submitting separate marketing applications may be necessary to receive some benefit that accrues only from approval under a particular type of application. This could significantly increase the resources and time required to bring a particular combination product to market.

Risks Related to Intellectual Property and Market Exclusivity

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

If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements and other means. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it could help our competitors and adversely affect our business. Our ability to protect our trade secrets may be impaired by a number of risks and uncertainties, including those discussed under "Other Regulatory and Litigation Risks - *Increasing use of social media and artificial intelligence-based platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage*" and "Other Risks Related to Our Business - *Significant disruptions of information technology systems or breaches of data security could adversely affect our business*" below. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our Company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. For example, certain of our U.S. patents (including those pertaining to our key products, such as EYLEA) have been and may in the future be challenged by parties who file a request for post-grant review or *inter partes* review under the America Invents Act of 2011 or *ex parte* reexamination, as further described in Note 11 to our Condensed Consolidated Financial Statements included in this report. Post-grant proceedings are increasingly common in the United States and are costly to defend. In addition, patent applications filed outside the United States may be challenged by other parties, for example, by filing pre-grant third-party observations that argue against patentability or a post-grant opposition. Such opposition proceedings are increasingly common in Europe and are costly to defend. For example, in 2021, anonymous parties initiated opposition proceedings in the European Patent Office ("EPO") against our European Patent No. 2,944,306 (which concerns pre-filled syringes comprising ophthalmic formulations containing VEGF antagonists such as aflibercept for intravitreal administration), as further described in Note 11 to our Condensed Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (the "USPTO"), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions or our ability to obtain, maintain, and enforce our intellectual property rights. Any such changes could

also affect the value of our intellectual property or narrow the scope of our patents. We cannot be certain that our intellectual property rights related to any current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such change or other rulemaking.

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

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

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

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

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we are currently party to patent infringement and other proceedings relating to EYLEA, as described in Note 11 to our Condensed Consolidated Financial Statements.

We are aware of patents and pending patent applications owned by others that claim compositions and methods of treatment relating to targets and conditions that we are also pursuing with our products and/or product candidates. Although we do not believe that any of our products or our late-stage 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

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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 have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. Biosimilar versions of EYLEA have been recently approved 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. In the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product could be approved by the FDA) expired on May 18, 2024. While no Following the anticipated near-term launch of biosimilar versions of competition to EYLEA have been launched in the United States to date, when these or other biosimilar versions of EYLEA start to be marketed in the United States, we will no longer benefit from U.S. market exclusivity for EYLEA. 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

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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 Any future loss of market exclusivity for a product (such as EYLEA or EYLEA HD) would likely

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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 may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. As we increase our production in anticipation of potential regulatory approval for our product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. The

COVID-19 pandemic has exacerbated, and 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 and may in the future include, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products 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 and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity and establishing fill/finish capabilities 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 (refer to Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for information about expected capital expenditures relating to this and other projects). In addition, we may need to develop or acquire additional manufacturing capabilities to the extent we or our collaborators pursue the development of drugs generated by means other than our existing "Trap" or *VelociSuite*® technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill/finish activities. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities and any future fill/finish activities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or

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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

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products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, and it could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

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

Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future (including our ability to conduct any fill/finish activities in the future), the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as further described in Note 11 to our Condensed Consolidated Financial Statements. A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of our marketed products do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.

We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing or otherwise authorized for use. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we or our collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results. For example, during each of the years ended December 31, 2022 and 2021, we recorded a charge to write down inventory related to REGEN-COV.

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

Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborators' facilities. We and our collaborators would be unable to manufacture these materials if the relevant facility were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, supply chain interruptions or constraints (including with respect to natural gas and other raw materials), contaminations, fire, climate change, natural disasters, acts of war or terrorism, or other problems.

Many of our products and product candidates are very difficult to manufacture. As our products and most of our product candidates are biologics, they require processing steps that are more difficult than those required for many other chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us or our collaborators in a timely manner), 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 the COVID-19 pandemic and the armed conflict between Russia and Ukraine, which have exacerbated many of these issues, or other public health outbreaks, epidemics, or pandemics or geopolitical developments). 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 if the recently proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted or if other trade restrictions were to be imposed. 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 are required to substitute for these sources to comply with such regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales.

