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 June 30, 2021

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
1.000% Notes due 2022	LLY22	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
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.700% Notes due 2049	LLY49A	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 July 30, 2021:

Class	Number of Shares Outstanding
Common	956,580,893

Eli Lilly and Company

Form 10-Q
For the Quarter Ended June 30, 2021

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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, as amended (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 impact of the evolving COVID-19 pandemic and the global response thereto;
- uncertainties related to our efforts to develop potential treatments for COVID-19;
- 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 of acquisitions and business development transactions and related integration 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 IT systems, networks, and facilities, or those of third parties with whom we share our data;
- 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 or disruptions, including as a result of regulatory actions relating to our facilities;
- reliance on third-party relationships and outsourcing arrangements;
- regulatory changes or other developments;
- regulatory actions regarding currently marketed 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;
- the impact of global macroeconomic conditions and trade disruptions or disputes;
- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); and
- regulatory compliance problems or government investigations.

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, 2020, particularly under the caption "Risk Factors".

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue (Note 2)	**$ 6,740.1**	$ 5,499.4	**$ 13,545.7**	$ 11,359.2
Costs, expenses, and other:				
Cost of sales	**1,953.2**	1,222.0	**3,831.8**	2,437.1
Research and development	**1,672.8**	1,390.2	**3,357.6**	2,782.3
Marketing, selling, and administrative	**1,685.7**	1,448.6	**3,261.7**	2,998.2
Acquired in-process research and development (Note 3)	**25.0**	241.8	**324.3**	294.1
Asset impairment, restructuring, and other special charges (Note 5)	**—**	—	**211.6**	59.9
Other–net, (income) expense (Note 11)	**(190.5)**	(446.9)	**(511.6)**	(536.0)
	5,146.2	3,855.7	**10,475.4**	8,035.6
Income before income taxes	**1,593.9**	1,643.7	**3,070.3**	3,323.6
Income taxes (Note 7)	**203.7**	231.7	**324.8**	455.1
Net income	**$ 1,390.2**	$ 1,412.0	**$ 2,745.5**	$ 2,868.5
Earnings per share:				
Basic	**$ 1.53**	$ 1.56	**$ 3.02**	$ 3.16
Diluted	**$ 1.53**	$ 1.55	**$ 3.01**	$ 3.15
Shares used in calculation of earnings per share:				
Basic	**907.3**	907.2	**908.2**	907.7
Diluted	**910.4**	910.9	**911.6**	911.6

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net income	**$ 1,390.2**	$ 1,412.0	**$ 2,745.5**	$ 2,868.5
Other comprehensive income (loss), net of tax (Note 10)	**108.5**	203.0	**209.3**	(159.3)
Comprehensive income	**$ 1,498.7**	$ 1,615.0	**$ 2,954.8**	$ 2,709.2

See notes to consolidated condensed financial statements.

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

	June 30, 2021	December 31, 2020
Assets	**(Unaudited)**	
Current Assets		
Cash and cash equivalents (Note 6)	**$ 3,220.0**	$ 3,657.1
Short-term investments (Note 6)	**51.2**	24.2
Accounts receivable, net of allowances of **$23.9 (2021)** and $25.9 (2020)	**5,829.4**	5,875.3
Other receivables	**1,073.4**	1,053.7
Inventories	**3,824.9**	3,980.3
Prepaid expenses and other	**3,296.6**	2,871.5
Total current assets	**17,295.5**	17,462.1
Investments (Note 6)	**3,474.9**	2,966.8
Goodwill	**3,884.2**	3,766.5
Other intangibles, net	**7,985.4**	7,450.0
Deferred tax assets	**2,674.9**	2,830.4
Property and equipment, net of accumulated depreciation of **$9,842.2 (2021)** and $9,570.7 (2020)	**8,855.5**	8,681.9
Other noncurrent assets	**3,638.6**	3,475.4
Total assets	**$ 47,809.0**	$ 46,633.1
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	**$ 1,778.5**	$ 8.7
Accounts payable	**1,597.8**	1,606.7
Employee compensation	**755.5**	997.2
Sales rebates and discounts	**7,035.8**	5,853.0
Dividends payable	**770.8**	770.6
Income taxes payable	**529.9**	495.1
Other current liabilities	**2,624.9**	2,750.3
Total current liabilities	**15,093.2**	12,481.6
Other Liabilities		
Long-term debt	**14,736.6**	16,586.6
Accrued retirement benefits (Note 8)	**3,918.5**	4,094.5
Long-term income taxes payable	**3,738.0**	3,837.8
Deferred tax liabilities	**1,857.3**	2,099.9
Other noncurrent liabilities	**1,801.9**	1,707.5
Total other liabilities	**26,052.3**	28,326.3
Commitments and Contingencies (Note 9)		
Eli Lilly and Company Shareholders' Equity		
Common stock	**598.1**	598.2
Additional paid-in capital	**6,669.2**	6,778.5
Retained earnings	**8,530.1**	7,830.2
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 10)	**(6,287.1)**	(6,496.4)
Cost of common stock in treasury	**(52.7)**	(55.7)
Total Eli Lilly and Company shareholders' equity	**6,444.4**	5,641.6
Noncontrolling interests	**219.1**	183.6
Total equity	**6,663.5**	5,825.2
Total liabilities and equity	**$ 47,809.0**	$ 46,633.1

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 April 1, 2020	956,929	$ 598.1	$ 6,556.1	$ 5,879.4	$ (3,013.2)	$ (6,885.9)	487	$ (55.7)	$ 118.4
Net income				1,412.0					74.5
Other comprehensive income, net of tax						203.0			
Cash dividends declared per share: $0.74				(674.0)					
Issuance of stock under employee stock plans, net	24	—	(3.1)						
Stock-based compensation			76.8						
Other			(0.4)	(0.2)					(13.8)
Balance at June 30, 2020	956,953	$ 598.1	$ 6,629.4	$ 6,617.2	$ (3,013.2)	$ (6,682.9)	487	$ (55.7)	$ 179.1
Balance at April 1, 2021	**959,482**	**$ 599.7**	**$ 6,579.2**	**$ 9,181.3**	**$ (3,013.2)**	**$ (6,395.6)**	**463**	**$ (52.7)**	**$ 200.6**
Net income				**1,390.2**					**31.4**
Other comprehensive income, net of tax						**108.5**			
Cash dividends declared per share: $1.70				**(1,542.9)**					
Retirement of treasury shares	**(2,467)**	**(1.6)**		**(498.5)**			**(2,467)**	**500.0**	
Purchase of treasury shares							**2,467**	**(500.0)**	
Issuance of stock under employee stock plans, net	**23**	**—**	**(1.9)**						
Stock-based compensation			**91.9**						
Other									**(12.9)**
Balance at June 30, 2021	**957,038**	**$ 598.1**	**$ 6,669.2**	**$ 8,530.1**	**$ (3,013.2)**	**$ (6,287.1)**	**463**	**$ (52.7)**	**$ 219.1**

