UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2023

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

Indiana	35-0470950
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Lilly Corporate Center, Indianapolis, Indiana 46285
(Address and zip code of principal executive offices)

Registrant's telephone number, including area code (317) 276-2000

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

Title of Each Class	Trading Symbols	Name of Each Exchange On Which Registered
Common Stock (no par value)	LLY	New York Stock Exchange
7 1/8% Notes due 2025	LLY25	New York Stock Exchange
1.625% Notes due 2026	LLY26	New York Stock Exchange
2.125% Notes due 2030	LLY30	New York Stock Exchange
0.625% Notes due 2031	LLY31	New York Stock Exchange
0.500% Notes due 2033	LLY33	New York Stock Exchange
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.625% Notes due 2043	LLY43	New York Stock Exchange
1.700% Notes due 2049	LLY49A	New York Stock Exchange
1.125% Notes due 2051	LLY51	New York Stock Exchange
1.375% Notes due 2061	LLY61	New York Stock Exchange

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 of common stock outstanding as of October 30, 2023:

Class	Number of Shares Outstanding
Common	949,307,237

Eli Lilly and Company

Form 10-Q
For the Quarter Ended September 30, 2023

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Forward-Looking Statements

This Quarterly Report on Form 10-Q and our other publicly available documents include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act), and are subject to the safe harbor created thereby under the Private Securities Litigation Reform Act of 1995. In particular, information appearing under "Management's Discussion and Analysis of Results of Operations and Financial Condition" includes forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts, and generally can be identified by the use of words such as "may," "believe," "will," "expect," "project," "estimate," "intend," "anticipate," "plan," "continue," or similar expressions or future or conditional verbs.

Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those expressed in forward-looking statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. Investors therefore should not place undue reliance on forward-looking statements. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- the significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals;
- the impact and outcome of acquisitions and business development transactions and related costs;
- the expiration of intellectual property protection for certain of our products and competition from generic and/or biosimilar products;
- our ability to protect and enforce patents and other intellectual property;
- changes in patent law or regulations related to data package exclusivity;
- competitive developments affecting current products and our pipeline;
- market uptake of recently launched products;
- information technology system inadequacies, breaches, or operating failures;
- unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in our information technology systems, networks, and facilities, or those of third parties with whom we share our data;
- the impact of global macroeconomic conditions, trade disruptions, disputes, unrest, war, regional dependencies, or other costs, uncertainties and risks related to engaging in business globally;
- unexpected safety or efficacy concerns associated with our products;
- litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as we are largely self-insured;
- issues with product supply and regulatory approvals stemming from manufacturing difficulties, disruptions, or shortages, including as a result of unpredictability and variability in demand, labor shortages, third-party performance, quality, or regulatory actions related to our facilities;
- dependence on certain products for a significant percentage of our total revenue and an increasingly consolidated supply chain;
- reliance on third-party relationships and outsourcing arrangements;
- the impact of public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic;
- regulatory changes or other developments;
- regulatory actions regarding operations and products;
- continued pricing pressures and the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- devaluations in foreign currency exchange rates or changes in interest rates and inflation;
- changes in tax law, tax rates, or events that differ from our assumptions related to tax positions;
- asset impairments and restructuring charges;
- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC);
- regulatory compliance problems or government investigations; and
- actual or perceived deviation from environmental-, social-, or governance-related requirements or expectations.

More information on factors that could cause actual results or events to differ materially from those anticipated is included from time to time in our reports filed with the SEC, including in our Annual Report on Form 10-K for the year ended December 31, 2022, particularly under the caption "Risk Factors." Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and under Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K to be a complete statement of all potential risks and uncertainties.

All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are expressly qualified in their entirety by the cautionary statements included in or incorporated by reference into this Quarterly Report on Form 10-Q. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this Quarterly Report on Form 10-Q.

PART I. Financial Information

Item 1. Financial Statements

Consolidated Condensed Statements of Operations
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars and shares in millions, except per-share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue (Note 2)	**$ 9,498.6**	$ 6,941.6	**$ 24,770.7**	$ 21,239.6
Costs, expenses, and other:				
Cost of sales	**1,860.1**	1,579.1	**5,294.2**	5,081.7
Research and development	**2,409.1**	1,802.9	**6,750.7**	5,194.9
Marketing, selling, and administrative	**1,803.9**	1,614.2	**5,478.5**	4,797.2
Acquired in-process research and development (Note 3)	**2,975.1**	62.4	**3,177.2**	668.4
Asset impairment, restructuring, and other special charges (Note 5)	**—**	206.5	**—**	206.5
Other–net, (income) expense (Note 11)	**23.2**	111.0	**24.3**	580.9
	9,071.4	5,376.1	**20,724.9**	16,529.6
Income before income taxes	**427.2**	1,565.5	**4,045.8**	4,710.0
Income taxes (Note 7)	**484.6**	113.8	**995.1**	402.9
Net income (loss)	**$ (57.4)**	$ 1,451.7	**$ 3,050.7**	$ 4,307.1
Earnings (loss) per share:				
Basic	**$ (0.06)**	$ 1.61	**$ 3.39**	$ 4.78
Diluted	**$ (0.06)**	$ 1.61	**$ 3.38**	$ 4.76
Shares used in calculation of earnings (loss) per share:				
Basic	**899.8**	900.7	**900.2**	901.8
Diluted	**899.8**	903.8	**903.1**	904.5

See notes to consolidated condensed financial statements.

Consolidated Condensed Statements of Comprehensive Income (Loss)
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net income (loss)	**$ (57.4)**	$ 1,451.7	**$ 3,050.7**	$ 4,307.1
Other comprehensive income (loss), net of tax (Note 10)	**3.8**	(8.1)	**59.7**	47.3
Comprehensive income (loss)	**$ (53.6)**	$ 1,443.6	**$ 3,110.4**	$ 4,354.4

See notes to consolidated condensed financial statements.

Consolidated Condensed Balance Sheets
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	September 30, 2023	December 31, 2022
Assets	**(Unaudited)**	
Current Assets		
Cash and cash equivalents (Note 6)	**$ 2,380.8**	$ 2,067.0
Short-term investments (Note 6)	**113.1**	144.8
Accounts receivable, net of allowances of **$13.4 (2023)** and $16.0 (2022)	**8,167.1**	6,896.0
Other receivables	**2,196.7**	1,662.9
Inventories	**4,901.4**	4,309.7
Prepaid expenses and other current assets	**5,247.9**	2,954.1
Total current assets	**23,007.0**	18,034.5
Investments (Note 6)	**2,691.7**	2,901.8
Goodwill	**4,085.2**	4,073.0
Other intangibles, net	**6,781.7**	7,206.6
Deferred tax assets	**4,574.8**	2,792.9
Property and equipment, net of accumulated depreciation of **$10,767.8 (2023)** and $10,233.4 (2022)	**11,863.2**	10,144.0
Other noncurrent assets	**4,911.9**	4,337.0
Total assets	**$ 57,915.5**	$ 49,489.8
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	**$ 2,244.7**	$ 1,501.1
Accounts payable	**2,435.1**	1,930.6
Employee compensation	**1,233.2**	1,059.8
Sales rebates and discounts	**11,522.3**	8,784.1
Dividends payable	**—**	1,017.2
Income taxes payable	**1,977.5**	475.1
Other current liabilities	**2,585.4**	2,370.3
Total current liabilities	**21,998.2**	17,138.2
Other Liabilities		
Long-term debt	**17,923.6**	14,737.5
Accrued retirement benefits (Note 8)	**1,311.9**	1,305.1
Long-term income taxes payable	**3,468.3**	3,709.6
Other noncurrent liabilities	**1,906.1**	1,824.0
Total other liabilities	**24,609.9**	21,576.2
Commitments and Contingencies (Note 9)		
Eli Lilly and Company Shareholders' Equity		
Common stock	**593.6**	594.1
Additional paid-in capital	**7,160.0**	6,921.4
Retained earnings	**10,309.9**	10,042.6
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 10)	**(3,784.9)**	(3,844.6)
Cost of common stock in treasury	**(45.0)**	(50.5)
Total Eli Lilly and Company shareholders' equity	**11,220.4**	10,649.8
Noncontrolling interests	**87.0**	125.6
Total equity	**11,307.4**	10,775.4
Total liabilities and equity	**$ 57,915.5**	$ 49,489.8

See notes to consolidated condensed financial statements.

Consolidated Condensed Statements of Equity
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions, except per-share data, and shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interests
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury[1]		
	Shares	Amount					Shares	Amount	
Balance at July 1, 2022	950,619	$ 594.1	$ 6,746.0	$ 8,556.0	$ (3,013.2)	$ (4,287.7)	450	$ (50.5)	$ 114.5
Net income (loss)				1,451.7					(15.7)
Other comprehensive loss, net of tax						(8.1)			
Issuance of stock under employee stock plans, net	8		(2.1)						
Stock-based compensation			85.1						
Other				(1.2)					(3.0)
Balance at September 30, 2022	950,627	$ 594.1	$ 6,829.0	$ 10,006.5	$ (3,013.2)	$ (4,295.8)	450	$ (50.5)	$ 95.8
Balance at July 1, 2023	**949,688**	**$ 593.6**	**$ 6,948.6**	**$ 10,368.5**	**$ (3,013.2)**	**$ (3,788.7)**	**402**	**$ (45.0)**	**$ 85.5**
Net income (loss)				**(57.4)**					**4.1**
Other comprehensive income, net of tax						**3.8**			
Issuance of stock under employee stock plans, net	**17**		**(4.2)**						
Stock-based compensation			**215.6**						
Other				**(1.2)**					**(2.6)**
Balance at September 30, 2023	**949,705**	**$ 593.6**	**$ 7,160.0**	**$ 10,309.9**	**$ (3,013.2)**	**$ (3,784.9)**	**402**	**$ (45.0)**	**$ 87.0**

[1] As of September 30, 2023, there was $2.50 billion remaining under our $5.00 billion share repurchase program authorized in May 2021.

See notes to consolidated condensed financial statements.

(Dollars in millions, except per-share data, and shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interests
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury[1]		
	Shares	Amount					Shares	Amount	
Balance at January 1, 2022	954,116	$ 596.3	$ 6,833.4	$ 8,958.5	$ (3,013.2)	$ (4,343.1)	463	$ (52.7)	$ 175.6
Net income (loss)				4,307.1					(63.7)
Other comprehensive income, net of tax						47.3			
Cash dividends declared per share: $1.96				(1,765.9)					
Retirement of treasury shares	(5,607)	(3.5)		(1,496.5)			(5,607)	1,500.0	
Purchase of treasury shares							5,607	(1,500.0)	
Issuance of stock under employee stock plans, net	2,118	1.3	(282.6)				(13)	2.2	
Stock-based compensation			278.2						
Other				3.3					(16.1)
Balance at September 30, 2022	950,627	$ 594.1	$ 6,829.0	$ 10,006.5	$ (3,013.2)	$ (4,295.8)	450	$ (50.5)	$ 95.8
Balance at January 1, 2023	**950,632**	**$ 594.1**	**$ 6,921.4**	**$ 10,042.6**	**$ (3,013.2)**	**$ (3,844.6)**	**450**	**$ (50.5)**	**$ 125.6**
Net income				**3,050.7**					**4.6**
Other comprehensive income, net of tax						**59.7**			
Cash dividends declared per share: $2.26				**(2,034.0)**					
Retirement of treasury shares	**(2,299)**	**(1.4)**		**(748.6)**			**(2,299)**	**750.0**	
Purchase of treasury shares							**2,299**	**(750.0)**	
Issuance of stock under employee stock plans, net	**1,372**	**0.9**	**(269.7)**				**(48)**	**8.8**	
Stock-based compensation			**508.3**						
Other				**(0.8)**				**(3.3)**	**(43.2)**
Balance at September 30, 2023	**949,705**	**$ 593.6**	**$ 7,160.0**	**$ 10,309.9**	**$ (3,013.2)**	**$ (3,784.9)**	**402**	**$ (45.0)**	**$ 87.0**

[1] As of September 30, 2023, there was $2.50 billion remaining under our $5.00 billion share repurchase program authorized in May 2021.

See notes to consolidated condensed financial statements.

Consolidated Condensed Statements of Cash Flows
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Nine Months Ended September 30,	
	2023	**2022**
Cash Flows from Operating Activities		
Net income	**$ 3,050.7**	$ 4,307.1
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	**1,139.6**	1,147.5
Change in deferred income taxes	**(1,834.8)**	(2,195.6)
Stock-based compensation expense	**508.3**	278.2
Net investment losses	**144.5**	676.4
Gains on sale of product rights	**(1,853.9)**	(94.5)
Acquired in-process research and development	**3,177.2**	668.4
Other changes in operating assets and liabilities, net of acquisitions and divestitures	**117.2**	823.4
Other operating activities, net	**103.2**	312.1
Net Cash Provided by Operating Activities	**4,552.0**	5,923.0
Cash Flows from Investing Activities		
Purchases of property and equipment	**(2,377.0)**	(1,353.6)
Proceeds from sales and maturities of short-term investments	**155.2**	83.1
Purchases of short-term investments	**(79.2)**	(65.0)
Proceeds from sales of and distributions from noncurrent investments	**476.2**	251.6
Purchases of noncurrent investments	**(474.8)**	(474.1)
Proceeds from sale of product rights	**1,604.3**	65.8
Purchases of in-process research and development	**(3,364.0)**	(993.1)
Other investing activities, net	**(169.1)**	(334.1)
Net Cash Used for Investing Activities	**(4,228.4)**	(2,819.4)
Cash Flows from Financing Activities		
Dividends paid	**(3,051.2)**	(2,651.4)
Net change in short-term borrowings	**97.0**	1,741.3
Proceeds from issuance of long-term debt	**3,958.5**	—
Repayments of long-term debt	**—**	(1,560.0)
Purchases of common stock	**(750.0)**	(1,500.0)
Other financing activities, net	**(303.4)**	(295.2)
Net Cash Used for Financing Activities	**(49.1)**	(4,265.3)
Effect of exchange rate changes on cash and cash equivalents	**39.3**	(39.4)
Net increase (decrease) in cash and cash equivalents	**313.8**	(1,201.1)
Cash and cash equivalents at January 1	**2,067.0**	3,818.5
Cash and Cash Equivalents at September 30	**$ 2,380.8**	$ 2,617.4

See notes to consolidated condensed financial statements.

Note 1: Basis of Presentation

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the consolidated condensed financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2022. We issued our financial statements by filing them with the Securities and Exchange Commission and have evaluated subsequent events up to the time of the filing of this Quarterly Report on Form 10-Q.

All per-share amounts, unless otherwise noted in the footnotes, are presented on a diluted basis; that is, based on the weighted-average number of common shares outstanding plus the effect of incremental shares from our stock-based compensation programs, if dilutive.

We operate as a single operating segment engaged in the discovery, development, manufacturing, marketing, and sales of pharmaceutical products worldwide. A global research and development organization and a supply chain organization are responsible for the discovery, development, manufacturing, and supply of our products. Regional commercial organizations market, distribute, and sell the products. The business is also supported by global corporate staff functions. Our determination that we operate as a single segment is consistent with the financial information regularly reviewed by the chief operating decision maker for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods.