We and our collaborators and other third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. Recently, the FDA issued CRLs to multiple companies (including us, as further discussed below) 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 and third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of our collaborators or other third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition. For example, in June 2023, the FDA issued a CRL concerning the Company's BLA for EYLEA HD for the treatment of wAMD, DME, and DR due to unresolved observations resulting from an inspection at a third-party fill/finish provider, which resulted in a delay of the FDA approval of EYLEA HD by nearly two months. See also Similarly, in August 2024, the FDA issued a CRL concerning the Company's BLA for linvoseltamab in relapsed/refractory multiple myeloma due to findings from a pre-approval inspection at a third-party fill/finish provider for another company's product candidate. Refer to Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations – - Overview – - Additional Information - Clinical Development Programs – Linvoseltamab." Programs" for more information. Significant noncompliance with the requirements discussed in this paragraph could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

Other Regulatory and Litigation Risks

If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We have previously been subject to, and may also in the future be subject to, claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.

The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA's review of promotional activities includes healthcare provider-directed and direct-to-consumer advertising, certain communications regarding unapproved uses, industry-sponsored scientific and educational activities, and sales representatives' communications. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the U.S. Department of Health and Human Services ("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 Bipartisan Budget Act of 2018 has increased the criminal and civil penalties that can be imposed for violating certain federal healthcare laws, including the federal anti-kickback statute.

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

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, damages, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment for individuals and the curtailment or restructuring of

operations. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which

would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws. As described further in Note 11 to our Condensed Consolidated Financial Statements included in this report, we are party to civil 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; and we are cooperating with other pending government investigations. Any adverse decision, finding, allegation, or exercise of enforcement or regulatory discretion in any such proceedings or investigations could harm our business, prospects, operating results, and financial condition.

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

We continue to dedicate significant resources to comply with these requirements and need to be prepared to comply with additional reporting obligations outside the United States. In addition, several states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities; restrict when pharmaceutical companies may provide meals or gifts to prescribers or engage in other marketing-related activities; require identification or licensing of sales representatives; and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

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

We participate in the Medicaid Drug Rebate program, the Public Health Service's 340B 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.

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 financial results. The final regulation In September 2024, CMS modified the regulations governing the Medicaid Drug Rebate program issued by CMS has increased and will continue to Program, which could further increase our costs and the complexity of compliance, has been impact rebate liabilities, and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we have taken in our implementation of the final regulation. 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. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. Moreover, HRSA established an ADR process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. . 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, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

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

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

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

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

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

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, intellectual property rights, and the framework for dispute resolution and asserting our rights against others, are subject to extensive legislation and regulation. Changes in applicable U.S. federal, state, and foreign laws and agency regulations 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 (such as those discussed above under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *Changes to product reimbursement and coverage policies and practices may materially harm our business, prospects, operating results, and financial condition*") or the PPACA or other healthcare reform laws. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our products could adversely affect our business. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could materially and adversely affect our business.

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

We have operations and conduct business in 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 are in the process of establishing commercial capabilities related to Libtayo in many jurisdictions outside the United States following our entry into 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, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

We have large-scale manufacturing operations in Limerick, Ireland and have also established offices in the United Kingdom, Germany, 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 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 could materially adversely impact our effective tax rate or cash flows.

We face risks related to the personal data we collect, process, and share.

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

We have operations and conduct business in several countries outside the United States and plan to significantly expand 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*." These activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws, including the EU's General Data Protection Regulations ("GDPR"). The GDPR has a wide range of compliance obligations, including increased consent and transparency requirements and data subject rights. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher)). In addition to the GDPR, certain EU Member States have issued or will be issuing their own implementation legislation. In 2021, the EC introduced new standard contractual clauses required to be incorporated into certain new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside the EU. Many of the countries that have comprehensive data privacy laws have modeled their requirements after the GDPR. Compliance with these requirements has been and is expected to continue to be costly and time consuming.

We conduct clinical trials in many countries around the world, which have new or evolving data privacy laws that are often not interpreted consistently by regulatory authorities, institutional review boards/ethics committees, or clinical trial sites. This complexity has resulted in increased liability in the management of clinical trial data, as well as additional

compliance, contractual, and due-diligence obligations that could lead to a delay in clinical trial site start-up. There also has been an increase of enforcement activities in various EU countries that require evidence of compliance with local data privacy requirements. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving privacy and data protection laws. Complying with varying jurisdictional requirements could increase the costs and complexity of compliance, including the risk of substantial financial penalties for insufficient notice and consent, failure to respond to data subject rights requests, lack of a legal basis for the transfer of personal information out of the EU or other countries with localization laws (i.e., laws mandating that personal data collected in a foreign country be processed and stored within that country), or improper processing of personal data. Failure by us or our collaborators to comply with the strict rules on the transfer of personal data into the U.S. could result in the imposition of criminal and administrative sanctions on us or such collaborators or impact the flow of personal data, which could adversely affect our business.