[1] As of June 30, 2021, there was $500.0 million remaining under our $8.00 billion share repurchase program authorized in June 2018. A $5.00 billion share repurchase program was authorized in May 2021. There were no shares repurchased under the $5.00 billion share repurchase program during the three months ended June 30, 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, 2020	958,056	$ 598.8	$ 6,685.3	$ 4,920.4	$ (3,013.2)	$ (6,523.6)	530	$ (60.8)	$ 92.2
Net income				2,868.5					100.7
Other comprehensive loss, net of tax						(159.3)			
Cash dividends declared per share: $0.74				(674.0)					
Retirement of treasury shares	(3,627)	(2.3)		(497.7)			(3,627)	500.0	
Purchase of treasury shares							3,627	(500.0)	
Issuance of stock under employee stock plans, net	2,524	1.6	(204.1)				(43)	5.1	
Stock-based compensation			148.6						
Other			(0.4)						(13.8)
Balance at June 30, 2020	956,953	$ 598.1	$ 6,629.4	$ 6,617.2	$ (3,013.2)	$ (6,682.9)	487	$ (55.7)	$ 179.1
Balance at January 1, 2021	**957,077**	**$ 598.2**	**$ 6,778.5**	**$ 7,830.2**	**$ (3,013.2)**	**$ (6,496.4)**	**487**	**$ (55.7)**	**$ 183.6**
Net income				**2,745.5**					**47.8**
Other comprehensive income, net of tax						**209.3**			
Cash dividends declared per share: $1.70				**(1,542.9)**					
Retirement of treasury shares	**(2,467)**	**(1.6)**		**(498.5)**			**(2,467)**	**500.0**	
Purchase of treasury shares							**2,467**	**(500.0)**	
Issuance of stock under employee stock plans, net	**2,428**	**1.5**	**(285.8)**				**(24)**	**3.0**	
Stock-based compensation			**177.4**						
Other			**(0.9)**	**(4.2)**					**(12.3)**
Balance at June 30, 2021	**957,038**	**$ 598.1**	**$ 6,669.2**	**$ 8,530.1**	**$ (3,013.2)**	**$ (6,287.1)**	**463**	**$ (52.7)**	**$ 219.1**

[1] As of June 30, 2021, there was $500.0 million remaining under our $8.00 billion share repurchase program authorized in June 2018. A $5.00 billion share repurchase program was authorized in May 2021. There were no shares repurchased under the $5.00 billion share repurchase program during the six months ended June 30, 2021.

See notes to consolidated condensed financial statements.

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

	Six Months Ended June 30,	
	2021	**2020**
Cash Flows from Operating Activities		
Net income	**$ 2,745.5**	$ 2,868.5
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	**719.6**	598.0
Change in deferred income taxes	**(413.8)**	(93.5)
Stock-based compensation expense	**177.4**	148.6
Net investment gains	**(518.1)**	(765.0)
Acquired in-process research and development (Note 3)	**324.3**	294.1
Other changes in operating assets and liabilities, net of acquisitions and divestitures	**118.4**	(481.6)
Other non-cash operating activities, net	**319.6**	308.7
Net Cash Provided by Operating Activities	**3,472.9**	2,877.8
Cash Flows from Investing Activities		
Net purchases of property and equipment	**(681.6)**	(540.1)
Proceeds from sales and maturities of short-term investments	**21.3**	111.2
Purchases of short-term investments	**(26.6)**	—
Proceeds from sales of noncurrent investments	**461.9**	412.0
Purchases of noncurrent investments	**(503.1)**	(154.8)
Cash paid for acquisitions, net of cash acquired (Note 3)	**(747.4)**	(849.3)
Purchases of in-process research and development	**(341.8)**	(254.4)
Other investing activities, net	**50.5**	4.1
Net Cash Used for Investing Activities	**(1,766.8)**	(1,271.3)
Cash Flows from Financing Activities		
Dividends paid	**(1,543.1)**	(1,345.5)
Net change in short-term borrowings	**196.3**	(235.4)
Proceeds from issuance of long-term debt	**—**	988.6
Repayments of long-term debt	**—**	(276.3)
Purchases of common stock	**(500.0)**	(500.0)
Other financing activities, net	**(294.8)**	(197.9)
Net Cash Used for Financing Activities	**(2,141.6)**	(1,566.5)
Effect of exchange rate changes on cash and cash equivalents	**(1.6)**	(12.4)
Net (decrease) increase in cash and cash equivalents	**(437.1)**	27.6
Cash and cash equivalents at January 1	**3,657.1**	2,337.5
Cash and Cash Equivalents at June 30	**$ 3,220.0**	$ 2,365.1

See notes to consolidated condensed financial statements.

Notes to Consolidated Condensed Financial Statements
(Tables present dollars in millions, except per-share data)

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, 2020. We issue 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.

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.

Note 2: Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net product revenue	**$ 6,070.5**	$ 5,077.7	**$ 12,390.5**	$ 10,481.2
Collaboration and other revenue [(1)]	**669.6**	421.7	**1,155.2**	878.0
Revenue	**$ 6,740.1**	$ 5,499.4	**$ 13,545.7**	$ 11,359.2

[(1)] Collaboration and other revenue associated with prior period transfers of intellectual property was $31.0 million and $73.9 million during the three and six months ended June 30, 2021, respectively, and $34.7 million and $70.0 million during the three and six months ended June 30, 2020, 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 collaboration, as well as royalties, upfront and milestone payments we receive under these types of contracts. See Note 4 for additional information related to certain of 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 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 increase (decrease) 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 less than 1 percent of U.S. revenue during each of the three and six months ended June 30, 2021, and approximately (2) percent and 1 percent of U.S. revenue for the three and six months ended June 30, 2020, respectively.

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:

	June 30, 2021	December 31, 2020
Contract liabilities	**$ 270.9**	$ 276.8

During the three and six months ended June 30, 2021 and 2020, 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 by product for the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,					
	2021			2020		
	U.S.	Outside U.S.	Total	U.S.	Outside U.S.	Total
Revenue—to unaffiliated customers:						
Diabetes:						
Trulicity®	**$ 1,147.6**	**$ 388.0**	**$ 1,535.6**	$ 952.5	$ 277.2	$ 1,229.8
Humalog® (1)	**329.1**	**278.6**	**607.6**	281.7	273.3	555.1
Humulin®	**221.1**	**94.3**	**315.3**	214.3	99.3	313.6
Jardiance (2)	**194.4**	**162.1**	**356.5**	145.1	116.9	262.0
Basaglar®	**133.4**	**77.3**	**210.7**	229.7	60.7	290.4
Other Diabetes	**54.2**	**95.4**	**149.8**	50.0	78.3	128.1
Total Diabetes	**2,079.8**	**1,095.7**	**3,175.5**	1,873.3	905.7	2,779.0
Oncology:						
Alimta®	**353.5**	**257.1**	**610.6**	317.2	221.9	539.1
Verzenio®	**209.7**	**131.6**	**341.3**	141.7	66.9	208.6
Cyramza®	**101.4**	**167.3**	**268.7**	94.1	162.7	256.7
Erbitux®	**135.8**	**11.2**	**147.0**	115.8	13.7	129.5
Tyvyt®	**—**	**105.0**	**105.0**	—	64.1	64.1
Other Oncology	**27.9**	**53.5**	**81.4**	13.9	56.6	70.6
Total Oncology	**828.3**	**725.7**	**1,554.0**	682.7	585.9	1,268.6
Immunology:						
Taltz®	**399.8**	**169.3**	**569.1**	289.2	106.0	395.2
Olumiant®	**17.8**	**190.6**	**208.4**	13.2	131.8	145.0
Other Immunology	**4.8**	**3.2**	**7.9**	8.1	—	8.1
Total Immunology	**422.4**	**363.1**	**785.4**	310.5	237.8	548.3
Neuroscience:						
Cymbalta®	**12.4**	**163.3**	**175.6**	7.7	172.1	179.9
Emgality®	**112.1**	**44.2**	**156.3**	80.6	6.8	87.4
Zyprexa®	**8.4**	**86.9**	**95.4**	9.1	87.5	96.6
Other Neuroscience	**33.8**	**51.1**	**84.9**	6.6	52.1	58.6
Total Neuroscience	**166.7**	**345.5**	**512.2**	104.0	318.5	422.5
Other:						
COVID-19 Antibodies (3)	**83.4**	**65.7**	**148.9**	—	—	—
Forteo®	**122.8**	**95.6**	**218.4**	119.6	133.0	252.7
Cialis®	**(5.2)**	**286.3**	**281.0**	23.4	107.3	130.7
Other	**6.0**	**58.4**	**64.6**	31.4	66.4	97.6
Total Other	**207.0**	**506.0**	**712.9**	174.4	306.7	481.0
Revenue	**$ 3,704.2**	**$ 3,035.9**	**$ 6,740.1**	$ 3,144.8	$ 2,354.6	$ 5,499.4

Numbers may not add due to rounding.

(1) Humalog revenue includes insulin lispro.

(2) Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.

(3) COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to Emergency Use Authorizations (EUAs).

The following table summarizes revenue by product for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,					
	2021			2020		
	U.S.	Outside U.S.	Total	U.S.	Outside U.S.	Total
Revenue—to unaffiliated customers:						
Diabetes:						
Trulicity	**$ 2,264.3**	**$ 723.7**	**$ 2,988.1**	$ 1,882.0	$ 577.1	$ 2,459.1
Humalog [1]	**661.7**	**562.9**	**1,224.6**	680.3	570.5	1,250.8
Humulin	**440.1**	**196.9**	**637.0**	428.4	200.8	629.3
Jardiance [2]	**345.6**	**322.9**	**668.5**	289.7	239.8	529.5
Basaglar	**308.6**	**148.7**	**457.3**	460.1	134.0	594.1
Other Diabetes	**120.7**	**190.4**	**311.1**	124.0	161.2	285.1
Total Diabetes	**4,141.0**	**2,145.5**	**6,286.6**	3,864.5	1,883.4	5,747.9
Oncology:						
Alimta	**614.6**	**554.9**	**1,169.6**	641.5	457.7	1,099.2
Verzenio	**382.5**	**227.8**	**610.3**	271.1	125.6	396.7
Cyramza	**181.5**	**327.7**	**509.2**	183.2	312.5	495.7
Erbitux	**243.7**	**25.7**	**269.4**	233.7	26.7	260.3
Tyvyt	**—**	**214.6**	**214.6**	—	121.5	121.5
Other Oncology	**48.5**	**104.7**	**153.2**	11.1	85.5	96.7
Total Oncology	**1,470.8**	**1,455.4**	**2,926.3**	1,340.6	1,129.5	2,470.1
Immunology:						
Taltz	**649.4**	**322.9**	**972.4**	616.7	222.0	838.7
Olumiant	**42.5**	**359.7**	**402.2**	24.5	260.2	284.7
Other Immunology	**15.2**	**9.6**	**24.7**	10.7	—	10.7
Total Immunology	**707.1**	**692.2**	**1,399.3**	651.9	482.2	1,134.1
Neuroscience:						
Cymbalta	**23.3**	**328.9**	**352.3**	19.3	370.9	390.3
Emgality	**213.6**	**62.2**	**275.7**	147.9	13.6	161.5
Zyprexa	**15.3**	**175.8**	**191.1**	20.3	174.7	195.0
Other Neuroscience	**56.2**	**102.3**	**158.5**	26.7	112.5	139.2
Total Neuroscience	**308.4**	**669.2**	**977.6**	214.2	671.7	886.0
Other:						
COVID-19 Antibodies [3]	**734.0**	**225.1**	**959.1**	—	—	—
Forteo	**220.5**	**196.4**	**416.9**	242.2	282.9	525.0
Cialis	**3.4**	**404.4**	**407.8**	49.5	274.3	323.8
Other	**60.2**	**111.9**	**172.1**	110.7	161.5	272.3
Total Other	**1,018.1**	**937.8**	**1,955.9**	402.4	718.7	1,121.1
Revenue	**$ 7,645.5**	**$ 5,900.2**	**$ 13,545.7**	$ 6,473.6	$ 4,885.6	$ 11,359.2

Numbers may not add due to rounding.

[1] Humalog revenue includes insulin lispro.

[2] Jardiance revenue includes Glyxambi, Synjardy, and Trijardy XR.

[3] COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to EUAs.

The following table summarizes revenue by geographical area:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue—to unaffiliated customers [1]:				
U.S.	**$ 3,704.2**	$ 3,144.8	**$ 7,645.5**	$ 6,473.6
Europe	**1,209.8**	873.0	**2,531.0**	1,934.1
Japan	**665.4**	666.7	**1,237.2**	1,259.0
China	**522.5**	239.8	**884.7**	507.1
Other foreign countries	**638.1**	575.2	**1,247.3**	1,185.5
Revenue	**$ 6,740.1**	$ 5,499.4	**$ 13,545.7**	$ 11,359.2

Numbers may not add due to rounding.

[1] Revenue is attributed to the countries based on the location of the customer.

Note 3: Acquisitions

In January 2021 and February 2020, we completed the acquisitions of Prevail Therapeutics Inc. (Prevail) and Dermira, Inc. (Dermira), respectively. These transactions, as further discussed in this note below in Acquisitions of Businesses, were accounted for as business combinations 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 these acquisitions are included in our consolidated condensed financial statements from the date of acquisition.

We also acquired assets in development which are further discussed in this note below in Asset Acquisitions. Upon each acquisition, the cost allocated to acquired in-process research and development (IPR&D) was immediately expensed because the compound had no alternative future use. We recognized acquired IPR&D charges of $25.0 million and $324.3 million for the three and six months ended June 30, 2021, respectively, and $241.8 million and $294.1 million for the three and six months ended June 30, 2020, respectively.

Acquisitions of Businesses

Prevail Acquisition

Overview of Transaction

In January 2021, we acquired all shares of Prevail for a purchase price that included $22.50 per share in cash (or an aggregate of $747.4 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles Prevail stockholders to up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions, upon the first regulatory approval of a Prevail product in one of the following countries: U.S., Japan, United Kingdom, Germany, France, Italy or Spain. To achieve the full value of the CVR, such regulatory approval must occur by December 31, 2024. If such regulatory approval occurs after December 31, 2024, the value of the CVR will be reduced by approximately 8.3 cents per month until December 1, 2028, at which point the CVR will expire without payment.