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

Research and development costs are expensed as incurred. Research and development costs consist of expenses incurred in performing research and development activities, including but not limited to, compensation and benefits, facilities and overhead expense, clinical trial expense, and fees paid to contract research organizations.

Acquired IPR&D includes the initial costs and development milestones incurred related to externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use. Development milestones are milestone payment obligations that are incurred prior to regulatory approval of the compound and are expensed when the event triggering an obligation to pay the milestone occurs.

Reclassifications

Certain reclassifications have been made to prior periods in the consolidated condensed financial statements and accompanying notes to conform with the current presentation. Development milestone payments related to externally developed IPR&D projects, acquired directly in a transaction other than a business combination, were previously included in cash flows from operating activities in the consolidated condensed statements of cash flows and are now included in purchases of IPR&D in cash flows from investing activities. The reclassification resulted in an increase to net cash provided by operating activities and net cash used in investing activities of $418.3 million for the nine months ended September 30, 2022.

Note 2: Revenue

The following table summarizes our revenue recognized in our consolidated condensed statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net product revenue	**$ 7,306.2**	$ 6,119.2	**$ 20,524.2**	$ 19,123.0
Collaboration and other revenue[(1)]	**2,192.4**	822.4	**4,246.5**	2,116.6
Revenue	**$ 9,498.6**	$ 6,941.6	**$ 24,770.7**	$ 21,239.6

[(1)] Collaboration and other revenue associated with prior period transfers of intellectual property was $31.3 million and $86.8 million during the three and nine months ended September 30, 2023, respectively, and $43.3 million and $130.9 million during the three and nine months ended September 30, 2022, respectively.

We recognize revenue primarily from two different types of contracts, product sales to customers (net product revenue) and collaborations and other arrangements. Revenue recognized from collaborations and other arrangements includes our share of profits from the collaborations, as well as royalties, upfront and milestone payments we receive under these types of contracts. See Note 4 for additional information related to our collaborations and other arrangements. Collaboration and other revenue disclosed above includes the revenue from the Jardiance® and Trajenta® families of products resulting from our collaboration with Boehringer Ingelheim, as well as from the sales of rights for the olanzapine portfolio, including Zyprexa®, and for Baqsimi®, all of which are discussed in Note 4. Substantially all of the remainder of collaboration and other revenue is related to contracts accounted for as contracts with customers.

Adjustments to Revenue

Adjustments to revenue recognized as a result of changes in estimates for our most significant United States (U.S.) sales returns, rebates, and discounts liability balances for products shipped in previous periods were 2 percent and 3 percent of U.S. revenue during the three months ended September 30, 2023 and 2022, respectively, and less than 1 percent of U.S. revenue during the nine months ended September 30, 2023 and 2022.

Contract Liabilities

Our contract liabilities result from arrangements where we have received payment in advance of performance under the contract and do not include sales returns, rebates, and discounts. Changes in contract liabilities are generally due to either receipt of additional advance payments or our performance under the contract.

The following table summarizes contract liability balances:

	September 30, 2023	December 31, 2022
Contract liabilities	**$ 200.7**	$ 219.2

During the three and nine months ended September 30, 2023 and 2022, revenue recognized from contract liabilities as of the beginning of the respective year was not material. Revenue expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied is not expected to be material in any one year.

Disaggregation of Revenue

The following table summarizes revenue, including net product revenue and collaboration and other revenue, by product for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,					
	2023			2022		
	U.S.	Outside U.S.	Total	U.S.	Outside U.S.	Total
Diabetes:						
Trulicity®	**$ 1,259.0**	**$ 414.6**	**$ 1,673.6**	$ 1,418.3	$ 432.0	$ 1,850.4
Mounjaro®	**1,277.0**	**132.4**	**1,409.3**	97.3	90.0	187.3
Jardiance(1)	**415.9**	**284.8**	**700.8**	350.9	222.4	573.3
Humalog® (2)	**194.2**	**201.2**	**395.4**	248.1	198.8	447.0
Humulin®	**145.5**	**61.2**	**206.7**	169.5	68.7	238.2
Basaglar® (3)	**111.4**	**68.2**	**179.6**	124.8	68.1	193.0
Baqsimi	**3.8**	**9.3**	**13.1**	35.2	7.8	43.0
Other diabetes	**53.2**	**88.6**	**141.9**	44.5	86.2	130.4
Total diabetes	**3,460.0**	**1,260.3**	**4,720.4**	2,488.6	1,174.0	3,662.6
Oncology:						
Verzenio®	**684.6**	**355.7**	**1,040.2**	414.8	202.9	617.7
Cyramza®	**88.0**	**136.1**	**224.1**	87.5	144.6	232.1
Erbitux®	**134.0**	**19.9**	**153.9**	126.3	18.7	144.9
Alimta®	**21.2**	**32.3**	**53.5**	64.6	54.8	119.4
Other oncology	**73.8**	**201.5**	**275.4**	39.5	139.6	179.2
Total oncology	**1,001.6**	**745.5**	**1,747.1**	732.7	560.6	1,293.3
Immunology:						
Taltz®	**509.3**	**234.9**	**744.2**	493.8	186.1	679.9
Olumiant® (4)	**65.7**	**165.7**	**231.4**	22.9	160.0	182.9
Other immunology	**—**	**11.4**	**11.4**	—	3.6	3.6
Total immunology	**575.0**	**412.0**	**986.9**	516.7	349.7	866.4
Neuroscience:						
Zyprexa(5)	**49.9**	**1,431.5**	**1,481.4**	8.0	73.4	81.4
Emgality®	**126.5**	**42.1**	**168.5**	114.0	54.6	168.5
Other neuroscience	**31.0**	**87.0**	**118.2**	23.8	99.4	123.3
Total neuroscience	**207.4**	**1,560.6**	**1,768.1**	145.8	227.4	373.2
Other:						
Forteo®	**101.2**	**45.2**	**146.4**	112.7	64.4	177.1
Cialis®	**4.9**	**82.0**	**86.8**	8.1	107.7	115.7
COVID-19 antibodies(6)	**—**	**—**	**—**	386.6	—	386.6
Other	**18.0**	**24.8**	**42.9**	30.9	35.7	66.6
Total other	**124.1**	**152.0**	**276.1**	538.3	207.8	746.0
Revenue	**$ 5,368.1**	**$ 4,130.5**	**$ 9,498.6**	$ 4,422.1	$ 2,519.4	$ 6,941.6

Numbers may not add due to rounding.
(1) Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.
(2) Humalog revenue includes insulin lispro.
(3) Basaglar revenue includes Rezvoglar®.
(4) Olumiant revenue includes sales for baricitinib that were made pursuant to Emergency Use Authorization (EUA) or similar regulatory authorizations.
(5) Zyprexa revenue includes sale of rights for the olanzapine portfolio.
(6) COVID-19 antibodies include sales for bamlanivimab administered alone, for bamlanivimab and etesevimab administered together, and for bebtelovimab and were made pursuant to EUAs or similar regulatory authorizations.

The following table summarizes revenue, including net product revenue and collaboration and other revenue, by product for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,					
	2023			2022		
	U.S.	Outside U.S.	Total	U.S.	Outside U.S.	Total
Diabetes:						
Trulicity	**$ 4,177.7**	**$ 1,285.6**	**$ 5,463.2**	$ 4,162.4	$ 1,341.1	$ 5,503.5
Mounjaro	**2,729.1**	**228.4**	**2,957.5**	109.9	93.3	203.2
Jardiance[1]	**1,131.5**	**815.1**	**1,946.6**	831.4	622.4	1,453.7
Humalog[2]	**695.6**	**601.2**	**1,296.8**	855.8	656.4	1,512.3
Humulin	**488.6**	**175.4**	**664.0**	562.3	223.1	785.4
Baqsimi	**633.1**	**25.4**	**658.4**	79.5	21.7	101.2
Basaglar[3]	**329.7**	**213.4**	**543.1**	339.9	218.8	558.7
Other diabetes	**131.1**	**260.7**	**392.0**	116.1	254.8	371.0
Total diabetes	**10,316.4**	**3,605.2**	**13,921.6**	7,057.3	3,431.6	10,489.0
Oncology:						
Verzenio	**1,734.2**	**983.7**	**2,717.9**	1,100.5	575.1	1,675.6
Cyramza	**303.6**	**417.5**	**721.1**	259.3	434.3	693.6
Erbitux	**398.3**	**48.0**	**446.3**	361.0	47.4	408.3
Alimta	**59.2**	**113.5**	**172.6**	490.5	200.5	691.1
Other oncology	**194.7**	**521.4**	**716.2**	124.1	422.3	546.4
Total oncology	**2,690.0**	**2,084.1**	**4,774.1**	2,335.4	1,679.6	4,015.0
Immunology:						
Taltz	**1,293.8**	**681.2**	**1,975.0**	1,212.6	561.6	1,774.2
Olumiant[4]	**158.8**	**520.4**	**679.2**	104.6	520.1	624.7
Other immunology	**—**	**39.0**	**39.0**	0.1	12.1	12.1
Total immunology	**1,452.6**	**1,240.6**	**2,693.2**	1,317.3	1,093.8	2,411.0
Neuroscience:						
Zyprexa[5]	**69.1**	**1,581.9**	**1,651.0**	26.2	235.5	261.7
Emgality	**354.0**	**138.2**	**492.2**	330.8	144.4	475.2
Other neuroscience	**89.7**	**282.9**	**372.6**	87.0	337.0	424.0
Total neuroscience	**512.8**	**2,003.0**	**2,515.8**	444.0	716.9	1,160.9
Other:						
Forteo	**269.2**	**147.6**	**416.8**	261.4	191.7	453.0
Cialis	**21.6**	**281.1**	**302.7**	25.8	454.7	480.4
COVID-19 antibodies[6]	**—**	**—**	**—**	1,970.9	14.7	1,985.5
Other	**73.0**	**73.4**	**146.5**	119.4	125.1	244.8
Total other	**363.8**	**502.1**	**866.0**	2,377.5	786.2	3,163.7
Revenue	**$ 15,335.6**	**$ 9,435.0**	**$ 24,770.7**	$ 13,531.5	$ 7,708.1	$ 21,239.6

Numbers may not add due to rounding.
(1) Jardiance revenue includes Glyxambi, Synjardy, and Trijardy XR.
(2) Humalog revenue includes insulin lispro.
(3) Basaglar revenue includes Rezvoglar.
(4) Olumiant revenue includes sales for baricitinib that were made pursuant to EUA or similar regulatory authorizations.
(5) Zyprexa revenue includes sale of rights for the olanzapine portfolio.
(6) COVID-19 antibodies include sales for bamlanivimab administered alone, for bamlanivimab and etesevimab administered together, and for bebtelovimab and were made pursuant to EUAs or similar regulatory authorizations.

The following table summarizes revenue by geographical area:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue[(1)]:				
U.S.	**$ 5,368.1**	$ 4,422.1	**$ 15,335.6**	$ 13,531.5
Europe	**2,568.6**	1,056.4	**4,837.1**	3,224.8
Japan	**390.8**	487.7	**1,233.6**	1,352.3
China	**390.8**	343.4	**1,162.6**	1,102.0
Other foreign countries	**780.3**	632.0	**2,201.8**	2,029.1
Revenue	**$ 9,498.6**	$ 6,941.6	**$ 24,770.7**	$ 21,239.6

Numbers may not add due to rounding.
(1) Revenue is attributed to the countries based on the location of the customer or other party.

Note 3: Acquisitions

We engage in various forms of business development activities to enhance our product pipeline, including acquisitions, collaborations, investments, and licensing arrangements. In connection with these arrangements, our partners may be entitled to future royalties and/or commercial milestones based on sales should products be approved for commercialization and/or milestones based on the successful progress of compounds through the development process.

In December 2022, we completed the acquisition of Akouos, Inc. (Akouos). This transaction, as further discussed below in Acquisition of a Business, was accounted for as a business combination under the acquisition method of accounting. Under this method, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated condensed financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of this acquisition is included in our consolidated condensed financial statements from the date of acquisition.

We also acquired assets in development which are further discussed below in Asset Acquisitions. Upon each acquisition, the cost allocated to acquired IPR&D was immediately expensed if the compound has no alternative future use. Milestone payment obligations incurred prior to regulatory approval of the compound are expensed as acquired IPR&D when the event triggering an obligation to pay the milestone occurs. We recognized acquired IPR&D charges of $2.98 billion and $3.18 billion for the three and nine months ended September 30, 2023, respectively, and $62.4 million and $668.4 million for the three and nine months ended September 30, 2022, respectively.

Acquisition of a Business

Akouos Acquisition

Overview of Transaction

In December 2022, we acquired all shares of Akouos for a purchase price that included $12.50 per share in cash (or an aggregate of $327.2 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles the Akouos shareholders up to an additional $3.00 per share in cash (or an aggregate of approximately $122 million) payable, subject to certain terms and conditions, upon the achievement of certain specified milestones.

Under the terms of the agreement, we acquired potential gene therapy treatments for hearing loss and other inner ear conditions. The lead gene therapies in clinical development that we acquired included GJB2 (which encodes connexin 26) for a common form of monogenic deafness and hearing loss; AK-OTOF for hearing loss due to mutations in the otoferlin gene; AK-CLRN1 for Usher Type 3A, an autosomal recessive disorder characterized by progressive loss of both hearing and vision; and AK-antiVEGF for vestibular schwannoma.

Assets Acquired and Liabilities Assumed

Our access to Akouos information was limited prior to the acquisition. As a consequence, we are in the process of determining fair values and tax bases of a significant portion of the assets acquired and liabilities assumed, including the identification and valuation of intangible assets and tax exposures. The final determination of these amounts will be completed as soon as possible but no later than one year from the acquisition date. The final determination may result in asset and liability fair values and tax bases that differ from the preliminary estimates and require changes to the preliminary amounts recognized.

The following table summarizes the preliminary amounts recognized for assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at December 1, 2022		
Cash	$	153.2
Acquired IPR&D[(1)]		184.0
Goodwill[(2)]		187.1
Other assets and liabilities, net		23.0
Acquisition date fair value of consideration transferred		547.3
Less:		
Cash acquired		(153.2)
Fair value of CVR liability[(3)]		(66.9)
Cash paid, net of cash acquired	$	327.2

(1) Acquired IPR&D intangibles primarily relate to GJB2.
(2) The goodwill recognized from this acquisition is attributable primarily to future unidentified projects and products and the assembled workforce for Akouos and is not deductible for tax purposes.
(3) See Note 6 for a discussion on the estimation of the CVR liability.

The results of operations attributable to Akouos for the three and nine months ended September 30, 2023 were immaterial.

Pro forma information has not been included as this acquisition did not have a material impact on our consolidated condensed statements of operations for the three and nine months ended September 30, 2022.