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"). For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with many research institutions that are subject to 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 PHI protected health information ("PHI") in a manner that is not permitted under HIPAA. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive PHI from a healthcare provider or research institution that has not satisfied HIPAA's requirements for its disclosure. There are instances where we collect and maintain personal data, which may include health information that is outside the scope of HIPAA but within the scope of state health privacy laws or similar state level privacy legislation. This information may be received throughout the clinical trial process, in the course of our research collaborations, directly from individuals who enroll in our patient assistance programs, and from our own employees in a pandemic response process (such as in connection with the COVID-19 pandemic).

Consumer protection laws impact the manner in which we develop and maintain processes to support our patient assistance programs, product marketing activities, and the sharing of employee and clinical data for internal and third-party commercial activities. Several U.S. states have proposed and passed consumer privacy laws, which were modeled after the California Consumer Privacy Act of 2018 ("CCPA") and influenced by the GDPR. The CCPA is a consumer protection law that establishes requirements for data use and sharing transparency and provides California residents with personal data privacy rights regarding the use, disclosure, and retention of their personal data. Amendments to the CCPA have, among other things, imposed new obligations to provide notice where personal data will be de-identified. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. These laws and regulations are constantly evolving and may impose limitations on our business activities. Several additional state consumer privacy laws recently went into effect and many other consumer privacy laws are expected to go into effect in the near future. Notably, these state laws provide more restrictions on the use of sensitive personal data, including health information. These states require robust consent and authorizations prior to any collection or use of this data, which may have a large impact on our ability to market to individuals in these jurisdictions based on their health conditions. At the federal level, Section 5 of the FTC Act is a consumer protection law that bars unfair and deceptive acts and practices and requires, among other things, companies to notify individuals that they will safeguard their personal data and that they will fulfil the commitments made in their privacy notices. The FTC has brought legal actions against organizations that have violated consumers' privacy rights or have misled them by failing to maintain appropriate security. For example, in 2023 recent years the FTC has issued several enforcement actions related to privacy in the healthcare space, under both Section 5 of the FTC Act and the Health Breach Notification Rule, involving companies allegedly using consumer health data for marketing purposes in violation of their own policies and assurances.

Furthermore, health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws may apply directly 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. Individuals about whom we or our collaborators obtain health or other personal data, as well as the providers and third parties who share this data with us, may have statutory or contractual limits that impact our ability to further use and disclose the data. Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. Compliance with these laws requires a flexible privacy framework as they are constantly evolving. Federal regulators, state attorneys general, and plaintiffs' attorneys have been active in this space.

If we or any collaborators fail to comply with applicable federal, state, local, or foreign regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products. Any threatened or actual government enforcement action could also generate adverse publicity and could result in additional regulatory oversight.

Increasing use of social media and artificial intelligence-based platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is a risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal data of our employees, clinical trial participants, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Additionally, artificial intelligence ("AI")-based solutions, including generative AI, are increasingly being used in the biopharmaceutical industry (including by us). The use of AI solutions by our employees or third parties on which we rely may continue to increase and may lead to the public disclosure of confidential information (including personal data and proprietary information) in contravention of our internal policies, data protection laws, other applicable laws, or contractual requirements. The misuse of AI solutions 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. 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 Libtayo, Dupixent, and any other products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" 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 heavily 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 Libtayo, Dupixent, and any other products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" 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, such as due to the armed conflict between Russia and Ukraine) or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates. See also

"Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales.*"

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

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

We may acquire companies, businesses, products, or product candidates that complement or augment our existing business. For example, in May 2022 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 President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. These systems are also critical to enable remote working arrangements, which have been growing in importance. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses and ransomware, which may impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches – whether by employees or others – which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property, result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage or extortion) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks and incidents. For example, in the

past we have experienced, and expect to continue to experience, 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, 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, including in connection with the current Russia-Ukraine or Hamas-Israel armed conflict.

Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, and to oversee and monitor the security measures of our suppliers and/or service providers, there can be no assurance that our efforts will prevent service interruptions or security breaches. In addition, we depend in part on third-party security measures over which we do not have full control to protect against data security breaches.