Under the terms of the agreement, we acquired potentially disease-modifying AAV9-based gene therapies for patients with neurodegenerative diseases. The acquisition establishes a new modality for drug discovery and development, extending our research efforts through the creation of a gene therapy program that is being anchored by Prevail's portfolio of assets. The lead gene therapies in clinical development that we acquired were PR001 for patients with Parkinson's disease with GBA1 mutations and neuronopathic Gaucher disease and PR006 for patients with frontotemporal dementia with GRN mutations. Both PR001 and PR006 were granted Fast Track designation from the U.S. Food and Drug Administration (FDA).

Assets Acquired and Liabilities Assumed

Our access to Prevail 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 January 22, 2021		
Cash	$	90.5
Acquired IPR&D[(1)]		824.0
Goodwill[(2)]		118.8
Deferred tax liabilities		(98.0)
Other assets and liabilities, net		(31.5)
Acquisition date fair value of consideration transferred		903.8
Less:		
Cash acquired		(90.5)
Fair value of CVR liability[(3)]		(65.9)
Cash paid, net of cash acquired	$	747.4

[(1)] Acquired IPR&D intangibles primarily relate to PR001.

[(2)] The goodwill recognized from this acquisition is not deductible for tax purposes.

[(3)] See Note 6 for a discussion on the estimation of the CVR liability.

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 six months ended June 30, 2021 and 2020.

Dermira Acquisition

Overview of Transaction

In February 2020, we acquired all shares of Dermira for a purchase price of approximately $849.3 million, net of cash acquired. Under the terms of the agreement, we acquired lebrikizumab, a novel, investigational, monoclonal antibody being evaluated for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the FDA. We also acquired Qbrexza® (glycopyrronium) cloth, a medicated cloth approved by the FDA for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating). During the six months ended June 30, 2021, we sold the rights to Qbrexza. See Note 5 for additional information.

Assets Acquired and Liabilities Assumed

The fair values recognized related to the assets acquired and liabilities assumed in this acquisition included goodwill of $86.8 million, other intangibles of $1.20 billion primarily related to lebrikizumab, deferred income tax liabilities of $49.5 million, and long-term debt of $375.5 million. After the acquisition, we repaid $276.2 million of long-term debt assumed as part of our acquisition of Dermira.

Asset Acquisitions

The following table summarizes our asset acquisitions during the six months ended June 30, 2021 and 2020:

Counterparty	Compound(s) or Therapy	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
Precision Biosciences, Inc.	Research and development of potential in vivo therapies for genetic disorders	January 2021	Pre-clinical	**$ 107.8**
Merus N.V.	CD3-engaging T-cell re-directing bispecific antibodies for the potential treatment of cancer	January 2021	Pre-clinical	**46.5**
Asahi Kasei Pharma Corporation	AK1780, an orally bioavailable P2X7 receptor antagonist for the potential treatment of chronic pain conditions	January 2021	Phase I	**20.0**
Rigel Pharmaceuticals, Inc.	R552, a receptor-interacting serine/threonine-protein kinase 1 (RIPK1) inhibitor, for the potential treatment of autoimmune and inflammatory diseases	March 2021	Phase I	**125.0**
MiNA Therapeutics Limited	Pre-clinical targets that could lead to potential new medicines	May 2021	Pre-clinical	**25.0**
Sitryx Therapeutics Limited	Pre-clinical targets that could lead to potential new medicines for autoimmune diseases	March 2020	Pre-clinical	52.3
AbCellera Biologics Inc. (AbCellera)[2]	Neutralizing antibodies for the treatment and prevention of COVID-19	March 2020	Pre-clinical	25.0
Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences)	Neutralizing antibodies for the treatment and prevention of COVID-19	May 2020	Pre-clinical	20.0
Undisclosed	Pre-clinical target that could lead to potential new medicine	May 2020	Pre-clinical	174.8
Evox Therapeutics Limited	Pre-clinical targets for the potential treatment of neurological disorders	June 2020	Pre-clinical	22.0

[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.

[2] We recognized an acquired IPR&D expense of $25.0 million in May 2020 upon closing of the transaction.

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.

Subsequent Events

Protomer Technologies Inc. (Protomer)

In July 2021, we acquired Protomer, a private biotechnology company with a glucose-sensing insulin program. Under the terms of the agreement, we acquired Protomer for an upfront cash payment of $61.6 million. As a result of the transaction, we will record an acquired IPR&D charge of approximately $65 million in the third quarter of 2021.

Kumquat Biosciences Inc. (Kumquat)

In July 2021, we entered into an exclusive agreement with Kumquat focused on the discovery, development and commercialization of potential small molecules that stimulate tumor-specific immune responses. Under the terms of the agreement, we paid an upfront cash payment of $50.0 million and invested $20.0 million in Kumquat's common stock at a premium. As a result of the transaction, we will record an acquired IPR&D charge of $55.0 million in the third quarter of 2021.

Note 4: Collaborations and Other 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. See Note 2 for amounts of collaboration and other revenue recognized from these types of arrangements.

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 collaboration 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 insulin, Basaglar. Glyxambi, Synjardy, and Trijardy XR are included in the Jardiance product family. Jentadueto is included in the Trajenta product family.

The table below summarizes the net amount of significant milestones capitalized (deferred) at June 30, 2021 and December 31, 2020 for the compounds included in this collaboration:

	Net Milestones Capitalized (Deferred) [1] as of:	
Product Family	**June 30, 2021**	**December 31, 2020**
Jardiance [2]	**$ 146.2**	$ 156.2
Trajenta [3]	**101.6**	114.6
Basaglar	**(158.6)**	(168.0)

[1] In connection with the regulatory approvals of Jardiance and Trajenta, milestone payments made were capitalized as intangible assets and are being amortized to cost of sales through the term of the collaboration. In connection with the regulatory approvals of Basaglar, milestone payments received were recorded as contract liabilities and are being amortized through the term of the collaboration (2029) to collaboration and other revenue. 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.

[2] The collaboration agreement with Boehringer Ingelheim for Jardiance ends upon expiration of the compound patent and any supplementary protection certificates or extensions thereto.

[3] The collaboration agreement with Boehringer Ingelheim for Trajenta ends upon expiration of the compound patent and any supplementary protection certificates or extensions thereto.

For the Jardiance product family, we and Boehringer Ingelheim 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. Beginning January 1, 2021, 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 Basaglar in the U.S. We record our sales of Basaglar 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 our net product revenue recognized with respect to Basaglar:

	Three Months Ended June 30,		Six Months Ended June 30,	
Product Family	**2021**	**2020**	**2021**	**2020**
Jardiance	**$ 356.5**	$ 262.0	**$ 668.5**	$ 529.5
Basaglar	**210.7**	290.4	**457.3**	594.1
Trajenta	**89.2**	76.8	**183.8**	170.0

Olumiant

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte), which provides us the development and commercialization rights to its Janus tyrosine kinase (JAK) inhibitor compound, now known as Olumiant (baricitinib), and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double digit royalty payments on global net sales with rates ranging up to 20 percent. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones. In 2020, the agreement was amended to include the treatment of COVID-19, with Incyte obtaining the right to receive an additional royalty ranging up to the low teens on global net sales for the treatment of COVID-19 that exceed a specified aggregate global net sales threshold.