Asset Acquisitions

The following table summarizes our significant asset acquisitions during the nine months ended September 30, 2023 and 2022:

Counterparty	Compound(s), Therapy or Asset	Acquisition Month	Phase of Development[(1)]	Acquired IPR&D Expense
DICE Therapeutics, Inc.	DC-806, an oral IL-17 inhibitor for the treatment of chronic diseases in immunology	August 2023	Phase II	**$ 1,915.5**
Versanis Bio, Inc.	Bimagrumab, a monoclonal antibody for the treatment of people living with obesity and obesity-related complications	August 2023	Phase II	**604.1**
Emergence Therapeutics AG	ETx-22, a Nectin-4 antibody-drug conjugate for the treatment of urothelial cancer	August 2023	Pre-clinical	**406.5**
BioMarin Pharmaceutical Inc.	Priority Review Voucher	February 2022	Not applicable	110.0

(1) The phase of development presented is as of the date of the arrangement and represents the phase of development of the most advanced asset acquired, where applicable.

In connection with our acquisition of Petra Pharma Corporation (Petra), we were required to make milestone payments to Petra shareholders contingent upon the occurrence of certain future events linked to the success of the mutant-selective PI3Kα inhibitor. In the second quarter of 2022, we entered into agreements with substantially all Petra shareholders to acquire their rights to receive any future milestone payments in exchange for a one-time payment. As a result of these agreements, we recognized a charge of $333.8 million as acquired IPR&D during the nine months ended September 30, 2022. Any remaining contingent milestones payments linked to the success of the mutant-selective PI3Kα inhibitor are not expected to be material.

We recognized no other significant acquired IPR&D charges during the three and nine months ended September 30, 2023 and 2022.

Subsequent Events

In October 2023, we announced an agreement to acquire POINT Biopharma Global Inc. (POINT) for a purchase price of $12.50 per share in cash (an aggregate of approximately $1.4 billion) payable at closing. The proposed acquisition is subject to customary closing conditions, including the tender of a majority of the outstanding shares of POINT's common stock, the receipt of required antitrust clearance, and license transfer approval from the U.S. Nuclear Regulatory Commission.

Note 4: Collaborations and Other Arrangements

Collaborations and Other Similar Arrangements

We often enter into collaborative and other similar arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These arrangements often require milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner.

Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Each arrangement is unique in nature, and our more significant arrangements are discussed below.

Boehringer Ingelheim Diabetes Collaboration

We and Boehringer Ingelheim have a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Currently included in the collaboration are Boehringer Ingelheim's oral diabetes products: Jardiance, Glyxambi, Synjardy, Trijardy XR, Trajenta, and Jentadueto® as well as our basal insulins, Basaglar and Rezvoglar. Glyxambi, Synjardy, and Trijardy XR are included in the Jardiance product family. Jentadueto is included in the Trajenta product family. Rezvoglar is included in the Basaglar product family.

In connection with the regulatory approvals of Jardiance, Trajenta, and Basaglar in the U.S., Europe, and Japan, milestone payments made for Jardiance and Trajenta were capitalized as intangible assets and are being amortized to cost of sales, and milestone payments received for Basaglar were recorded as contract liabilities and are being amortized to collaboration and other revenue. The milestones pertaining to Jardiance and Trajenta are being amortized through their respective term under the collaboration, which, depending on country or region, is determined based on the latest to occur of (a) a defined number of years following launch date, (b) the expiration of the compound patent, or (c) the expiration of marketing authorization exclusivity. The milestones pertaining to Basaglar are being amortized through 2029. The table below summarizes the net milestones capitalized with respect to the Jardiance and Trajenta families of products and the net milestones deferred with respect to the Basaglar product family as of September 30, 2023 and December 31, 2022:

	Net Milestones Capitalized (Deferred)[1]	
	September 30, 2023	December 31, 2022
Jardiance	**$ 101.3**	$ 116.2
Trajenta	**45.0**	63.5
Basaglar	**(116.6)**	(130.6)

[1] This represents the amounts that have been capitalized (deferred) from the start of this collaboration through the end of the reporting period, net of amount amortized.

For the Jardiance product family, we and Boehringer Ingelheim generally share equally the ongoing development and commercialization costs in the most significant markets, and we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. We receive a royalty on net sales of Boehringer Ingelheim's products in the most significant markets and recognize the royalty as collaboration and other revenue. Boehringer Ingelheim is entitled to potential performance payments depending on the net sales of the Jardiance product family; therefore, our reported revenue for Jardiance may be reduced by any potential performance payments we make related to this product family. The royalty received by us related to the Jardiance product family may also be increased or decreased depending on whether net sales for this product family exceed or fall below certain thresholds. We pay to Boehringer Ingelheim a royalty on net sales for the Basaglar product family in the U.S. We record our sales of the Basaglar product family to third parties as net product revenue with the royalty payments made to Boehringer Ingelheim recorded as cost of sales.

The following table summarizes our collaboration and other revenue recognized with respect to the Jardiance and Trajenta families of products and net product revenue recognized with respect to the Basaglar product family:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Jardiance	**$ 700.8**	$ 573.3	**$ 1,946.6**	$ 1,453.7
Basaglar	**179.6**	193.0	**543.1**	558.7
Trajenta	**95.2**	103.8	**284.7**	293.0

Olumiant

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte), which provides us the development and commercialization rights to baricitinib, which is branded and trademarked as Olumiant, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases and COVID-19. Incyte has the right to receive tiered, double digit royalty payments on worldwide net sales with rates ranging up to 20 percent. Incyte has the right to receive an additional royalty ranging up to the low teens on worldwide net sales for the treatment of COVID-19 that exceed a specified aggregate worldwide net sales threshold. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones.

In connection with the regulatory approvals of Olumiant in the U.S., Europe, and Japan, as well as achievement of a sales-based milestone, milestone payments of $330.0 million were capitalized as intangible assets as of September 30, 2023 and December 31, 2022 and are being amortized to cost of sales through the term of the collaboration. This represents the cumulative amounts that have been capitalized from the start of this collaboration through the end of each reporting period.

As of September 30, 2023, Incyte is eligible to receive up to $100.0 million of additional payments from us in potential sales-based milestones.

We record our sales of Olumiant, including sales of baricitinib that were made pursuant to EUA or similar regulatory authorizations, to third parties as net product revenue with the royalty payments made to Incyte recorded as cost of sales. The following table summarizes our net product revenue recognized with respect to Olumiant:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Olumiant	**$ 231.4**	$ 182.9	**$ 679.2**	$ 624.7

COVID-19 Antibodies

We have a worldwide license and collaboration agreement with AbCellera Biologics Inc. (AbCellera) to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including bamlanivimab and bebtelovimab, for which we hold development and commercialization rights. AbCellera has the right to receive tiered royalty payments on worldwide net sales of bamlanivimab and bebtelovimab with percentages ranging in the mid-teens to mid-twenties. Royalty payments made to AbCellera were recorded as cost of sales.

Pursuant to EUAs or similar regulatory authorizations, we recognized net product revenue associated with our sales of our COVID-19 antibodies of $386.6 million and $1.99 billion, primarily related to bebtelovimab, for the three and nine months ended September 30, 2022, respectively. We did not have sales of our COVID-19 antibodies during the three and nine months ended September 30, 2023.

Lebrikizumab

We have a worldwide license agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively, Roche), which provides us the worldwide development and commercialization rights to lebrikizumab. Roche has the right to receive tiered royalty payments on future worldwide net sales ranging in percentages from high single digits to high teens if the product is successfully commercialized. As of September 30, 2023, Roche is eligible to receive up to $160.0 million of payments from us contingent upon the achievement of success-based regulatory milestones and up to $1.03 billion in a series of sales-based milestones, contingent upon the commercial success of lebrikizumab.

We have a license agreement with Almirall, S.A. (Almirall), under which Almirall licensed the rights to develop and commercialize lebrikizumab for the treatment or prevention of dermatology indications, including, but not limited to, atopic dermatitis in Europe. We have the right to receive tiered royalty payments on future net sales in Europe ranging in percentages from low double digits to low twenties if the product is successfully commercialized. As of September 30, 2023, we are eligible to receive payments of $65.0 million from Almirall contingent upon the achievement of success-based regulatory milestones and up to $1.25 billion in a series of sales-based milestones, contingent upon the commercial success of lebrikizumab. During the three and nine months ended September 30, 2023 and 2022, collaboration and other revenue recognized under this license agreement was not material.

Divestitures

We periodically enter into arrangements to sell the rights of a product. We recognize the net gain or loss associated with the sale of rights of a product as collaboration and other revenue when control of the asset transfers to the other party.

We may be eligible to receive milestone payments contingent upon the occurrence of certain future events linked to the success of the divested product. Milestones are included in the transaction price only to the extent a significant reversal in the amount of revenue recognized is not probable of occurring when the uncertainties associated with the milestones are subsequently resolved.

We may enter into a supply arrangement as part of a divestiture of product rights. Our sale of product inventory under the supply agreement is recognized as net product revenue at the earlier of when control of the asset transfers to the other party or when the product has no alternative use to us and we have right to payment.

Olanzapine Portfolio (including Zyprexa)

In July 2023, we sold the rights for the olanzapine portfolio, including Zyprexa, to Cheplapharm Arzneimittel GmbH (Cheplapharm), a European company. Under the terms of the agreement, we received $1.05 billion in cash and will receive an additional $305.0 million in cash upon the one year anniversary of closing. We included both in the transaction price as of September 30, 2023. We are eligible to receive milestone payments of up to $50.0 million, that have not been included in the transaction price as of September 30, 2023.

We entered into a supply agreement with Cheplapharm that obligates Cheplapharm to purchase Zyprexa product we are manufacturing at an amount which represents a standalone selling price. As the product we are manufacturing under this supply agreement has no alternative use to us and we have right to payment, we will recognize net product revenue over time as we manufacture the product.

During the three and nine months ended September 30, 2023, we recognized $1.42 billion in revenue primarily related to the net gain on the sale of rights for the olanzapine portfolio.

Baqsimi

In June 2023, we sold the rights for Baqsimi to Amphastar Pharmaceuticals, Inc. (Amphastar). Under the terms of the agreement, we received $500.0 million in cash and will receive an additional $125.0 million in cash upon the one year anniversary of closing. We included both in the transaction price as of September 30, 2023. We are eligible to receive payments of up to $450.0 million in a series of sales-based milestones, that have not been included in the transaction price as of September 30, 2023.

We entered into a supply agreement with Amphastar that obligates Amphastar to purchase Baqsimi product we are manufacturing at an amount which represents a standalone selling price. As the product we are manufacturing under this supply agreement has no alternative use to us and we have right to payment, we will recognize net product revenue over time as we manufacture the product.

During the nine months ended September 30, 2023, we recognized $579.0 million in revenue primarily related to the net gain on the sale of rights for Baqsimi.

Note 5: Asset Impairment, Restructuring, and Other Special Charges

There were no asset impairment, restructuring, and other special charges recognized during the three and nine months ended September 30, 2023.

We recognized $206.5 million of asset impairment, restructuring, and other special charges during the three and nine months ended September 30, 2022, primarily related to an intangible asset impairment for GBA1 Gene Therapy, acquired in the acquisition of Prevail Therapeutics Inc., as a result of changes in key assumptions used in the valuation due to delays in estimated launch timing.

Note 6: Financial Instruments

Investments in Equity and Debt Securities

Our equity investments are accounted for using three different methods depending on the type of equity investment:

- Investments in companies over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other-net, (income) expense.
- For equity investments that do not have readily determinable fair values, we measure these investments at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. Any change in recorded value is recorded in other-net, (income) expense.
- Our public equity investments are measured and carried at fair value. Any change in fair value is recognized in other-net, (income) expense.

We adjust our equity investments without readily determinable fair values based upon changes in the equity instruments' values resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. Downward adjustments resulting from an impairment are recorded based upon impairment considerations, including the financial condition and near-term prospects of the issuer, general market conditions, and industry specific factors. Adjustments recorded for the three and nine months ended September 30, 2023 and 2022 were not material.

The net losses recognized in our consolidated condensed statements of operations for equity securities were $62.9 million and $141.5 million for the three and nine months ended September 30, 2023, respectively, and $123.3 million and $667.6 million for the three and nine months ended September 30, 2022, respectively. The net gains (losses) recognized for the three and nine months ended September 30, 2023 and 2022 on equity securities sold during the respective periods were not material.

As of September 30, 2023, we had approximately $915 million of unfunded commitments to invest in venture capital funds, which we anticipate will be paid over a period of up to 10 years.

We record our available-for-sale debt securities at fair value, with changes in fair value reported as a component of accumulated other comprehensive income (loss). We periodically assess our investment in available-for-sale securities for impairment losses and credit losses. The amount of credit losses are determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration. Impairment and credit losses related to available-for-sale securities were not material for the three and nine months ended September 30, 2023 and 2022.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of September 30, 2023:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 628.3	$ 88.2	$ 201.6	$ 109.4	$ 229.1

A summary of the amount of unrealized gains and losses in accumulated other comprehensive loss and the fair value of available-for-sale securities in an unrealized gain or loss position follows:

	September 30, 2023	December 31, 2022
Unrealized gross gains	**$ 0.1**	$ 0.6
Unrealized gross losses	**59.7**	49.2
Fair value of securities in an unrealized gain position	**30.4**	46.8
Fair value of securities in an unrealized loss position	**559.6**	568.7

As of September 30, 2023, the available-for-sale securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities, which are sensitive to changes in the yield curve and other market conditions. Approximately 99 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of September 30, 2023, we do not intend to sell, and it is not more likely than not that we will be required to sell, the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of a material default on interest or principal payments for our debt securities.