If we or our suppliers and/or service providers fail to maintain or protect our information technology systems and data security effectively and in compliance with U.S. and foreign laws, or fail to anticipate, plan for, or manage significant disruptions to these systems, we or our suppliers and/or service providers could have difficulty preventing, detecting, or controlling such disruptions or security breaches, which could result in legal proceedings, liability under U.S. and foreign laws that protect the

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

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

The COVID-19 pandemic previously adversely affected, and the COVID-19 pandemic or other actual or threatened public health outbreaks, epidemics, or pandemics may in the future adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate; our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, and business partners and customers; and the demand for our marketed products.

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 June 30, 2024 September 30, 2024, we had an aggregate of $2.704 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 June 30, 2024 September 30, 2024, we had $1.921 billion $2.012 billion in cash and cash equivalents and $15.611 billion $16.276 billion in marketable securities (including $1.174 billion $1.308 billion in equity securities). Our investments consist primarily of debt securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- net product sales of our marketed products (as recorded by us or our collaborators), in particular EYLEA HD, EYLEA, Dupixent, and Libtayo, as well as our overall operating results;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and the market share for, our marketed products, especially EYLEA 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; 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, 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;
- general market conditions;
- impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

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

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our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of

volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of June 30, 2024 September 30, 2024, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.4% 39.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2024 September 30, 2024. If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

There can be no assurance that we will repurchase shares of our Common Stock or that we will repurchase shares at favorable prices.

In January 2023, April 2024, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion $3.0 billion of our Common Stock and, in April 2024, authorized an additional $3.0 billion for share repurchases (of which an aggregate of $3.631 billion $2.893 billion remained available as of June 30, 2024 September 30, 2024). There can be no assurance of any future share repurchases or share repurchase program authorizations. Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, if at all.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of June 30, 2024 September 30, 2024, holders of Class A Stock held 14.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to substantially influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of June 30, 2024 September 30, 2024:

- our current executive officers and directors beneficially owned 5.4% 5.3% 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 June 30, 2024 September 30, 2024, and 17.1% 17.0% 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 June 30, 2024 September 30, 2024; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.4% 39.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of June 30, 2024 September 30, 2024. In addition, these five shareholders plus our Chief Executive Officer held approximately 46.5% 46.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of June 30, 2024 September 30, 2024.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements, could deter, delay, or prevent an acquisition or other "change of control" of us and could adversely affect the price of our Common Stock.

Our certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our Company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual shareholder meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our Company and an "interested shareholder," a plan of merger or consolidation of our Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "*Our existing shareholders may be able to exert substantial influence over matters requiring shareholder approval and over our management.*"

Further, certain of our 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 June 30, 2024 September 30, 2024. 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	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)*	Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs *(In millions)*
4/1/2024–4/30/2024										
5/1/2024–5/31/2024										
6/1/2024–6/30/2024										
7/1/2024–7/31/2024										
8/1/2024–8/31/2024										
9/1/2024–9/30/2024										
Total										

(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.

(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.

(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 As disclosed in the table below, during the three months ended June 30, 2024 September 30, 2024, no director certain of our directors and/or executive officer officers adopted modified, or terminated any plans for trading arrangement arrangements intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

Name	Position	Date of Plan Adoption	Scheduled End Date of Trading Arrangement(a)	Total Number of Securities to Be Sold Under the Plan
Joseph L. Goldstein, M.D.	Director	8/7/2024	2/7/2025	1,929
Jason Pitofsky	Vice President, Controller	8/7/2024	5/10/2025	3,791
Arthur F. Ryan	Director	8/3/2024	10/31/2025	1,200

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

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
10.1*	Amendment No. 3 to Master Agreement, dated as of August 1, 2024, by and between Regeneron Pharmaceuticals, Inc. and Alnylam Pharmaceuticals, Inc.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the registrant's Condensed Consolidated Balance Sheets as of June 30, 2024 September 30, 2024 and December 31, 2023; (ii) the registrant's Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six nine months ended June 30, 2024 September 30, 2024 and 2023; (iii) the registrant's Condensed Consolidated Statements of Stockholders' Equity for the three and six nine months ended June 30, 2024 September 30, 2024 and 2023; (iv) the registrant's Condensed Consolidated Statements of Cash Flows for the six nine months ended June 30, 2024 September 30, 2024 and 2023; and (v) the notes to the registrant's Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

SIGNATURES

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

REGENERON PHARMACEUTICALS, INC.