In connection with the regulatory approvals of Olumiant in the U.S., Europe, and Japan, milestone payments of $210.0 million were capitalized as intangible assets as of June 30, 2021 and December 31, 2020 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 June 30, 2021, Incyte is eligible to receive up to $100.0 million of additional payments from us contingent upon certain success-based regulatory milestones. Incyte is also eligible to receive up to $150.0 million of potential sales-based milestones.

We record our sales of Olumiant 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Olumiant	**$ 208.4**	$ 145.0	**$ 402.2**	$ 284.7

COVID-19 antibodies

In 2020, we entered into a worldwide license and collaboration agreement with AbCellera to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including bamlanivimab, for which we hold development and commercialization rights. AbCellera has the right to receive tiered royalty payments on global net sales of bamlanivimab with percentages ranging in the mid-teens to mid-twenties. Royalty payments made to AbCellera are recorded as cost of sales.

In 2020, we entered into a license and collaboration agreement with Junshi Biosciences to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including etesevimab, for which we hold development and commercialization rights outside of Greater China (which includes mainland China, Hong Kong and Macau Special Administrative Regions and Taiwan) and for which Junshi Biosciences maintains all rights in Greater China. Junshi Biosciences has the right to receive royalty payments in the mid-teens on our net sales of etesevimab. Junshi Biosciences also has the right to receive certain development, success-based regulatory and sales-based milestones. In connection with the regulatory authorizations of etesevimab (for administration with bamlanivimab) in the U.S. and Europe, milestone payments of $60.0 million were capitalized as intangible assets as of June 30, 2021 and are being amortized to cost of sales over the estimated useful life of etesevimab. As of June 30, 2021, Junshi Biosciences is eligible to receive up to $15.0 million of additional payments contingent upon certain success-based regulatory milestones and up to $120.0 million of potential sales-based milestones.

Pursuant to EUAs, we recognized $148.9 million and $959.1 million of net product revenue associated with our sales of our COVID-19 antibodies during the three and six months ended June 30, 2021, respectively.

Sintilimab Injection

We have a collaboration agreement with Innovent Biologics, Inc. (Innovent) to jointly develop and commercialize sintilimab injection in China, where it is branded and trademarked as Tyvyt. In 2019, we and Innovent began co-commercializing Tyvyt in China. In 2020, we obtained an exclusive license for sintilimab injection from Innovent for geographies outside of China. Innovent, with collaboration from us, has filed the initial registration of sintilimab injection in the U.S., and we will pursue initial registration of sintilimab injection in other markets and all other subsequent registrations of sintilimab injection. We have exclusive commercialization rights outside of China.

In connection with a regulatory approval for Tyvyt in China in the second quarter of 2021, a milestone payment of $40.0 million was capitalized as an intangible asset as of June 30, 2021 and is being amortized to cost of sales through the term of the collaboration.

As of June 30, 2021, Innovent is eligible to receive up to $825.0 million for geographies outside of China and up to $195.0 million in China in success-based regulatory and sales-based milestones. Innovent is also eligible to receive tiered double digit royalties on net sales for geographies outside of China.

We record our sales of Tyvyt to third parties as net product revenue, with payments made to Innovent for its portion of the gross margin reported as cost of sales. We report as collaboration and other revenue our portion of the gross margin for Tyvyt sales made by Innovent to third parties. The following table summarizes our revenue recognized in China with respect to Tyvyt:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Tyvyt	**$ 105.0**	$ 64.1	**$ 214.6**	$ 121.5

Tanezumab

We have a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the treatment of osteoarthritis pain and cancer pain. The companies equally share the ongoing development costs and, if successful, in the U.S. will co-commercialize and equally share in gross margin and certain commercialization expenses. As a result of an amendment to the agreement in 2020, Pfizer will be responsible for commercialization activities and costs outside the U.S., and we have the right to receive tiered royalties in percentages from the high teens to mid-twenties for net sales in Japan as well as low double digit royalties on annual net sales greater than $150.0 million in all other territories outside of the U.S. and Japan. As of June 30, 2021, Pfizer is eligible to receive up to $147.5 million in success-based regulatory milestones based on current development plans and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab.

Lebrikizumab

As a result of our acquisition of Dermira, we have a worldwide licensing agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively Roche), which provides us the global development and commercialization rights to lebrikizumab. Roche has the right to receive tiered royalty payments on future global net sales ranging in percentages from high single digits to high teens if the product is successfully commercialized. As of June 30, 2021, Roche is eligible to receive up to $180.0 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.

As a result of our acquisition of Dermira, 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 June 30, 2021, we are eligible to receive additional payments of $85.0 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.

As of June 30, 2021 and December 31, 2020, $20.1 million and $29.7 million, respectively, were recorded as contract liabilities on the consolidated condensed balance sheets and are expected to be recognized as collaboration and other revenue over the remaining Phase III development period. During the three and six months ended June 30, 2021 and 2020, milestones received and collaboration and other revenue recognized were not material.

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

The components of the charges included in asset impairment, restructuring, and other special charges in our consolidated condensed statements of operations are described below.

	Six Months Ended June 30,	
	2021	**2020**
Severance	**$ 11.5**	$ 9.8
Asset impairment and other special charges	**200.1**	50.1
Total asset impairment, restructuring, and other special charges	**$ 211.6**	$ 59.9

There were no asset impairment, restructuring, and other special charges recognized during the three months ended June 30, 2021 and 2020.

Asset impairment, restructuring, and other special charges recognized during the six months ended June 30, 2021 were primarily related to an intangible asset impairment of $108.1 million resulting from the sale of the rights to Qbrexza, as well as acquisition and integration costs associated with the acquisition of Prevail. During the three months ended March 31, 2021, we entered into an agreement to sell our rights to Qbrexza, subject to closing conditions which were completed in the second quarter of 2021. The assets associated with Qbrexza were written down to fair value less cost to sell, which were determined based upon a discounted cash flow valuation.

Asset impairment, restructuring, and other special charges recognized during the six months ended June 30, 2020 were primarily related to acquisition and integration costs associated with the acquisition of Dermira.

We recognized inventory impairment charges of $423.0 million and $504.5 million during the three and six months ended June 30, 2021, respectively, in cost of sales in our consolidated condensed statements of operations for excess inventory related to our COVID-19 antibodies. As part of our response to the COVID-19 pandemic, and at the request of the U.S. and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic has continued to evolve during 2021, we incurred excess inventory charges primarily due to the combination of changes to current and forecasted demand from U.S. and international governments, including changes to our agreement with the U.S. government, and near-term expiry dates of COVID-19 antibodies.