Activity related to our available-for-sale securities was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Proceeds from sales	**$ 60.0**	$ 50.5	**$ 121.8**	$ 115.6
Realized gross gains on sales	**0.3**	—	**0.6**	0.2
Realized gross losses on sales	**1.9**	7.5	**3.6**	9.0

Realized gains and losses on sales of available-for-sale investments are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

Fair Value of Investments

The following table summarizes certain fair value information at September 30, 2023 and December 31, 2022 for investment assets measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

	Carrying Amount	Cost[1]	Fair Value Measurements Using			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
September 30, 2023						
Cash equivalents[2]	**$ 1,201.4**	**$ 1,201.4**	**$ 1,196.5**	**$ 4.9**	**$ —**	**$ 1,201.4**
Short-term investments:						
U.S. government and agency securities	**$ 30.2**	**$ 30.6**	**$ 30.2**	**$ —**	**$ —**	**$ 30.2**
Corporate debt securities	**57.4**	**57.7**	**—**	**57.4**	**—**	**57.4**
Asset-backed securities	**0.6**	**0.6**	**—**	**0.6**	**—**	**0.6**
Other securities	**24.9**	**24.9**	**—**	**11.0**	**13.9**	**24.9**
Short-term investments	**$ 113.1**					
Noncurrent investments:						
U.S. government and agency securities	**$ 139.3**	**$ 160.0**	**$ 139.3**	**$ —**	**$ —**	**$ 139.3**
Corporate debt securities	**198.6**	**222.3**	**—**	**198.6**	**—**	**198.6**
Mortgage-backed securities	**144.9**	**161.9**	**—**	**144.9**	**—**	**144.9**
Asset-backed securities	**57.2**	**59.5**	**—**	**57.2**	**—**	**57.2**
Other securities	**171.1**	**77.0**	**—**	**6.2**	**164.9**	**171.1**
Marketable equity securities	**532.0**	**443.2**	**532.0**	**—**	**—**	**532.0**
Equity investments without readily determinable fair values[3]	**531.4**					
Equity method investments[3]	**917.2**					
Noncurrent investments	**$ 2,691.7**					
December 31, 2022						
Cash equivalents[2]	$ 657.4	$ 657.4	$ 650.4	$ 7.0	$ —	$ 657.4
Short-term investments:						
U.S. government and agency securities	$ 30.8	$ 31.1	$ 30.8	$ —	$ —	$ 30.8
Corporate debt securities	53.4	53.5	—	53.4	—	53.4
Asset-backed securities	2.0	2.0	—	2.0	—	2.0
Other securities	58.6	58.6	—	39.1	19.5	58.6
Short-term investments	$ 144.8					
Noncurrent investments:						
U.S. government and agency securities	$ 146.4	$ 163.2	$ 146.4	$ —	$ —	$ 146.4
Corporate debt securities	213.9	235.8	—	213.9	—	213.9
Mortgage-backed securities	149.2	161.5	—	149.2	—	149.2
Asset-backed securities	50.6	52.5	—	50.6	—	50.6
Other securities	398.6	34.5	—	311.0	87.6	398.6
Marketable equity securities	683.6	484.7	683.6	—	—	683.6
Equity investments without readily determinable fair values[3]	478.4					
Equity method investments[3]	781.1					
Noncurrent investments	$ 2,901.8					

[1] For available-for-sale debt securities, amounts disclosed represent the securities' amortized cost.
[2] We consider all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents. The cost of these investments approximates fair value.
[3] Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments.

We determine our Level 1 and Level 2 fair value measurements based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. Level 3 fair value measurements for other investment securities are determined using unobservable inputs, including the investments' cost adjusted for impairments and price changes from orderly transactions. Fair values are not readily available for certain equity investments measured under the measurement alternative.

Debt

In February 2023, we issued $750.0 million of 5.000 percent fixed-rate notes due in 2026, which are callable at par after one year, $1.00 billion of 4.700 percent fixed-rate notes due in 2033, $1.25 billion of 4.875 percent fixed-rate notes due in 2053, and $1.00 billion of 4.950 percent fixed-rate notes due in 2063, all with interest to be paid semi-annually. We used the net cash proceeds from the offering of $3.96 billion for general business purposes, including the repayment of outstanding commercial paper.

In September 2023, we renewed our $4.00 billion 364-day credit facility, which will expire in September 2024 and is available to support our commercial paper program. We have not drawn against the $4.00 billion 364-day facility as of September 30, 2023.

Fair Value of Debt

The following table summarizes certain fair value information at September 30, 2023 and December 31, 2022 for our short-term and long-term debt:

			Fair Value Measurements Using			
	Carrying Amount		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Short-term commercial paper borrowings						
September 30, 2023	**$**	**(1,594.9)**	**$ —**	**$ (1,592.5)**	**$ —**	**$ (1,592.5)**
December 31, 2022		(1,498.0)	—	(1,492.0)	—	(1,492.0)
Long-term debt, including current portion						
September 30, 2023	**$**	**(18,573.4)**	**$ —**	**$ (15,412.6)**	**$ —**	**$ (15,412.6)**
December 31, 2022		(14,740.6)	—	(12,329.3)	—	(12,329.3)

Risk Management and Related Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life science products account for a substantial portion of our trade receivables; collateral is generally not required. We seek to mitigate the risk associated with this concentration through our ongoing credit-review procedures and insurance. The majority of our cash is held by a few major financial institutions that have been identified as Global Systemically Important Banks (G-SIBs) by the Financial Stability Board. G-SIBs are subject to rigorous regulatory testing and oversight and must meet certain capital requirements. We monitor our exposures with these institutions and do not expect any of these institutions to fail to meet their obligations. In accordance with documented corporate risk-management policies, we monitor the amount of credit exposure to any one financial institution or corporate issuer based on credit rating of our counterparty. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect significant counterparties to fail to meet their obligations given their investment grade credit ratings.

We have entered into accounts receivable factoring agreements with financial institutions to sell certain of our non-U.S. accounts receivable. These transactions are accounted for as sales and result in a reduction in accounts receivable because the agreements transfer effective control over, and risk related to, the receivables to the buyers. Our factoring agreements do not allow for recourse in the event of uncollectibility, and we do not retain any interest in the underlying accounts receivable once sold. We derecognized $403.8 million and $422.1 million of accounts receivable as of September 30, 2023 and December 31, 2022, respectively, under these factoring arrangements. The costs of factoring such accounts receivable were not material for the three and nine months ended September 30, 2023 and 2022.

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and are intended to offset losses and gains on the assets, liabilities, and transactions being hedged. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative instruments that are designated and qualify as fair value hedges, the derivative instrument is marked to market, with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative instruments that are designated and qualify as cash flow hedges, gains and losses are reported as a component of accumulated other comprehensive income (loss) (see Note 10) and reclassified into earnings in the same period the hedged transaction affects earnings. For derivative and non-derivative instruments that are designated and qualify as net investment hedges, the foreign currency translation gains or losses due to spot rate fluctuations are reported as a component of accumulated other comprehensive income (loss) (see Note 10). Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in earnings during the period of change.

We may enter into foreign currency forward or option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, British pound, Chinese yuan, Japanese yen, and Swiss franc). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward and option contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other–net, (income) expense. Forward contracts generally have maturities not exceeding 12 months. At September 30, 2023, we had outstanding foreign currency forward commitments as follows, all of which have settlement dates within 180 days:

September 30, 2023			
Purchase		Sell	
Currency	Amount (in millions)	Currency	Amount (in millions)
Euro	5,774.2	U.S. dollars	6,170.9
U.S. dollars	3,420.4	Euro	3,224.2
U.S. dollars	240.0	Chinese yuan	1,736.5
British pounds	185.7	U.S. dollars	229.7
U.S. dollars	200.2	Japanese yen	29,626.8

Foreign currency exchange risk is also managed through the use of foreign currency debt, cross-currency interest rate swaps, and foreign currency forward contracts. Our foreign currency-denominated notes had carrying amounts of $6.74 billion and $6.83 billion as of September 30, 2023 and December 31, 2022, respectively, of which $5.38 billion and $5.45 billion have been designated as, and are effective as, economic hedges of net investments in certain of our foreign operations as of September 30, 2023 and December 31, 2022, respectively. At September 30, 2023, we had outstanding cross-currency swaps with notional amounts of $1.01 billion swapping U.S. dollars to euro and $1.00 billion swapping Swiss francs to U.S. dollars which have settlement dates ranging through 2028. Our cross-currency interest rate swaps, for which a majority convert a portion of our U.S. dollar-denominated fixed-rate debt to foreign-denominated fixed-rate debt, have also been designated as, and are effective as, economic hedges of net investments. At September 30, 2023, we had outstanding foreign currency forward contracts to sell 5.23 billion euro and to sell 1.80 billion Chinese yuan with settlement dates ranging through 2024, which have been designated as, and are effective as, economic hedges of net investments.

In the normal course of business, our operations are exposed to fluctuations in interest rates which can vary the costs of financing, investing, and operating. We seek to address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest-rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest-rate exposures, we strive to achieve an acceptable balance between fixed- and floating-rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance.

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. Cash proceeds from or payments to counterparties resulting from the termination of interest rate swaps are classified as operating activities in our consolidated condensed statements of cash flows. At September 30, 2023, all of our total long-term debt is at a fixed rate. We have converted approximately 12 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

We also may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. The change in fair value of these instruments is recorded as part of other comprehensive income (loss) (see Note 10) and, upon completion of a debt issuance and termination of the swap, is amortized to interest expense over the life of the underlying debt. As of September 30, 2023, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.00 billion, which have settlement dates ranging through 2025.

The Effect of Risk-Management Instruments on the Consolidated Condensed Statements of Operations

The following effects of risk-management instruments were recognized in other–net, (income) expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Fair value hedges:				
Effect from hedged fixed-rate debt	**$ (29.9)**	$ (62.9)	**$ (29.0)**	$ (215.7)
Effect from interest rate contracts	**29.9**	62.9	**29.0**	215.7
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**3.2**	4.1	**10.3**	12.3
Cross-currency interest rate swaps	**24.7**	33.1	**(5.3)**	75.0
Net losses on foreign currency exchange contracts not designated as hedging instruments	**201.0**	129.6	**177.8**	280.7
Total	**$ 228.9**	$ 166.8	**$ 182.8**	$ 368.0

During the three and nine months ended September 30, 2023 and 2022, the amortization of losses related to the portion of our risk management hedging instruments, fair value hedges, and cash flow hedges that was excluded from the assessment of effectiveness was not material.

The Effect of Risk-Management Instruments on Other Comprehensive Income (Loss)

The effective portion of risk-management instruments that was recognized in other comprehensive income (loss) is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net investment hedges:				
Foreign currency-denominated notes	**$ 183.5**	$ 435.1	**$ 62.3**	$ 822.8
Cross-currency interest rate swaps	**28.6**	92.1	**9.0**	171.4
Foreign currency forward contracts	**217.7**	107.8	**199.3**	121.4
Cash flow hedges:				
Forward-starting interest rate swaps	**84.3**	57.5	**141.4**	337.7
Cross-currency interest rate swaps	**16.4**	19.9	**30.5**	38.4

During the next 12 months, we expect to reclassify $13.1 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the three and nine months ended September 30, 2023 and 2022, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Risk-Management Instruments

The following table summarizes certain fair value information at September 30, 2023 and December 31, 2022 for risk management assets and liabilities measured at fair value on a recurring basis:

		Fair Value Measurements Using			
	Carrying Amount	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
September 30, 2023					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Other current liabilities	$ (5.6)	$ —	$ (5.6)	$ —	$ (5.6)
Other noncurrent liabilities	(157.7)	—	(157.7)	—	(157.7)
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	346.2	—	346.2	—	346.2
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	71.3	—	71.3	—	71.3
Cross-currency interest rate contracts designated as cash flow hedges:					
Other receivables	58.3	—	58.3	—	58.3
Other noncurrent assets	30.7	—	30.7	—	30.7
Foreign exchange contracts designated as net investment hedges:					
Other receivables	106.0	—	106.0	—	106.0
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	32.9	—	32.9	—	32.9
Other current liabilities	(100.5)	—	(100.5)	—	(100.5)
Contingent consideration liabilities:					
Other current liabilities	(39.0)	—	—	(39.0)	(39.0)
Other noncurrent liabilities	(63.9)	—	—	(63.9)	(63.9)

	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2022					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Other noncurrent liabilities	$ (134.3)	$ —	$ (134.3)	$ —	$ (134.3)
Interest rate contracts designated as cash flow hedges:					
Other receivables	162.9	—	162.9	—	162.9
Other noncurrent assets	246.0	—	246.0	—	246.0
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	67.6	—	67.6	—	67.6
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	53.1	—	53.1	—	53.1
Foreign exchange contracts designated as hedging instruments:					
Other current liabilities	(38.3)	—	(38.3)	—	(38.3)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	26.6	—	26.6	—	26.6
Other current liabilities	(21.5)	—	(21.5)	—	(21.5)
Contingent consideration liabilities:					
Other current liabilities	(39.5)	—	—	(39.5)	(39.5)
Other noncurrent liabilities	(70.6)	—	—	(70.6)	(70.6)

Risk-management instruments above are disclosed on a gross basis. There are various rights of setoff associated with certain of the risk-management instruments above that are subject to enforceable master netting arrangements or similar agreements. Although various rights of setoff and master netting arrangements or similar agreements may exist with the individual counterparties to the risk-management instruments above, individually, these financial rights are not material.

Contingent consideration liabilities relate to our liabilities arising in connection with the CVRs issued as a result of acquisitions of businesses. The fair values of the CVR liabilities were estimated using a discounted cash flow analysis and Level 3 inputs, including projections representative of a market participant's view of the expected cash payments associated with the agreed upon regulatory milestones based on probabilities of technical success, timing of the potential milestone events for the compounds, and estimated discount rates.

Note 7: Income Taxes

The effective tax rates were 113.4 percent and 24.6 percent for the three and nine months ended September 30, 2023, respectively, primarily driven by the non-deductible acquired IPR&D charges in the third quarter of 2023. The effective tax rates were 7.3 percent and 8.6 percent for the three and nine months ended September 30, 2022, respectively, reflecting the favorable tax impacts of net investment losses on equity securities and an intangible asset impairment charge.

At September 30, 2023 and December 31, 2022, prepaid expenses and other current assets included prepaid taxes of $4.08 billion and $2.37 billion, respectively.

The U.S. examination of tax years 2016-2018 began in 2019 and remains ongoing. While it is reasonably possible that the Internal Revenue Service (IRS) examination of these tax years could conclude within the next 12 months, final resolution of certain matters is dependent upon several factors, including the potential for formal administrative proceedings. As a result, an estimate of the range of reasonably possible changes in unrecognized tax benefits cannot be made. The IRS commenced its examination of tax years 2019-2021 during the third quarter of 2023.

Note 8: Retirement Benefits

Net pension and retiree health (benefit) cost included the following components:

	Defined Benefit Pension Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Components of net periodic cost:				
Service cost	**$ 72.5**	$ 87.1	**$ 217.8**	$ 264.4
Interest cost	**162.3**	98.9	**486.0**	299.0
Expected return on plan assets	**(264.0)**	(235.1)	**(791.5)**	(711.6)
Amortization of prior service cost	**0.6**	0.6	**1.8**	1.9
Recognized actuarial loss	**30.6**	85.3	**91.5**	256.8
Net periodic cost	**$ 2.0**	$ 36.8	**$ 5.6**	$ 110.5

	Retiree Health Benefit Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Components of net periodic benefit:				
Service cost	**$ 7.9**	$ 11.7	**$ 23.8**	$ 35.0
Interest cost	**15.3**	9.4	**46.0**	28.4
Expected return on plan assets	**(45.5)**	(38.0)	**(136.6)**	(114.1)
Amortization of prior service benefit	**(13.3)**	(13.7)	**(39.7)**	(41.1)
Recognized actuarial (gain) loss	**(1.5)**	0.2	**(4.4)**	0.7
Net periodic benefit	**$ (37.1)**	$ (30.4)	**$ (110.9)**	$ (91.1)

Note 9: Contingencies

We are involved in various lawsuits, claims, government investigations and other legal proceedings that arise in the ordinary course of business. These claims or proceedings can involve various types of parties, including governments, competitors, customers, suppliers, service providers, licensees, employees, or shareholders, among others. These matters may involve patent infringement, antitrust, securities, pricing, sales and marketing practices, environmental, commercial, contractual rights, licensing obligations, health and safety matters, consumer fraud, employment matters, product liability and insurance coverage, among others. The resolution of these matters often develops over a long period of time and expectations can change as a result of new findings, rulings, appeals or settlement arrangements. Legal proceedings that are significant or that we believe could become significant or material are described below.