Date: August 1, October 31, 2024

By: /s/ Christopher Fenimore

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

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Exhibit 10.1

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

Amendment No. 3
to the Master Agreement

This Amendment No. 3 ("**Amendment No. 3**") to the Master Agreement is entered into and effective as of August 1, 2024 ("**Amendment No. 3 Effective Date**") by and between Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York ("**Regeneron**"), and Alnylam Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("**Alnylam**"). All capitalized terms not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

Recitals

WHEREAS, Regeneron and Alnylam are parties to that certain Master Agreement dated April 8, 2019 ("**Master Agreement**") as amended by Amendment No. 1 to the Master Agreement dated April 10, 2023 ("**Amendment No. 1**") and Amendment No. 2 to the Master Agreement dated March 7, 2024 **("Amendment No. 2")** (the Master Agreement, together with Amendments No. 1 and No. 2, the "**Agreement**");

WHEREAS, the Parties now wish to further amend the Agreement to enable the conduct of certain technology development activities related to the generation and evaluation of [**] and to clarify certain terms:

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

1. **Defined Terms:** The following new defined term is hereby added to Article 1 of the Agreement, effective as of the Effective Date of the Agreement:

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

2. The Parties hereby agree that Sections 3.2.3(f)(ii) and (iii) of the Agreement are hereby restated and amended and new Sections 3.2.3(f)(iv) and 3.2.3(f)(v) are hereby added to the Agreement, effective as of the Effective Date of the Agreement:

3.2.3(f) (ii) The Parties agree to conduct certain technology development activities related to formulation and the evaluation of [**] in accordance with the mutually agreed research plan attached as Schedule 1.275 to Amendment No. 1 (the "**[**] Research Plan**"). The [**] Research Plan may be updated or amended by mutual written agreement of the Parties (via the JSC and reflected in the JSC meeting minutes) from time to time. In the event of any dispute between the Parties related to an update or

amendment to the [**] Research Plan, then such dispute will be deemed to be a Deadlocked Dispute and resolved in accordance with Section 2.2.3(a)(ii). Under the [**] Research Plan, Alnylam will provide the siRNAs for the activities under the workplan. For clarity, the [**] Research Plan is not part of the [**] Development Plan.

(iii) The Parties agree to conduct certain technology development activities related to the generation and evaluation of [**], in accordance with the mutually agreed research plan attached hereto as Schedule 1.278 (the "**[**] Research Plan**"). Each Party will provide [**] updates on such Party's Technology Development Activities under the [**] Research Plan to the JSC. The [**] Research Plan may be updated or amended by

mutual written agreement of the Parties (via the JSC and reflected in the JSC meeting minutes) from time to time. In the event of any dispute between the Parties related to an update or amendment to the [**] Research Plan, then such dispute will be deemed to be a Deadlocked Dispute and resolved in accordance with Section 2.2.3(a)(ii). Under the [**] Research Plan**,** Regeneron will provide one or more antibody ligand(s) and Alnylam will provide siRNAs for the activities under the workplan. For clarity, the [**] Research Plan is not part of the [**] Development Plan.

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

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

3. The Parties hereby agree that Sections 5.1.5 and 5.2.3 of the Agreement are hereby restated and amended, effective as of the Effective Date of the Agreement:

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

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

4. Except as specifically amended herein, all other terms of the Agreement shall remain in full force and effect. The Parties may execute this Amendment No. 3 in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement. This Amendment No. 3 may be executed or delivered electronically or by facsimile transmission, and the Parties hereby agree that any electronic or facsimile signatures hereto are legal, valid and enforceable as originals.

[*signatures follow*]

THIS AMENDMENT NO. 3 IS EXECUTED by the authorized representatives of the Parties as of the Amendment No. 3 Effective Date.

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Jeff Poulton

Name: Jeff Poulton
Title: Chief Financial Officer

REGENERON PHARMACEUTICALS, INC.

By: /s/ Kerry Reinertsen

Name: Kerry Reinertsen
Title: SVP Strategic Alliances

Schedule 1.278
[**] Research Plan

[**]

Exhibit 31.1

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

I, Leonard S. Schleifer, certify that:

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

Date: August 1, October 31, 2024

/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: August 1, October 31, 2024

/s/ Christopher Fenimore
Christopher Fenimore
Senior Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

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

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2024 September 30, 2024 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)

August 1, October 31, 2024

/s/ Christopher Fenimore

Christopher Fenimore

Senior Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

August 1, October 31, 2024

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