Note 6: 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. A large portion of our cash is held by a few major financial institutions. 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. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

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.

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 review equity investments other than public equity investments for indications of impairment and observable price changes on a regular basis.

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 loss 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 loss. 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, and Japanese yen). 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. We may enter into foreign currency forward and option contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At June 30, 2021, we had outstanding foreign currency forward commitments to purchase 1.97 billion U.S. dollars and sell 1.65 billion euro, commitments to purchase 2.55 billion euro and sell 3.05 billion U.S. dollars, commitments to purchase 190.8 million U.S. dollars and sell 21.10 billion Japanese yen, and commitments to purchase 250.4 million British pounds and sell 349.4 million U.S. dollars, which all settled within 30 days.

Foreign currency exchange risk is also managed through the use of foreign currency debt and cross-currency interest rate swaps. Our foreign currency-denominated notes had carrying amounts of $5.80 billion and $6.02 billion as of June 30, 2021 and December 31, 2020, respectively, of which $4.36 billion and $4.50 billion have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations as of June 30, 2021 and December 31, 2020, respectively. At June 30, 2021, we had outstanding cross- currency swaps with notional amounts of $3.82 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.

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 June 30, 2021, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 13 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), 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 June 30, 2021, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.75 billion, which have settlement dates ranging between 2023 and 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Fair value hedges:				
Effect from hedged fixed-rate debt	**$ 31.1**	$ 7.0	**$ (50.4)**	$ 124.4
Effect from interest rate contracts	**(31.1)**	(7.0)	**50.4**	(124.4)
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**4.2**	4.1	**8.3**	8.1
Cross-currency interest rate swaps	**(23.4)**	(11.5)	**48.1**	(24.4)
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	**(73.2)**	(22.9)	**59.8**	(28.6)
Total	**$ (92.4)**	$ (30.3)	**$ 116.2**	$ (44.9)

During the three and six months ended June 30, 2021 and 2020, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net investment hedges:				
Foreign currency-denominated notes	**$ (57.8)**	$ (72.4)	**$ 149.9**	$ (5.0)
Cross-currency interest rate swaps	**(46.5)**	(60.8)	**104.1**	55.0
Cash flow hedges:				
Forward-starting interest rate swaps	**(165.2)**	38.2	**129.9**	(331.6)
Cross-currency interest rate swaps	**(6.9)**	4.9	**19.4**	(64.9)

During the next 12 months, we expect to reclassify $17.0 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the three and six months ended June 30, 2021 and 2020, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at June 30, 2021 and December 31, 2020 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

			Fair Value Measurements Using			
	Carrying Amount	Cost [1]	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
June 30, 2021						
Cash equivalents	**$ 1,789.1**	**$ 1,789.1**	**$ 1,789.1**	**$ —**	**$ —**	**$ 1,789.1**
Short-term investments:						
U.S. government and agency securities	**$ 11.9**	**$ 11.9**	**$ 11.9**	**$ —**	**$ —**	**$ 11.9**
Corporate debt securities	**6.3**	**6.2**	**—**	**6.3**	**—**	**6.3**
Asset-backed securities	**3.4**	**3.2**	**—**	**3.4**	**—**	**3.4**
Other securities	**29.6**	**29.6**	**20.9**	**—**	**8.7**	**29.6**
Short-term investments	**$ 51.2**					
Noncurrent investments:						
U.S. government and agency securities	**$ 131.9**	**$ 130.0**	**$ 131.9**	**$ —**	**$ —**	**$ 131.9**
Corporate debt securities	**219.3**	**213.1**	**—**	**219.3**	**—**	**219.3**
Mortgage-backed securities	**111.0**	**107.8**	**—**	**111.0**	**—**	**111.0**
Asset-backed securities	**19.1**	**18.9**	**—**	**19.1**	**—**	**19.1**
Other securities	**103.6**	**21.3**	**—**	**—**	**103.6**	**103.6**
Marketable equity securities	**1,687.3**	**361.8**	**1,687.3**	**—**	**—**	**1,687.3**
Equity investments without readily determinable fair values [2]	**466.0**					
Equity method investments [2]	**736.7**					
Noncurrent investments	**$ 3,474.9**					
December 31, 2020						
Cash equivalents	$ 2,097.9	$ 2,097.9	$ 2,097.9	$ —	$ —	$ 2,097.9
Short-term investments:						
U.S. government and agency securities	$ 9.9	$ 9.9	$ 9.9	$ —	$ —	$ 9.9
Corporate debt securities	2.8	2.8	—	2.8	—	2.8
Asset-backed securities	1.2	1.2	—	1.2	—	1.2
Other securities	10.3	10.3	—	—	10.3	10.3
Short-term investments	$ 24.2					
Noncurrent investments:						
U.S. government and agency securities	$ 78.7	$ 74.3	$ 78.7	$ —	$ —	$ 78.7
Corporate debt securities	137.0	126.8	—	137.0	—	137.0
Mortgage-backed securities	106.4	101.4	—	106.4	—	106.4
Asset-backed securities	24.3	23.7	—	24.3	—	24.3
Other securities	110.5	31.8	—	—	110.5	110.5
Marketable equity securities	1,664.2	311.6	1,664.2	—	—	1,664.2
Equity investments without readily determinable fair values [2]	373.9					
Equity method investments [2]	471.8					
Noncurrent investments	$ 2,966.8					

[1] For available-for-sale debt securities, amounts disclosed represent the securities' amortized cost.

[2] Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments.

	Carrying Amount	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)	
Short-term commercial paper borrowings					
June 30, 2021	**$ (200.0)**	**$ —**	**$ (200.0)**	**$ —**	**$ (200.0)**
December 31, 2020	—	—	—	—	—
Long-term debt, including current portion					
June 30, 2021	**$ (16,315.1)**	**$ —**	**$ (17,970.9)**	**$ —**	**$ (17,970.9)**
December 31, 2020	(16,595.3)	—	(19,038.9)	—	(19,038.9)

	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
June 30, 2021					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Other receivables	**$ 11.7**	**$ —**	**$ 11.7**	**$ —**	**$ 11.7**
Other noncurrent assets	**99.2**	**$ —**	**99.2**	**$ —**	**99.2**
Other noncurrent liabilities	**(2.5)**	**—**	**(2.5)**	**—**	**(2.5)**
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**78.0**	**—**	**78.0**	**—**	**78.0**
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	**16.0**	**—**	**16.0**	**—**	**16.0**
Other noncurrent assets	**18.3**	**—**	**18.3**	**—**	**18.3**
Other current liabilities	**(47.2)**	**—**	**(47.2)**	**—**	**(47.2)**
Other noncurrent liabilities	**(19.2)**	**—**	**(19.2)**	**—**	**(19.2)**
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**14.0**	**—**	**14.0**	**—**	**14.0**
Other noncurrent liabilities	**(19.0)**	**—**	**(19.0)**	**—**	**(19.0)**
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	**5.4**	**—**	**5.4**	**—**	**5.4**
Other current liabilities	**(17.5)**	**—**	**(17.5)**	**—**	**(17.5)**
Contingent consideration liability:					
Other noncurrent liabilities	**(70.2)**	**—**	**—**	**(70.2)**	**(70.2)**
December 31, 2020					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Other noncurrent assets	158.9	—	158.9	—	158.9
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	38.1	—	38.1	—	38.1
Other noncurrent liabilities	(97.8)	—	(97.8)	—	(97.8)
Cross-currency interest rate contracts designated as net investment hedges:					
Other current liabilities	(92.6)	—	(92.6)	—	(92.6)
Other noncurrent liabilities	(97.2)	—	(97.2)	—	(97.2)
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	34.4	—	34.4	—	34.4
Other noncurrent liabilities	(2.9)	—	(2.9)	—	(2.9)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	41.1	—	41.1	—	41.1
Other current liabilities	(15.2)	—	(15.2)	—	(15.2)

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.