We are defending against the legal proceedings in which we are named as defendants vigorously. It is not possible to determine the final outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Litigation accruals, environmental liabilities, and the related estimated insurance recoverables are reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets. With respect to the product liability claims currently asserted against us, we have accrued for our estimated exposures to the extent they are both probable and reasonably estimable based on the information available to us. We accrue for certain product liability claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when both probable and reasonably estimable.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of additional product liability and related claims in the future. Due to a very restrictive market for litigation liability insurance, we are self-insured for litigation liability losses for all our currently and previously marketed products.

Patent Litigation

Alimta European Patent Litigation

In Europe, Alimta (pemetrexed) was protected by a patent through June 2021. A number of legal proceedings that were initiated prior to patent expiration are ongoing.

Emgality Patent Litigation

We are a named defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various claims in three different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults.

Following a trial, in November 2022, a jury returned a verdict in favor of Teva. In September 2023, the court granted our motion to overrule the jury verdict and found all asserted claims of the three patents invalid. Teva has appealed the decision. This matter is ongoing.

In June 2021, we were named as a defendant in a second litigation filed by Teva in the U.S. District Court for the District of Massachusetts seeking a ruling that two of Teva's patents, which are directed toward use of the active ingredient in Emgality to treat migraine, would be infringed by our continued sales of Emgality. We challenged these two patents by filing requests for Inter Partes Review with the Patent Trial and Appeal Board (PTAB) and in October 2022, the PTAB granted our requests. In September 2023, the PTAB issued decisions finding all claims of both patents invalid. Teva may appeal the decision. The corresponding district court litigation is stayed while this PTAB proceeding is ongoing.

Jardiance Patent Litigation

In November 2018, Boehringer Ingelheim, our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court for the District of Delaware alleging infringement arising from submissions of Abbreviated New Drug Applications (ANDA) by a number of generic companies seeking approval to market generic versions of Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Particularly with respect to Jardiance, the generic companies' ANDAs seek approval to market generic versions of Jardiance prior to the expiration of the relevant patents, and allege that certain patents are invalid or would not be infringed. We are not a party to this litigation. This matter is ongoing.

Environmental Proceedings

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as "Superfund," we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

Other Matters

Actos® Litigation

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) in a third party payor class action in the U.S. District Court for the Central District of California (*Painters et al. v. Takeda et al.*). Plaintiffs claim that they and similarly situated class members are entitled to recover money paid for or to reimburse Actos prescriptions because of alleged concealment of bladder cancer risk. Our agreement with Takeda calls for Takeda to defend and indemnify us against our losses and expenses with respect to U.S. litigation arising out of the manufacture, use, or sale of Actos and other related expenses in accordance with the terms of the agreement. In August 2023, the Ninth Circuit granted our and Takeda's petition for permission to appeal the class certification order. This matter is ongoing. Actos is a registered trademark of Takeda Pharmaceutical Company Limited.

340B Litigation and Investigations

We are the plaintiff in a lawsuit filed in January 2021 in the U.S. District Court for the Southern District of Indiana against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, the Health Resources and Services Administration (HRSA), and the Administrator of HRSA. The lawsuit challenges HHS's December 30, 2020 advisory opinion stating that drug manufacturers are required to deliver discounts under the 340B program to all contract pharmacies and HHS's Administrative Dispute Resolution regulations. We seek a declaratory judgment that the defendants violated the Administrative Procedure Act and the U.S. Constitution, a preliminary injunction enjoining implementation of the administrative dispute resolution process created by defendants and, with it, their application of the advisory opinion, and other related relief. In March 2021, the court entered an order preliminarily enjoining the government's enforcement of the administrative dispute resolution process against us. In May 2021, HRSA sent us an enforcement letter notifying us that it determined that our policy was contrary to the 340B statute. In response, in May 2021, we amended our complaint to bring claims related to HRSA's determination and filed a motion for preliminary injunction and temporary restraining order requesting that the U.S. District Court for the Southern District of Indiana enjoin defendants from taking any action against us relating to the 340B drug pricing program until after the court issues a final judgment on the aforementioned litigation. In May 2021, the court denied our motion for a temporary restraining order but deferred resolution of our motion for preliminary injunction. In June 2021, the defendants withdrew the HHS December 30, 2020 advisory opinion. In July 2021, the court held oral argument on the parties' cross motions for summary judgment, the defendants' motion to dismiss, and our motion for preliminary injunction related to HRSA's May 2021 enforcement letter. In October 2021, the court denied the defendants' motion to dismiss, and granted in part and denied in part the parties' cross motions for summary judgment. Both parties filed notices of appeal related to the court's summary judgment order. In October 2022, the U.S. Court of Appeals for the Seventh Circuit held oral argument. This matter is ongoing.

We, along with other pharmaceutical manufacturers, have been named as a defendant in petitions filed in 2021 and 2023 and currently pending before the HHS Administrative Dispute Resolution Panel. Petitioners seek declaratory, injunctive, and/or monetary relief related to the 340B program. As described above, the U.S. District Court for the Southern District of Indiana has entered a preliminary injunction enjoining the government's enforcement of this administrative dispute resolution process against us.

In July 2021, we, along with Sanofi-Aventis U.S., LLC (Sanofi), Novo Nordisk Inc. (Novo Nordisk), and AstraZeneca Pharmaceuticals LP (AstraZeneca), were named as a defendant in a purported class action lawsuit filed in the U.S. District Court for the Western District of New York by Mosaic Health, Inc. alleging antitrust and unjust enrichment claims related to the defendants' 340B distribution programs. We, with Sanofi, Novo Nordisk, and AstraZeneca, filed a motion to dismiss the lawsuit, which was granted in September 2022. In October 2022, the plaintiffs filed a motion for leave to amend their complaint. This matter is ongoing.

We received a civil investigative subpoena in February 2021 from the Office of the Attorney General for the State of Vermont relating to the sale of pharmaceutical products to Vermont covered entities under the 340B program. We are cooperating with this subpoena.

Branchburg Manufacturing Facility

In May 2021, we received a subpoena from the U.S. Department of Justice requesting the production of certain documents relating to our manufacturing site in Branchburg, New Jersey. We are cooperating with the subpoena.

Brazil Litigation – Cosmopolis Facility

Labor Attorney Litigation

First initiated in 2008, our subsidiary in Brazil, Eli Lilly do Brasil Limitada (Lilly Brasil), is named in a Public Civil Action brought by the Labor Public Attorney (LPA) for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, (the Labor Court) alleging possible harm to employees and former employees caused by alleged exposure to soil and groundwater contaminants at a former Lilly Brasil manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. In May 2014, the Labor Court judge ruled against Lilly Brasil, ordering it to undertake several remedial and compensatory actions including health coverage for a class of individuals and certain of their children. In July 2018, the appeals court (TRT) generally affirmed our appeal of the Labor Court's ruling, which included a liquidated award of 300 million Brazilian reais, which, when adjusted for inflation and the addition of pre and post judgment interest using the current Central Bank of Brazil's special system of clearance and custody rate, is approximately 1.24 billion Brazilian reais (approximately $247 million as of September 30, 2023). In August 2019, Lilly Brasil filed an appeal to the superior labor court (TST) and in June 2021, the TRT published its decision on the admissibility of Lilly Brasil's appeal, allowing the majority of the elements, which were allowed to proceed in June 2021; elements not proceeding are subject to an interlocutory appeal to the TST that was filed in June 2021. In September 2019, the TRT stayed a number of elements of its trial court decision pending the determination of Lilly Brasil's appeal to the TST. A mediation hearing is scheduled for November 2023.

In June 2019 and September 2020, the LPA filed applications in the Labor Court for enforcement of certain remedies granted by the TRT in its July 2018 decision, requested restrictions on Lilly Brasil’s assets in Brazil, and required Lilly Brasil and Antibióticos do Brasil Ltda. (ABL) to submit a list of potential beneficiaries of the Public Civil Action. In July 2019, the Labor Court issued a ruling requiring a freeze of Lilly Brasil’s immovable property or, alternatively, a security deposit or lien of 500 million Brazilian reais, which ruling in June 2021 was limited in scope and the security was reduced to 100 million Brazilian reais (approximately $20 million as of September 30, 2023). ABL and LPA appealed the June 2021 Labor Court ruling to the TST, which appeal is under review. The Labor Court is currently assessing the status of Lilly Brasil’s and ABL’s compliance with such portion of the July 2018 TRT decision and an inspection in the industrial plant occurred in October 2023. These matters are ongoing.

Individual Former Employee Litigation

Lilly Brasil is also named in various pending lawsuits filed in the Labor Court by individual former employees making related claims. These individual lawsuits are at various stages in the litigation process.

Puerto Rico Tax Matter

In May 2013, the Municipality of Carolina in Puerto Rico (Municipality) filed a lawsuit against us alleging noncompliance with respect to a contract with the Municipality and seeking a declaratory judgment. In December 2020, the Puerto Rico Appellate Court (AP) reversed the summary judgment previously granted by the Court of First Instance (CFI) in our favor, dismissing the Municipality's complaint in its entirety. The AP remanded the case to the CFI for trial on the merits. The trial began in May 2022; however, the Municipality filed a new motion requesting the CFI to execute an alleged judgment. The request was denied by the CFI in our favor and the Municipality filed for revision at the AP, which we opposed, staying the case. The AP denied the Municipality's motion for revision. This matter is ongoing and trial is expected to resume in mid-2024.

Average Manufacturer Price Litigation

In November 2014, we, along with another pharmaceutical manufacturer, were named as co-defendants in *United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al.*, which was filed in November 2014 and unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating average manufacturer prices. Following a trial in August 2022, the jury returned a verdict in favor of the plaintiff. Lilly filed its notice of appeal to the Seventh Circuit in June 2023. This matter is ongoing.

Health Choice Alliance

We are named as a defendant in two lawsuits filed in Texas and New Jersey state courts in October 2019 seeking damages under the Texas Medicaid Fraud Prevention Act and New Jersey Medicaid False Claims Act, respectively, for certain patient support programs related to our products Humalog, Humulin, and Forteo. The Texas state court action has been stayed. The New Jersey state court action was dismissed with prejudice pending an ongoing appeal before the Appellate Division of the New Jersey Superior Court. Oral argument before the Appellate Division in the New Jersey state court action is scheduled to take place in November 2023. This matter is ongoing.

Pricing Litigation

We, along with Sanofi, Novo Nordisk, and, in some matters, certain pharmacy benefit managers, have been named in numerous lawsuits, including putative class actions, by states and state attorneys general, counties, municipalities, third-party payers, consumers, and other parties related to insulin pricing and rebates paid by manufacturers to pharmacy benefit managers. These lawsuits assert various theories, including consumer protection and deceptive trade practice, fraud, false advertising, unjust enrichment, civil conspiracy, federal and state RICO statutes, antitrust, and unfair competition claims. These lawsuits have been brought in various state and federal courts from 2017 through 2023 and are at various stages in the litigation process. Starting in August 2023 after a ruling by the Judicial Panel for Multi-District Litigation, several of these cases were transferred to or filed in the District of New Jersey for coordinated or consolidated pre-trial proceedings.

Investigations, Subpoenas, and Inquiries

In connection with the pricing and sale of our insulin and other products, we have been subject to various investigations and received subpoenas, civil investigative demand requests, information requests, interrogatories, and other inquiries from various governmental entities. These include subpoenas from the New York and Vermont Attorney General Offices, civil investigative demands from the Washington, New Mexico, Colorado, Louisiana, Texas and Ohio Attorney General Offices, the U.S. Department of Justice, and the U.S. Federal Trade Commission, as well as information requests from the Mississippi, Washington D.C., California, Florida, Hawaii, and Nevada Attorney General Offices. In May 2023, Lilly entered into a non-monetary settlement agreement with the New York Attorney General's office that resolved all matters related to New York's insulin pricing subpoena.

In January 2022, the Michigan Attorney General filed a petition in Michigan state court seeking authorization to investigate Lilly for potential violations of the Michigan Consumer Protection Act (MCPA), and a complaint seeking a declaratory judgment that the Attorney General has authority to investigate Lilly's sale of insulin under the MCPA. The court authorized the proposed investigation and the issuance of civil investigative subpoenas. In April 2022, the parties entered into a stipulation providing that the State of Michigan will not issue any civil investigative subpoena to us under the MCPA until the declaratory judgment action is resolved. In July 2022, the court dismissed the case in its entirety. In June 2023, the Michigan Court of Appeals affirmed the judgment in our favor. In August 2023, the Michigan Attorney General filed an application for leave to appeal to the Michigan Supreme Court, which we opposed in September 2023.

We received a request in January 2019 from the House of Representatives' Committee on Oversight and Reform seeking commercial information and business records related to the pricing of insulin products, among other issues. We also received similar requests from the Senate Finance Committee and the Senate Committee on Health, Education, Labor, and Pensions, and separate requests from the House Committee on Energy and Commerce majority and minority members. In January 2021, the Senate Finance Committee released a report summarizing the findings of its investigation. In December 2021, the House of Representatives' Committee on Oversight and Reform majority and minority staffs released separate reports with findings from their investigations into drug pricing, including of insulin products.

We are cooperating with all of the aforementioned investigations, subpoenas, and inquiries.

Research Corporation Technologies, Inc.

In April 2016, we were named as a defendant in litigation filed by Research Corporation Technologies, Inc. (RCT) in the U.S. District Court for the District of Arizona. RCT is seeking damages for breach of contract, unjust enrichment, and conversion related to processes used to manufacture certain products, including Humalog and Humulin. In October 2021, the court issued a summary judgment decision in favor of RCT on certain issues, including with respect to a disputed royalty. Both parties filed motions for reconsideration, which were denied. We filed supplemental summary judgment motions, which the court denied. A trial date has not been set. Potential damages payable under the litigation, if finally awarded after an appeal, could be material but are not currently reasonably estimable. This matter is ongoing.

Note 10: Other Comprehensive Income (Loss)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the three months ended September 30, 2023 and 2022:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Net Unrealized Gains (Losses) on Available-For-Sale Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Net Unrealized Gains (Losses) on Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at July 1, 2023	**$ (1,885.3)**	**$ (33.5)**	**$ (2,058.8)**	**$ 188.9**	**$ (3,788.7)**
Other comprehensive income (loss) before reclassifications	**(88.7)**	**(13.5)**	**10.5**	**79.6**	**(12.1)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**1.4**	**13.0**	**1.5**	**15.9**
Net other comprehensive income (loss)	**(88.7)**	**(12.1)**	**23.5**	**81.1**	**3.8**
Balance at September 30, 2023	**$ (1,974.0)**	**$ (45.6)**	**$ (2,035.3)**	**$ 270.0**	**$ (3,784.9)**

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Net Unrealized Gains (Losses) on Available-For-Sale Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Net Unrealized Gains (Losses) on Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at July 1, 2022	$ (1,844.2)	$ (27.9)	$ (2,443.2)	$ 27.6	$ (4,287.7)
Other comprehensive income (loss) before reclassifications	(165.1)	(24.9)	47.8	63.0	(79.2)
Net amount reclassified from accumulated other comprehensive loss	—	13.5	57.2	0.4	71.1
Net other comprehensive income (loss)	(165.1)	(11.4)	105.0	63.4	(8.1)
Balance at September 30, 2022	$ (2,009.3)	$ (39.3)	$ (2,338.2)	$ 91.0	$ (4,295.8)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the nine months ended September 30, 2023 and 2022:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Net Unrealized Gains (Losses) on Available-For-Sale Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Net Unrealized Gains (Losses) on Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2023	**$ (1,874.2)**	**$ (37.1)**	**$ (2,062.3)**	**$ 129.0**	**$ (3,844.6)**
Other comprehensive income (loss) before reclassifications	**(74.6)**	**(11.3)**	**(11.9)**	**135.8**	**38.0**
Net amount reclassified from accumulated other comprehensive loss	**(25.2)**	**2.8**	**38.9**	**5.2**	**21.7**
Net other comprehensive income (loss)	**(99.8)**	**(8.5)**	**27.0**	**141.0**	**59.7**
Balance at September 30, 2023	**$ (1,974.0)**	**$ (45.6)**	**$ (2,035.3)**	**$ 270.0**	**$ (3,784.9)**

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Net Unrealized Gains (Losses) on Available-For-Sale Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Net Unrealized Gains (Losses) on Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2022	$ (1,550.2)	$ 3.7	$ (2,583.6)	$ (213.0)	$ (4,343.1)
Other comprehensive income (loss) before reclassifications	(459.7)	(55.5)	72.9	297.2	(145.1)
Net amount reclassified from accumulated other comprehensive loss	0.6	12.5	172.5	6.8	192.4
Net other comprehensive income (loss)	(459.1)	(43.0)	245.4	304.0	47.3
Balance at September 30, 2022	$ (2,009.3)	$ (39.3)	$ (2,338.2)	$ 91.0	$ (4,295.8)

The tax effects on the net activity related to each component of other comprehensive income (loss) were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Tax benefit (expense)	**2023**	**2022**	**2023**	**2022**
Foreign currency translation gains/losses	**$ (90.3)**	$ (133.3)	**$ (50.2)**	$ (234.2)
Net unrealized gains/losses on available-for-sale securities	**3.5**	3.4	**2.5**	13.1
Defined benefit pension and retiree health benefit plans	**(6.9)**	(22.4)	**(13.9)**	(73.2)
Net unrealized gains/losses on cash flow hedges	**(21.6)**	(16.9)	**(37.5)**	(80.8)
Benefit (expense) for income taxes allocated to other comprehensive income (loss) items	**$ (115.3)**	$ (169.2)	**$ (99.1)**	$ (375.1)

Except for the tax effects of foreign currency translation gains and losses related to our foreign currency-denominated notes, cross-currency interest rate swaps, and other foreign currency exchange contracts designated as net investment hedges (see Note 6), income taxes were not provided for foreign currency translation. Generally, the assets and liabilities of foreign operations are translated into U.S. dollars using the current exchange rate. For those operations, changes in exchange rates generally do not affect cash flows; therefore, resulting translation adjustments are made in shareholders' equity rather than in the consolidated condensed statements of operations.

Reclassifications out of accumulated other comprehensive loss were as follows:

Details about Accumulated Other Comprehensive Loss Components	**Three Months Ended September 30, 2023**	**Three Months Ended September 30, 2022**	**Nine Months Ended September 30, 2023**	**Nine Months Ended September 30, 2022**	**Affected Line Item in the Consolidated Condensed Statements of Operations**
Amortization of retirement benefit items:					
Prior service benefits, net	**$ (12.7)**	$ (13.1)	**$ (37.9)**	$ (39.2)	Other–net, (income) expense
Actuarial losses, net	**29.1**	85.5	**87.1**	257.5	Other–net, (income) expense
Total before tax	**16.4**	72.4	**49.2**	218.3	
Tax benefit	**(3.4)**	(15.2)	**(10.3)**	(45.8)	Income taxes
Net of tax	**13.0**	57.2	**38.9**	172.5	
Other, net of tax	**2.9**	13.9	**(17.2)**	19.9	Other–net, (income) expense
Total reclassifications, net of tax	**$ 15.9**	$ 71.1	**$ 21.7**	$ 192.4	

Note 11: Other–Net, (Income) Expense

Other–net, (income) expense consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Interest expense	**$ 124.6**	$ 81.5	**$ 347.7**	$ 247.6
Interest income	**(48.9)**	(20.1)	**(129.1)**	(37.3)
Net investment losses on equity securities (Note 6)	**62.9**	123.3	**141.5**	667.6
Retirement benefit plans	**(115.5)**	(92.4)	**(346.9)**	(280.0)
Other (income) expense	**0.1**	18.7	**11.1**	(17.0)
Other–net, (income) expense	**$ 23.2**	$ 111.0	**$ 24.3**	$ 580.9

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

(Tables present dollars in millions, except per-share data)

General

Management's discussion and analysis of results of operations and financial condition is intended to assist the reader in understanding and assessing significant changes and trends related to our results of operations and financial position. This discussion and analysis should be read in conjunction with the consolidated condensed financial statements and accompanying footnotes in Part I, Item 1 of this Quarterly Report on Form 10-Q. Certain statements in this Part I, Item 2 of this Quarterly Report on Form 10-Q constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" in this Quarterly Report on Form 10-Q and "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

EXECUTIVE OVERVIEW

This section provides an overview of our financial results, late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry.

Financial Results

The following table summarizes certain financial information:

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2023	2022		2023	2022	
Revenue	**$ 9,498.6**	$ 6,941.6	37	**$ 24,770.7**	$ 21,239.6	17
Net income (loss)	**(57.4)**	1,451.7	NM	**3,050.7**	4,307.1	(29)
Earnings (loss) per share - diluted	**(0.06)**	1.61	NM	**3.38**	4.76	(29)

NM - not meaningful

Revenue increased for the three months ended September 30, 2023 driven by increased volume, higher realized prices and the favorable impact of foreign exchange rates. Revenue increased for the nine months ended September 30, 2023 primarily driven by increased volume. The increase in revenue during the three and nine months ended September 30, 2023 was primarily driven by sales of Mounjaro® and Verzenio®, as well as from the sale of the rights for the olanzapine portfolio, including Zyprexa®, partially offset by the absence of COVID-19 antibodies revenue. Revenue for the nine months ended September 30, 2023 was also driven by the sale of rights for Baqsimi®, largely offset by lower sales of Alimta® following the entry of multiple generics in the first half of 2022.

Net income (loss) and earnings (loss) per share for the three and nine months ended September 30, 2023 decreased primarily due to higher acquired in-process research and development (IPR&D) charges and increased research and development and marketing, selling, and administrative expenses, partially offset by increased revenue.

See "Results of Operations" for additional information.

Late-Stage Pipeline

Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. We currently have approximately 45 new medicine candidates in clinical development or under regulatory review, and a larger number of projects in the discovery phase.

The following select new molecular entities (NMEs) and new indication line extension (NILEX) products are currently in Phase II or Phase III clinical trials or have been submitted for regulatory review or have received regulatory approval in the United States (U.S.), European Union (EU), or Japan. The table reflects the status of these NMEs and NILEX products, including relevant developments since our Annual Report on Form 10-K for the year ended December 31, 2022.

Compound	Indication/Study	Status	Developments
Diabetes and Obesity			
Empagliflozin (Jardiance®)[1]	Chronic kidney disease	Approved	Approved in the U.S. and in the EU in the third quarter of 2023. Submitted in Japan in 2022.
Tirzepatide	Obesity	Submitted	Submitted in the EU in the first quarter of 2023 and in the U.S. in the second quarter of 2023. Received Priority Review designation from the U.S. Food and Drug Administration (FDA). Announced in the second and third quarters of 2023 that Phase III trials met all primary and key secondary endpoints. Phase III trials are ongoing.
	Cardiovascular outcomes in type 2 diabetes	Phase III	Phase III trial is ongoing.
	Heart failure with preserved ejection fraction	Phase III	Phase III trials are ongoing.
	Morbidity and mortality in obesity	Phase III	Phase III trial is ongoing.
	Obstructive sleep apnea (OSA)	Phase III	Granted FDA Fast Track designation[2]. Phase III trial is ongoing.
	Higher doses	Phase II	Phase II trial initiated in the third quarter of 2023.
	Nonalcoholic steatohepatitis	Phase II	Phase II trial is ongoing.
Insulin Efsitora Alfa	Type 1 and 2 diabetes	Phase III	Phase III trials are ongoing.
Orforglipron	Obesity	Phase III	Phase III trials initiated in the second quarter of 2023.
	Type 2 diabetes	Phase III	Phase III trials initiated in the second and third quarters of 2023.
Retatrutide	Obesity, osteoarthritis, OSA	Phase III	Phase III trials initiated in the second and third quarters of 2023.
	Type 2 diabetes	Phase II	Phase II trial was completed.
Bimagrumab	Obesity	Phase II	Acquired in the acquisition of Versanis Bio, Inc. (Versanis) in the third quarter of 2023. Phase II trial is ongoing.
Lepodisiran	Cardiovascular disease	Phase II	Phase II trial is ongoing.
Muvalaplin	Cardiovascular disease	Phase II	Phase II trial is ongoing.
Solbinsiran	Cardiovascular disease	Phase II	Phase II trial is ongoing.
Volenrelaxin (Relaxin-LA)	Heart failure	Phase II	Phase II trial initiated in the first quarter of 2023.

Compound	Indication/Study	Status	Developments
Immunology			
Mirikizumab (Omvoh™)	Ulcerative colitis	Approved	Approved in Japan in the first quarter of 2023, in the EU in the second quarter of 2023, and in the U.S. in October 2023.
	Crohn's Disease	Phase III	Announced in October 2023 that a Phase III trial met the co-primary and all major secondary endpoints versus placebo. Phase III trials are ongoing.
Lebrikizumab[3]	Atopic dermatitis	Submitted	Submitted in the U.S. and the EU in 2022 and in Japan in the first quarter of 2023. Announced in October 2023 we received a complete response letter from the FDA based on inspection findings at a third-party manufacturer with no stated concerns about the clinical data package, safety, or label. Phase III trials are ongoing.
DC-806	Psoriasis	Phase II	Acquired in the acquisition of DICE Therapeutics, Inc. (DICE) in the third quarter of 2023. Phase II trial is ongoing.
Eltrekibart	Hidradenitis suppurativa	Phase II	Phase II trial is ongoing.
Peresolimab	Rheumatoid arthritis	Phase II	Phase II trial is ongoing.
RIPK1 inhibitor	Rheumatoid arthritis	Phase II	Phase II trial initiated in the second quarter of 2023.
Ucenprubart	Atopic dermatitis	Phase II	Phase II trial initiated in the second quarter of 2023.
BTLA MAB Agonist	Systemic lupus erythematosus	Discontinued	Phase II trial failed to demonstrate efficacy in the third quarter of 2023.
Neuroscience			
Donanemab	Early Alzheimer's disease	Submitted	Submitted for traditional approval in the U.S. in the second quarter of 2023 and in the EU and Japan in the third quarter of 2023. Granted FDA Breakthrough Therapy designation[4]. Announced in the second quarter of 2023 that a Phase III trial met primary and all secondary endpoints. Phase III trials are ongoing.
	Preclinical Alzheimer's disease	Phase III	Phase III trial is ongoing.
Remternetug	Early Alzheimer's disease	Phase III	Phase III trial is ongoing.
GBA1 Gene Therapy	Gaucher disease Type 1	Phase II	Phase II trial initiated in the second quarter of 2023.
	Parkinson's disease	Phase II	Granted FDA Fast Track designation[2]. Phase II trial is ongoing.
GRN Gene Therapy	Frontotemporal dementia	Phase II	Granted FDA Fast Track designation[2]. Phase II trial is ongoing.
O-GlcNAcase Inh	Alzheimer's disease	Phase II	Phase II trial is ongoing.
P2X7 Inhibitor	Pain	Phase II	Phase II trials were recently completed.
SSTR4 Agonist	Pain	Phase II	Phase II trials are ongoing.

Compound	Indication/Study	Status	Developments
Oncology			
Pirtobrutinib (Jaypirca®)	Mantle cell lymphoma	Approved[5]	FDA granted accelerated approval[5] in the U.S. in the first quarter of 2023. Submitted in the EU in 2022 and in Japan in the second quarter of 2023. Received a positive opinion from the Committee for Medicinal Products for Human Use in the EU in the second quarter of 2023. Phase III trial is ongoing.
	Chronic lymphocytic leukemia	Submitted	Submitted in the U.S. in the third quarter of 2023 under the accelerated approval pathway. Phase III trials are ongoing.
Selpercatinib (Retevmo®)	Lung cancer	Approved	Announced in the third quarter of 2023 that a Phase III trial met its primary endpoint. Phase III trial is ongoing.
	Thyroid cancer	Approved	Announced in the third quarter of 2023 that a Phase III trial met its primary endpoint.
Abemaciclib	Prostate cancer	Phase III	Phase III trials are ongoing.
Imlunestrant	Adjuvant breast cancer	Phase III	Phase III trial is ongoing.
	ER+HER2- metastatic breast cancer	Phase III	Phase III trial is ongoing.

[1] In collaboration with Boehringer Ingelheim.
[2] Fast Track designation is designed to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need.
[3] In collaboration with Almirall, S.A. in Europe.
[4] Breakthrough Therapy designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.
[5] Continued approval may be contingent on verification and description of clinical benefit in confirmatory Phase III trials.

Other Matters

Patent Matters

We depend on patents or other forms of intellectual property protection for most of our revenue, cash flows, and earnings.

See Note 9 to the consolidated condensed financial statements for a description of legal proceedings currently pending regarding certain of our patents.

Our compound patents for Humalog® (insulin lispro) have expired in the U.S. and major international markets, and we have also introduced lower-priced versions of Humalog as part of our insulin access and affordability solutions. On March 1, 2023, we announced price reductions for Humalog and an expansion of our Insulin Value Program that caps patient out-of-pocket costs at $35 or less per month. A competitor has a similar version of insulin lispro in the U.S. and in certain European markets. Due to the expansion of our insulin access and affordability solutions in the U.S. and the impact of competition and pricing pressure in the U.S. and certain international markets, we expect that lower revenue for Humalog due to realized price decline will continue over time.

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

Reforms, including those that may stem from periods of economic downturn or uncertainty, or as a result of high inflation, emergence or escalation of, and responses to, war or unrest, or government budgeting priorities, may continue to result in added pressure on pricing and reimbursement for our products.