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. As of June 30, 2021, we had approximately $758 million of unfunded commitments to invest in venture capital funds, which we anticipate will be paid over a period of up to 10 years.

Contingent consideration liability relates to our liability arising in connection with the CVR issued as a result of the Prevail acquisition. The fair value of the CVR liability was estimated using a discounted cash flow analysis and Level 3 inputs, including projections representative of a market participant's view of the expected cash payment associated with the first potential regulatory approval of a Prevail compound in the applicable countries based on probabilities of technical success, timing of the potential approval events for the compounds, and an estimated discount rate. See Note 3 for additional information related to the CVR arrangement.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of June 30, 2021:

		Maturities by Period			
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 502.9	$ 21.6	$ 163.9	$ 128.1	$ 189.3

The net gains recognized in our consolidated condensed statements of operations for equity securities were $215.4 million and $517.0 million for the three and six months ended June 30, 2021, respectively, and $576.8 million and $763.4 million for the three and six months ended June 30, 2020, respectively. The net gains/losses recognized during the three and six months ended June 30, 2021 and 2020 on equity securities sold during the respective periods were not material.

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 during the three and six months ended June 30, 2021 and 2020 were not material.

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

	June 30, 2021	December 31, 2020
Unrealized gross gains	**$ 14.5**	$ 20.9
Unrealized gross losses	**2.9**	0.5
Fair value of securities in an unrealized gain position	**338.1**	348.9
Fair value of securities in an unrealized loss position	**164.8**	11.4

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 six months ended June 30, 2021 and 2020.

As of June 30, 2021, 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 98 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of June 30, 2021, 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 default on interest or principal payments for any of our debt securities.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Proceeds from sales	**$ 44.4**	$ 194.8	**$ 87.7**	$ 232.8
Realized gross gains on sales	**0.7**	2.7	**1.8**	3.6
Realized gross losses on sales	**0.4**	7.2	**0.8**	8.0

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.

Accounts Receivable Factoring Arrangements

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 $694.3 million and $754.9 million of accounts receivable as of June 30, 2021 and December 31, 2020, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated condensed results of operations for the three and six months ended June 30, 2021 and 2020 were not material.

Note 7: Income Taxes

The effective tax rate was 12.8 percent for the three months ended June 30, 2021, compared with 14.1 percent for the three months ended June 30, 2020. The effective tax rate was 10.6 percent for the six months ended June 30, 2021, compared with 13.7 percent for the six months ended June 30, 2020. The lower effective tax rates for the three and six months ended June 30, 2021 were primarily due to the income tax impact of the excess inventory charges related to our COVID-19 antibodies and lower income tax expense related to lower net gains on investment securities compared to same period in 2020, partially offset by a lower net discrete tax benefit compared to the same period in 2020 and a nondeductible acquired IPR&D charge in the second quarter of 2020.

The U.S. examination of tax years 2016-2018 began in the fourth quarter of 2019 and remains ongoing. The resolution of this audit period will likely extend beyond the next 12 months.

Note 8: Retirement Benefits

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

	Defined Benefit Pension Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Components of net periodic benefit cost:				
Service cost	**$ 93.3**	$ 83.0	**$ 185.3**	$ 161.7
Interest cost	**84.8**	107.3	**169.1**	212.3
Expected return on plan assets	**(237.2)**	(220.6)	**(475.2)**	(441.8)
Amortization of prior service cost	**1.1**	1.1	**2.2**	2.2
Recognized actuarial loss	**122.6**	117.1	**244.4**	228.1
Net periodic benefit cost	**$ 64.6**	$ 87.9	**$ 125.8**	$ 162.5

	Retiree Health Benefit Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Components of net periodic benefit income:				
Service cost	**$ 12.9**	$ 10.6	**$ 24.6**	$ 20.4
Interest cost	**8.2**	10.9	**16.3**	21.9
Expected return on plan assets	**(36.5)**	(37.4)	**(73.1)**	(74.8)
Amortization of prior service benefit	**(14.9)**	(14.9)	**(29.8)**	(29.8)
Recognized actuarial loss	**0.8**	0.6	**1.6**	1.4
Net periodic benefit income	**$ (29.5)**	$ (30.2)	**$ (60.4)**	$ (60.9)

We contributed approximately $20 million to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans during the six months ended June 30, 2021. We contributed approximately $10 million in discretionary funding during the six months ended June 30, 2021. During the remainder of 2021, we expect to make contributions of approximately $10 million to our defined benefit pension and retiree health plans to satisfy minimum funding requirements.

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 believe the legal proceedings in which we are named as defendants are without merit and we are defending against them vigorously. It is not possible to determine the 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 condensed 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 product liability insurance, we are self-insured for product liability losses for all our currently and previously marketed products.

Patent Litigation

Alimta Patent Litigation

U.S. Patent Litigation

Alimta (pemetrexed) is protected by a vitamin regimen patent until November 2021, plus pediatric exclusivity through May 2022.

In August 2017, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Apotex Inc. (Apotex) alleging infringement of Alimta's vitamin regimen patent for its application to market a pemetrexed product. In December 2019, the U.S. District Court for the Southern District of Indiana granted our motion for summary judgment of infringement, and in December 2020, the U.S. Court of Appeals for the Federal Circuit affirmed that ruling. Apotex did not request reconsideration or a rehearing of that ruling and did not petition the U.S. Supreme Court to review the case. This matter is now closed.

In December 2019, we settled a lawsuit we filed against Eagle Pharmaceuticals, Inc. (Eagle) in response to its application to market a product using an alternative form of pemetrexed. Per the settlement agreement, Eagle has a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022.

European Patent Litigation

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

Emgality Patent Litigation

In September 2018, we were named as a 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 nine different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. Trial is expected in March 2022. 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 refractory migraine, would be infringed by our continued sales of Emgality.

Separately, the U.S. Patent and Trademark Office (USPTO) granted our request to initiate an *inter partes review* (IPR) to reexamine the validity of the nine Teva patents asserted against us in the litigation. In February 2020, the USPTO ruled in our favor and found that the claims asserted against us in six of Teva's nine patents were invalid. In March 2020, the USPTO ruled against us on the remaining three Teva patents, finding that we failed to show that the remaining three patents were unpatentable based on the subset of invalidity arguments available in an IPR proceeding. In April 2020, we appealed the USPTO’s March 2020 ruling, and Teva appealed the USPTO’s February 2020 ruling to the U.S. Court of Appeals for the Federal Circuit. The IPR appeals will proceed in parallel with the district court litigation.