Global concern over access to and affordability of pharmaceutical products continues to drive regulatory and legislative debate and action, as well as worldwide cost containment efforts by governmental authorities. Such measures include the use of mandated discounts, price reporting requirements, mandated reference prices, restrictive formularies, changes to available intellectual property protections, as well as other efforts. In August 2022, the U.S. government enacted the Inflation Reduction Act of 2022 (IRA). Among other measures, the IRA requires the U.S. Department of Health and Human Services (HHS) to effectively set prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D. Generally, these government prices apply nine (medicines approved under a New Drug Application) or thirteen (medicines approved under a Biologics License Application) years following initial FDA approval and will be capped at a statutory ceiling price that is likely to represent a significant discount from average prices to wholesalers and direct purchasers. While the law specifies a ceiling price, it does not set a minimum or floor price. In August 2023, HHS selected Jardiance, which is part of our collaboration with Boehringer Ingelheim, as one of the first ten medicines subject to government-set prices effective in 2026. Given our product portfolio, we expect additional of our significant products will be selected in future years, which would have the effect of accelerating revenue erosion prior to patent expiry. The effect of reducing prices and reimbursement for certain of our products would significantly impact our business and consolidated results of operations. The establishment of payment limits or other restrictions by drug affordability review boards and other state level actors would similarly impact us.

Other IRA provisions provide for rebate obligations on drug manufacturers that increase prices of Medicare Part B and Part D medicines at a rate greater than the rate of inflation and Part D benefit redesign that includes replacing the Part D coverage gap discount program with a new manufacturer discounting program. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties, which could be significant.

The IRA takes effect progressively with the first government-set prices effective in 2026. The IRA has and will meaningfully influence our business strategies and those of our competitors. In particular, the nine-year timeline to set prices for medicines approved under a new drug application reduces the attractiveness of investment in small molecule innovation. The IRA can cause changes to development approach and timing and investments at-risk. The full impact of the IRA on our business and the pharmaceutical industry, including the implications to us of competitors' products being selected for price setting, remains uncertain.

Additional policies, regulations, legislation, or enforcement, including those proposed and/or pursued by the U.S. Congress, the current U.S. presidential administration, and regulatory authorities worldwide, could adversely impact our business and consolidated results of operations.

Consolidation and integration of private payors and pharmacy benefit managers in the U.S. has also significantly impacted the market for pharmaceuticals by increasing payor leverage in negotiating manufacturer price or rebate concessions and pharmacy reimbursement rates. Furthermore, restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, courts, or private payers may adversely impact our business and consolidated results of operations. We expect that these actions may intensify and could particularly affect certain products which could adversely affect our business. In addition, we are engaged in litigation related to our 340B limited distribution program, access to insulin, and other matters that, if resolved adversely to us, could negatively impact our business and consolidated results of operations. It is not currently possible to predict the overall potential adverse impact to us or the general pharmaceutical industry of continued cost containment efforts worldwide.

In addition, regulatory issues concerning compliance with current Good Manufacturing Practices, quality assurance, safety signals, evolving standards, and increased scrutiny around excipients and potential impurities such as nitrosamines, and similar regulations and standards (and comparable foreign regulations and standards) for our products can lead to regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, contractual and manufacturing costs or penalties, inability to realize the benefit of capital expenditures, or delays or denials in new product approvals, line extensions or supplemental approvals of current products pending resolution of the issues, any of which could result in reputational harm or adversely affect our business. Moreover, increased focus on business combinations across industries and jurisdictions can lead to impediments to the completion of business combinations.

See "Business—Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access" in Part I, Item 1 and "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022. See also Note 9 to the consolidated condensed financial statements.

Product Supply

We have faced challenges, and expect to continue to face challenges, meeting strong demand for our incretin products. In the U.S., given very strong uptake of Mounjaro following its launch for type 2 diabetes in the second quarter of 2022, and as demand for Trulicity® has remained strong, we have experienced intermittent delays in fulfilling certain orders for these products. Outside the U.S., we have implemented actions to manage strong demand amid tight supply, including measures to minimize impact to existing Trulicity patients. We have also progressed efforts to bring tirzepatide to patients via different delivery presentations outside the U.S., such as single-use vials and multi-use pens. We expect to continue to experience disruptions in our supply of Trulicity in international markets and for demand and supply considerations to influence the timing of tirzepatide launches in new markets.

We anticipate tight supplies of our incretin products will persist while additional manufacturing capacity is operationalized. We expect additional internal and contracted manufacturing capacity will become fully operational around the world in the next several years as part of our ongoing efforts to meet the significant demand for our incretin medicines. For example, we recently began production at our Research Triangle Park site in North Carolina and expect to continue significant capacity expansion over time as we increase production at this site and others.

Tax Matters

We are subject to income taxes and various other taxes in the U.S. and in many foreign jurisdictions; therefore, changes in both domestic and international tax laws or regulations have affected and may affect our effective tax rate, results of operations, and cash flows. The U.S. and countries around the world are actively proposing and enacting tax law changes. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co-operation and Development and the European Commission could influence tax laws in countries in which we operate. Tax authorities in the U.S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions. Changes to existing U.S. and foreign tax laws and increased scrutiny by tax authorities in the U.S. and other jurisdictions could adversely impact our future consolidated results of operations and cash flows.

The European Commission published its Pillar Two Directive (Directive), a legislative proposal that would provide a global minimum level of taxation for multinational companies with operations in the EU, in 2021. In 2022, the EU Member States adopted the Directive which requires them to enact initial legislation effective for years beginning on or after December 31, 2023. Currently, both EU and non-EU countries are drafting or have enacted legislation in order to implement the Pillar Two rules by the effective date. We are continuing to follow Pillar Two legislative developments in order to evaluate the potential future impact it could have on our consolidated results of operations, financial position, and cash flows.

Foreign Currency Exchange Rates and Other Impacts

As a global company, we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro, Japanese yen, and Chinese yuan. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our consolidated results of operations in any given period. There is uncertainty in the future movements in foreign exchange rates, and fluctuations in these rates could adversely impact our consolidated results of operations and cash flows.

Other factors have had, and may continue to have, an impact on our consolidated results of operations. These factors include cost and wage inflation, availability of adequate capacity in global transportation, supply chain and labor market complexities, international tension and conflicts, global economic downturns or uncertainty, and an increase in overall demand in our industry for certain products and materials.

Acquisitions

We invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including acquisitions, collaborations, investments, and licensing arrangements. We view our business development activity as a way to enhance our pipeline and strengthen our business.

In the third quarter, we completed acquisitions of DICE, Versanis, and Emergence Therapeutics AG (Emergence) for an aggregate $2.98 billion, net of cash acquired.

In October 2023, we announced an agreement to acquire POINT Biopharma Global Inc. (POINT) for a purchase price of $12.50 per share in cash (an aggregate of approximately $1.4 billion) payable at closing. The proposed acquisition is subject to customary closing conditions, including the tender of a majority of the outstanding shares of POINT's common stock, the receipt of required antitrust clearance, and license transfer approval from the U.S. Nuclear Regulatory Commission.

See Note 3 to the consolidated condensed financial statements for further discussion regarding our recent and proposed acquisitions.

See "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 for additional information on risk factors that could impact our business and operations.

RESULTS OF OPERATIONS

Revenue

The following table summarizes our revenue activity by region:

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2023	2022		2023	2022	
U.S.	**$ 5,368.1**	$ 4,422.1	21	**$ 15,335.6**	$ 13,531.5	13
Outside U.S.	**4,130.5**	2,519.4	64	**9,435.0**	7,708.1	22
Revenue	**$ 9,498.6**	$ 6,941.6	37	**$ 24,770.7**	$ 21,239.6	17

Numbers may not add due to rounding.

The following are components of the change in revenue compared with the prior year:

	Three Months Ended September 30, 2023 vs. 2022			Nine Months Ended September 30, 2023 vs. 2022		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	9 %	69 %	31 %	10 %	30 %	17 %
Price	13	(7)	6	3	(5)	—
Foreign exchange rates	—	2	1	—	(2)	(1)
Percent change	21 %	64 %	37 %	13 %	22 %	17 %

Numbers may not add due to rounding.

In the U.S. for the three and nine months ended September 30, 2023, the increase in volume was primarily driven by Mounjaro, Verzenio, Trulicity, Jardiance, and Taltz®, partially offset by the absence of revenue from COVID-19 antibodies. In the U.S. for the nine months ended September 30, 2023, the increase in volume was also driven by $579.0 million from the sale of the rights for Baqsimi during the second quarter of 2023, partially offset by decreased volume from Alimta following the entry of multiple generics in the first half of 2022. In the U.S. for the three and nine months ended September 30, 2023, the higher realized prices were primarily driven by Mounjaro, partially offset by lower realized prices for Trulicity and Humalog. For the three and nine months ended September 30, 2023, the higher realized prices for Mounjaro were due to decreased utilization of savings card programs as access continues to expand. For the three and nine months ended September 30, 2023, the lower realized prices were due to unfavorable segment mix and higher contracted rebates, as well as changes to estimates for rebates and discounts for Trulicity and due to unfavorable segment mix for Humalog.

Outside the U.S. for the three and nine months ended September 30, 2023, the increase in volume was largely driven by $1.42 billion from the sale of the rights for the olanzapine portfolio, including Zyprexa, as well as increased volume for Verzenio. Outside the U.S. for the three and nine months ended September 30, 2023, the lower realized prices were primarily driven by a new supply arrangement associated with the sale of the rights for the olanzapine portfolio, and to a lesser extent, lower realized prices from Verzenio and Trulicity. Outside the U.S. for the nine months ended September 30, 2023, the lower realized prices were also driven by the impact of government pricing in China from volume-based procurement for Humalog.

The following table summarizes our revenue, including net product revenue and collaboration and other revenue, by product for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,				
	2023			2022	
Product	**U.S.**	**Outside U.S.**	**Total**	**Total**	**Percent Change**
Trulicity	**$ 1,259.0**	**$ 414.6**	**$ 1,673.6**	$ 1,850.4	(10)
Zyprexa[1]	**49.9**	**1,431.5**	**1,481.4**	81.4	NM
Mounjaro	**1,277.0**	**132.4**	**1,409.3**	187.3	NM
Verzenio	**684.6**	**355.7**	**1,040.2**	617.7	68
Taltz	**509.3**	**234.9**	**744.2**	679.9	9
Jardiance[2]	**415.9**	**284.8**	**700.8**	573.3	22
Humalog[3]	**194.2**	**201.2**	**395.4**	447.0	(12)
Olumiant®[4]	**65.7**	**165.7**	**231.4**	182.9	27
Cyramza®	**88.0**	**136.1**	**224.1**	232.1	(3)
Humulin®	**145.5**	**61.2**	**206.7**	238.2	(13)
Basaglar® [5]	**111.4**	**68.2**	**179.6**	193.0	(7)
Emgality®	**126.5**	**42.1**	**168.5**	168.5	—
Erbitux®	**134.0**	**19.9**	**153.9**	144.9	6
Forteo®	**101.2**	**45.2**	**146.4**	177.1	(17)
Cialis®	**4.9**	**82.0**	**86.8**	115.7	(25)
Alimta	**21.2**	**32.3**	**53.5**	119.4	(55)
Baqsimi	**3.8**	**9.3**	**13.1**	43.0	(70)
COVID-19 antibodies[6]	**—**	**—**	**—**	386.6	(100)
Other products	**176.0**	**413.4**	**589.7**	503.2	17
Revenue	**$ 5,368.1**	**$ 4,130.5**	**$ 9,498.6**	$ 6,941.6	37

Numbers may not add due to rounding.
NM - not meaningful
[1] Zyprexa revenue includes sale of rights for the olanzapine portfolio.
[2] Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.
[3] Humalog revenue includes insulin lispro.
[4] Olumiant revenue includes sales for baricitinib that were made pursuant to Emergency Use Authorization (EUA) or similar regulatory authorizations.
[5] Basaglar revenue includes Rezvoglar®.
[6] COVID-19 antibodies include sales for bamlanivimab administered alone, for bamlanivimab and etesevimab administered together, and for bebtelovimab and were made pursuant to EUAs or similar regulatory authorizations.

The following table summarizes our revenue, including net product revenue and collaboration and other revenue, by product for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,				
	2023			2022	
Product	**U.S.**	**Outside U.S.**	**Total**	**Total**	**Percent Change**
Trulicity	**$ 4,177.7**	**$ 1,285.6**	**$ 5,463.2**	$ 5,503.5	(1)
Mounjaro	**2,729.1**	**228.4**	**2,957.5**	203.2	NM
Verzenio	**1,734.2**	**983.7**	**2,717.9**	1,675.6	62
Taltz	**1,293.8**	**681.2**	**1,975.0**	1,774.2	11
Jardiance[1]	**1,131.5**	**815.1**	**1,946.6**	1,453.7	34
Zyprexa[2]	**69.1**	**1,581.9**	**1,651.0**	261.7	NM
Humalog[3]	**695.6**	**601.2**	**1,296.8**	1,512.3	(14)
Cyramza	**303.6**	**417.5**	**721.1**	693.6	4
Olumiant[4]	**158.8**	**520.4**	**679.2**	624.7	9
Humulin	**488.6**	**175.4**	**664.0**	785.4	(15)
Baqsimi	**633.1**	**25.4**	**658.4**	101.2	NM
Basaglar[5]	**329.7**	**213.4**	**543.1**	558.7	(3)
Emgality	**354.0**	**138.2**	**492.2**	475.2	4
Erbitux	**398.3**	**48.0**	**446.3**	408.3	9
Forteo	**269.2**	**147.6**	**416.8**	453.0	(8)
Cialis	**21.6**	**281.1**	**302.7**	480.4	(37)
Alimta	**59.2**	**113.5**	**172.6**	691.1	(75)
COVID-19 antibodies[6]	**—**	**—**	**—**	1,985.5	(100)
Other products	**488.5**	**1,177.4**	**1,666.3**	1,598.3	49
Revenue	**$ 15,335.6**	**$ 9,435.0**	**$ 24,770.7**	$ 21,239.6	17

Numbers may not add due to rounding.
NM - not meaningful
[1] Jardiance revenue includes Glyxambi, Synjardy, and Trijardy XR.
[2] Zyprexa revenue includes sale of rights for the olanzapine portfolio.
[3] Humalog revenue includes insulin lispro.
[4] Olumiant revenue includes sales for baricitinib that were made pursuant to EUA or similar regulatory authorizations.
[5] Basaglar revenue includes Rezvoglar.
[6] COVID-19 antibodies include sales for bamlanivimab administered alone, for bamlanivimab and etesevimab administered together, and for bebtelovimab and were made pursuant to EUAs or similar regulatory authorizations.

Revenue of Trulicity decreased 11 percent in the U.S. during the three months ended September 30, 2023, primarily driven by lower realized prices, partially offset by wholesaler buying patterns and increased demand. Revenue of Trulicity remained relatively flat in the U.S. during the nine months ended September 30, 2023, driven by increased demand and wholesaler buying patterns, offset by lower realized prices. The lower realized prices for the three and nine months ended September 30, 2023 were primarily due to unfavorable segment mix and higher contracted rebates, as well as changes to estimates for rebates and discounts, reflecting an unfavorable adjustment in the third quarter of 2023 and a favorable adjustment in the third quarter of 2022. Revenue outside the U.S. decreased 4 percent during the three months ended September 30, 2023, driven by lower realized prices and decreased volume, partially offset by the favorable impact of foreign exchange rates. Revenue outside the U.S. decreased 4 percent during the nine months ended September 30, 2023, driven by lower realized prices and unfavorable impact of foreign exchange rates, partially offset by increased volume. Volumes in international markets were affected by actions we have taken to manage strong demand amid tight supply, including measures to minimize impact to existing patients.

Revenue of Mounjaro in the U.S. during the three and nine months ended September 30, 2023 was $1.28 billion and $2.73 billion, respectively, reflecting increased demand and higher realized prices due to decreased utilization of savings card programs as access continues to expand. During the three and nine months ended September 30, 2023, we experienced intermittent delays fulfilling orders of certain Mounjaro doses given significant demand, which affected volume.

Revenue of Verzenio increased 65 percent and 58 percent in the U.S. during the three and nine months ended September 30, 2023, respectively, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 75 percent and 71 percent during the three and nine months ended September 30, 2023, respectively, driven by increased demand, partially offset by lower realized prices. The increase in revenue outside the U.S. for the nine months ended September 30, 2023 was also partially offset by the unfavorable impact of foreign exchange rates.

Revenue of Taltz increased 3 percent and 7 percent in the U.S. during the three and nine months ended September 30, 2023, respectively, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased 26 percent and 21 percent during the three and nine months ended September 30, 2023, respectively, primarily driven by increased volume, partially offset by lower realized prices.

Revenue of Jardiance increased 19 percent and 36 percent in the U.S. during the three and nine months ended September 30, 2023, respectively, primarily driven by increased demand. Revenue outside the U.S. increased 28 percent and 31 percent during the three and nine months ended September 30, 2023, respectively, primarily driven by increased volume. See Note 4 to the consolidated condensed financial statements for information regarding our collaboration with Boehringer Ingelheim involving Jardiance.

There was no worldwide revenue for COVID-19 antibodies during the three and nine months ended September 30, 2023, and we do not anticipate any revenue from COVID-19 antibodies in 2023.

Gross Margin, Costs, and Expenses

The following table summarizes our gross margin, costs, and expenses:

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2023	2022		2023	2022	
Gross margin	**$ 7,638.5**	$ 5,362.5	42	**$ 19,476.5**	$ 16,157.9	21
Gross margin as a percent of revenue	**80.4 %**	77.3 %		**78.6 %**	76.1 %	
Research and development	**$ 2,409.1**	$ 1,802.9	34	**$ 6,750.7**	$ 5,194.9	30
Marketing, selling, and administrative	**1,803.9**	1,614.2	12	**5,478.5**	4,797.2	14
Acquired IPR&D	**2,975.1**	62.4	NM	**3,177.2**	668.4	NM
Asset impairment, restructuring, and other special charges	**—**	206.5	(100)	**—**	206.5	(100)
Other–net, (income) expense	**23.2**	111.0	(79)	**24.3**	580.9	(96)
Income taxes	**484.6**	113.8	NM	**995.1**	402.9	NM
Effective tax rate	**113.4 %**	7.3 %		**24.6 %**	8.6 %	

NM - not meaningful

Gross margin as a percent of revenue for the three months ended September 30, 2023 increased 3.1 percentage points compared with the three months ended September 30, 2022, primarily driven by the sale of rights for the olanzapine portfolio and the absence of COVID-19 antibodies sales in 2023, as well as higher realized prices, partially offset by increased manufacturing expenses related to labor costs and investments in capacity expansion. Gross margin as a percent of revenue for the nine months ended September 30, 2023 increased 2.5 percentage points compared with the nine months ended September 30, 2022, primarily driven by the absence of COVID-19 antibodies sales in 2023 and the sales of the rights for the olanzapine portfolio and Baqsimi, partially offset by increased manufacturing expenses related to labor costs and investments in capacity expansion.

Research and development expenses increased 34 percent and 30 percent for the three and nine months ended September 30, 2023, respectively, primarily driven by higher development expenses for late-stage assets and additional investments in early-stage research.

Marketing, selling, and administrative expenses increased 12 percent and 14 percent for the three and nine months ended September 30, 2023, respectively, primarily driven by costs associated with launches of new products and indications, as well as compensation and benefits costs.

We recognized $2.98 billion and $3.18 billion of acquired IPR&D charges for the three and nine months ended September 30, 2023, respectively, primarily related to the acquisitions of DICE, Versanis, and Emergence. We recognized $62.4 million and $668.4 million of acquired IPR&D charges for the three and nine months ended September 30, 2022, respectively. The charges for the nine months ended September 30, 2022 primarily related to the buy-out of substantially all future obligations that were contingent upon the occurrence of certain events linked to the success of our mutant-selective PI3kα inhibitor and a purchase of a Priority Review Voucher. See Note 3 to the consolidated condensed financial statements for additional information.

There were no asset impairment, restructuring, and other special charges recognized for the three and nine months ended September 30, 2023. We recognized asset impairment, restructuring, and other special charges of $206.5 million for the three and nine months ended September 30, 2022, primarily related to an intangible asset impairment for GBA1 Gene Therapy due to changes in estimated launch timing. See Note 5 to the consolidated condensed financial statements for additional information.

Other–net, (income) expense included net investment losses on equity securities of $62.9 million and $141.5 million for three and nine months ended September 30, 2023, respectively. Other–net, (income) expense included net investment losses on equity securities of $123.3 million and $667.6 million for three and nine months ended September 30, 2022, respectively. See Note 11 to the consolidated condensed financial statements for additional information.

The effective tax rates were 113.4 percent and 24.6 percent for the three and nine months ended September 30, 2023, respectively, primarily driven by the non-deductible acquired IPR&D charges in the third quarter of 2023. The effective tax rates were 7.3 percent and 8.6 percent for the three and nine months ended September 30, 2022, respectively, reflecting the favorable tax impacts of net investment losses on equity securities and an intangible asset impairment charge.

FINANCIAL CONDITION AND LIQUIDITY

We believe our available cash and cash equivalents, together with our ability to generate operating cash flow and our access to short-term and long-term borrowings, are sufficient to fund our existing and planned capital requirements. For a discussion of our capital requirements, see "Management's Discussion and Analysis of Results of Operations and Financial Condition" in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2022.

We have announced additional investment commitments in new facilities in Indiana, North Carolina, and Limerick, Ireland to manufacture existing and future products. We expect that these investments will result in higher capital expenditures in excess of $8 billion over the next several years.

In the third quarter, we completed acquisitions of DICE, Versanis, and Emergence for an aggregate $2.98 billion, net of cash acquired. These acquisitions were funded primarily through cash on hand and the issuance of commercial paper. See Note 3 to the consolidated condensed financial statements for additional information.

In October 2023, we announced an agreement to acquire POINT for a purchase price of $12.50 per share in cash (an aggregate of approximately $1.4 billion) payable at closing. The proposed acquisition is subject to customary closing conditions, including the tender of a majority of the outstanding shares of POINT's common stock, the receipt of required antitrust clearance, and license transfer approval from the U.S. Nuclear Regulatory Commission. We anticipate funding this acquisition through cash on hand and the issuance of commercial paper.

Cash and cash equivalents increased to $2.38 billion as of September 30, 2023, compared with $2.07 billion as of December 31, 2022. Refer to the consolidated condensed statements of cash flows for additional information on the significant sources and uses of cash for the nine months ended September 30, 2023 and 2022.

In addition to our cash and cash equivalents, we held total investments of $2.80 billion and $3.05 billion as of September 30, 2023 and December 31, 2022, respectively. See Note 6 to the consolidated condensed financial statements for additional information.

As of September 30, 2023, total debt was $20.17 billion, an increase of $3.93 billion compared with $16.24 billion as of December 31, 2022. In February 2023, we issued $750.0 million of 5.000 percent fixed-rate notes due in 2026, which are callable at par after one year, $1.00 billion of 4.700 percent fixed-rate notes due in 2033, $1.25 billion of 4.875 percent fixed-rate notes due in 2053, and $1.00 billion of 4.950 percent fixed-rate notes due in 2063, all with interest to be paid semi-annually. We used the net cash proceeds from the offering of $3.96 billion for general business purposes, including the repayment of outstanding commercial paper. See Note 6 to the consolidated condensed financial statements for additional information.

As of September 30, 2023, we had a total of $7.33 billion of unused committed bank credit facilities, $7.00 billion of which is available to support our commercial paper program. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowing needs.

During the nine months ended September 30, 2023, we repurchased $750.0 million of shares under our $5.00 billion share repurchase program authorized in May 2021. As of September 30, 2023, we had $2.50 billion remaining under this program.

During the nine months ended September 30, 2023, we paid dividends of $3.05 billion, or $3.39 per share, to our shareholders. In November 2023, we declared a dividend for the fourth quarter of 2023 of $1.13 per share on outstanding common stock. The dividend of approximately $1.02 billion is payable on December 8, 2023 to shareholders of record at the close of business on November 15, 2023.

See "Executive Overview—Other Matters—Patent Matters" for information regarding losses of patent protection.

Both domestically and abroad, we continue to monitor the potential impacts of the economic environment; the creditworthiness of our wholesalers and other customers, including foreign government-backed agencies and suppliers; the uncertain impact of healthcare legislation; various international government funding levels; and fluctuations in interest rates, foreign currency exchange rates (see "Executive Overview—Other Matters—Foreign Currency Exchange Rates and Other Impacts"), and fair values of equity securities.

As we expand our manufacturing capacity in order to meet existing and expected demand of our incretin products, we have entered, and expect to continue to enter, into various agreements for contract manufacturing and for supply of materials. The executed agreements could, under certain circumstances, require us to pay up to approximately $8.5 billion if we do not purchase specified amounts of goods or services over the durations of the agreements, which generally range from 2 to 8 years.

CRITICAL ACCOUNTING ESTIMATES

For a discussion of our critical accounting estimates, refer to "Management's Discussion and Analysis of Results of Operations and Financial Condition" in Part II, Item 7 and the notes to our consolidated financial statements in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2022. See also Note 1 to the consolidated condensed financial statements. There have been no material changes to our critical accounting estimates since our Annual Report on Form 10-K for the year ended December 31, 2022.

AVAILABLE INFORMATION ON OUR WEBSITE

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents.

The website link to our SEC filings is **investor.lilly.com/financial-information/sec-filings**.

We routinely post important information for investors in the “Investors” section of our website, www.lilly.com. We may use our website as a means of disclosing material, non-public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the “Investors” section of our website, in addition to following our press releases, filings with the SEC, public conference calls, presentations, and webcasts. We may also use social media channels to communicate with investors and the public about our business, products and other matters, and those communications could be deemed to be material information. The information contained on, or that may be accessed through, our website or social media channels, is not incorporated by reference into, and is not a part of, this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For a discussion of our market risk, see “Quantitative and Qualitative Disclosures About Market Risk” in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2022.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*. Under applicable Securities and Exchange Commission (SEC) regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Quarterly Report on Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of David Ricks, president and chief executive officer, and Anat Ashkenazi, executive vice president and chief financial officer, evaluated our disclosure controls and procedures (as such terms are defined in our Annual Report on Form 10-K for the year ended December 31, 2022) as of September 30, 2023, and concluded that they were effective.

(b) *Changes in Internal Controls.* During the third quarter of 2023, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We rely extensively on information systems and technology to manage our business, including integrated supply chain operations, and global consolidated financial results. We are currently preparing to implement a new global enterprise resource planning (ERP) system, which will replace existing operating and financial systems. The ERP system is designed to accurately maintain our financial records, support integrated supply chain and other operational functionality, and provide timely information to our management team related to the operation of the business. We currently expect to commence and complete the global implementation in the first quarter of 2024, with post-implementation activities following thereafter. As the implementation and post-implementation activities take place, we will have changes to certain of our processes and procedures, and we will evaluate quarterly whether the changes materially affect our internal control over financial reporting.

PART II. Other Information

Item 1. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings. See Note 9 to the consolidated condensed financial statements for information on various legal proceedings.

This Item should be read in conjunction with "Legal Proceedings" in Part I, Item 3 of our Annual Report on Form 10-K for the year ended December 31, 2022.

Item 1A. Risk Factors

Our material risk factors are disclosed in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Information relating to the principal market for our common stock and related shareholder matters is described in "Management's Discussion and Analysis of Results of Operations and Financial Condition" in Part II, Item 7 and in "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in Part III, Item 12 of our Annual Report on Form 10-K for the year ended December 31, 2022.

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2023:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
July 2023	—	$ —	—	$ 2,500.0
August 2023	—	—	—	2,500.0
September 2023	—	—	—	2,500.0
Total	—	—	—	

During the three months ended September 30, 2023, we did not repurchase any shares under our $5.00 billion share repurchase program authorized in May 2021.

Item 5. Other Information

During the three months ended September 30, 2023, none of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits

The following documents are filed as a part of this Quarterly Report:

Exhibit	Description
3.1	Amended Articles of Incorporation, incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 4, 2022
3.2	Bylaws, as amended, incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on May 4, 2022
31.1	Rule 13a-14(a) Certification of David Ricks, Chair, President, and Chief Executive Officer*
31.2	Rule 13a-14(a) Certification of Anat Ashkenazi, Executive Vice President and Chief Financial Officer*
32	Section 1350 Certification*
101	Interactive Data Files (embedded within the Inline XBRL document)*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)*

* Filed herewith.

Long-term debt instruments under which the total amount of securities authorized does not exceed 10 percent of our consolidated assets are not filed as exhibits to this Quarterly Report. We will furnish a copy of these agreements to the Securities and Exchange Commission upon 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.

ELI LILLY AND COMPANY
(Registrant)

Date: November 2, 2023

/s/ Anat Ashkenazi
Anat Ashkenazi
Executive Vice President and Chief Financial Officer

Date: November 2, 2023

/s/ Donald Zakrowski
Donald Zakrowski
Senior Vice President, Finance, and Chief Accounting Officer

EXHIBIT 31.1 Rule 13a-14(a) Certification of David Ricks, Chair, President, and Chief Executive Officer

CERTIFICATIONS

I, David Ricks, Chair, President, and Chief Executive Officer, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

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(s) 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 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(s) 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: November 2, 2023

By: /s/ David Ricks
David Ricks
Chair, President, and Chief Executive Officer

EXHIBIT 31.2 Rule 13a-14(a) Certification of Anat Ashkenazi, Executive Vice President and Chief Financial Officer

CERTIFICATIONS

I, Anat Ashkenazi, Executive Vice President and Chief Financial Officer, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

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(s) 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 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(s) 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: November 2, 2023

By: /s/ Anat Ashkenazi
Anat Ashkenazi
Executive Vice President and Chief Financial Officer

EXHIBIT 32 Section 1350 Certification

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Eli Lilly and Company, an Indiana corporation (the Company), does hereby certify that, to the best of their knowledge:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 (the Form 10-Q) of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2023

/s/ David Ricks
David Ricks
Chair, President, and Chief Executive Officer

Date: November 2, 2023

/s/ Anat Ashkenazi
Anat Ashkenazi
Executive Vice President and Chief Financial Officer