Jardiance Patent Litigation

In November 2018, Boehringer Ingelheim (BI), our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court 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, including in some allegations the compound patent, are invalid or would not be infringed. We are not a party to this litigation. This litigation has been stayed.

Taltz Patent Litigation

In April 2021, we petitioned the High Court of Ireland to declare invalid the patent that Novartis Pharma AG (Novartis) purchased from Genentech, Inc. in 2020. Novartis responded by filing a claim against us alleging patent infringement related to our commercialization of Taltz and seeking damages for past infringement and an injunction against future infringement. This matter is ongoing.

In April 2021 and June 2021, Novartis petitioned the Court of Rome Intellectual Property Division and the Commercial Court of Vienna, respectively, in preliminary injunction infringement proceedings against us related to our commercialization of Taltz. In June 2021, the Court of Rome Intellectual Property Division dismissed Novartis' preliminary injunction action. Novartis has appealed the ruling and a hearing is scheduled in September 2021. Both matters are ongoing.

Zyprexa Canada Patent Litigation

Beginning in the mid-2000's, several generic companies in Canada challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals denied our appeal of a lower court's decision that certain patent claims were invalid for lack of utility. In 2013, Apotex Inc. and Apotex Pharmachem Inc. (collectively, Apotex) brought claims against us in the Ontario Superior Court of Justice at Toronto for damages related to our enforcement of the Zyprexa compound patent under Canadian regulations governing patented drugs. Apotex seeks compensation based on novel legal theories under the Statute of Monopolies, Trade-Mark Act, and common law. In March 2021, the Ontario Superior Court granted our motion for summary judgement, thereby dismissing Apotex's case. Apotex appealed that ruling to the Court of Appeal for Ontario in April 2021.

Product Liability Litigation

Actos® Product Liability

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in four purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario filed December 2011 (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*), one in Quebec filed July 2012 (*Whyte et al. v. Eli Lilly et al.*), one in Saskatchewan filed November 2017 (*Weiler v. Takeda Canada Inc. et al.*), and one in Alberta filed January 2013 (*Epp v. Takeda Canada Inc. et al.*). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. An agreement to settle these actions became effective in May 2021, and the settlement claims administration process is ongoing. The lawsuits have been dismissed or discontinued.

Byetta® Product Liability

First initiated in March 2009, we are named as a defendant in approximately 570 Byetta product liability lawsuits in the U.S. involving approximately 805 plaintiffs. Approximately 55 of these lawsuits, covering about 285 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 515 of the lawsuits, covering about 515 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. Two lawsuits, representing approximately two plaintiffs, have also been filed in various state courts. Approximately 565 of the lawsuits, involving approximately 800 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); while six plaintiffs allege Byetta caused or contributed to pancreatitis. In addition, one case alleges that Byetta caused or contributed to ampullary cancer. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings.

In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed the U.S. District Court for the Southern District of California's grant of summary judgment in the MDL based on that court's discovery rulings and remanded the cases back to the U.S. District Court for further proceedings. In March 2021, the U.S. District Court granted summary judgment for the defendants and in April 2021, the plaintiffs filed a notice of appeal to the U.S. Court of Appeals for the Ninth Circuit. As of July 2021, a number of plaintiffs in the MDL have dismissed their lawsuits, but the majority of the MDL lawsuits currently remain ongoing. In the state court actions, in November 2018, the California Court of Appeal reversed the Los Angeles County Superior Court of California's grant of summary judgment based on that court's discovery rulings and remanded for further proceedings. In April 2021, the Los Angeles County Superior Court of California granted summary judgment for the defendants.

We are aware of approximately 20 additional claimants who have not yet filed suit. These additional claims allege damages for pancreatic cancer or thyroid cancer.

Cialis Product Liability

First initiated in August 2015, we are named as a defendant in approximately 350 Cialis product liability lawsuits in the U.S. These cases, many of which were originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have filed cases and an unspecified number of future cases coordinated into a federal multidistrict litigation (MDL) in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra®. The JPML ordered the transfer of the existing cases to the now-renamed MDL *In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*. In April 2020, the MDL court granted summary judgment to the defendants on all of the claims brought against them by the plaintiffs. In May 2020, plaintiffs filed an appeal in the U.S. Court of Appeals for the Ninth Circuit. The plaintiffs' appeal has been administratively closed until August 2021 pending completion of a procedure to resolve the claims in this litigation.

Jardiance Product Liability

First initiated in January 2019, we and Boehringer Ingelheim Pharmaceuticals, Inc., a subsidiary of BI, have been named as a defendant in approximately 95 product liability lawsuits in the U.S., mostly in Stamford Superior Court in Connecticut, alleging that Jardiance caused or contributed to plaintiffs' Fournier's gangrene. Our agreement with BI calls for BI to defend and indemnify us against any damages, costs, expenses, and certain other losses with respect to product liability claims in accordance with the terms of the agreement.

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

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 the HHS's December 30, 2020 advisory opinion stating that drug manufacturers are required to deliver discounts under the 340B program to all contract pharmacies. We seek a declaratory judgment that the defendants violated the Administrative Procedures 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 Lilly. In May 2021, HRSA notified us that it determined that Lilly's policy was contrary to the 340B statute. In response, in May 2021, we 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. This matter is ongoing.

In January 2021, we, along with other pharmaceutical manufacturers, were named as a defendant in a petition currently pending before the HHS Administrative Dispute Resolution Panel. Petitioner seeks declaratory and other injunctive 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, Novo Nordisk Inc., and AstraZeneca Pharmaceuticals LP, 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 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 United States 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 lawsuit brought by the Labor Attorney for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals 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 actions of unspecified financial impact, including paying lifetime health coverage for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. We appealed this decision. In July 2018, the appeals court affirmed the labor court's ruling with a liquidated award of 300 million Brazilian real (for moral damages, donation of equipment, and creation of a foundation) which, adjusted for inflation and interest using the current Central Bank of Brazil's special system of clearance and custody rate (SELIC), is approximately 950 million Brazilian real (approximately $185 million as of June 30, 2021). The appeals court restricted the broad health coverage awarded by the labor court to health problems that claimants could show arose from exposure to the alleged contamination. In August 2019, Lilly Brasil filed an appeal to the superior labor court. In September 2019, the appeals court stayed a number of elements of its prior decision, including the obligation to provide health coverage for contractors, their children, and children of employees who worked at the Cosmopolis facility, pending the determination of Lilly Brasil's appeal to the superior labor court. The cost of any such health coverage has not been determined. In June 2021, the appeals court published its decision on the admissibility of Lilly Brasil's appeal, admitting the majority of the elements of the appeal to proceed; elements not proceeding are subject to an interlocutory appeal to the appeals court filed in June 2021.

In June 2019, the Labor Attorney filed an application in the labor court for enforcement of the healthcare coverage granted by the appeals court in its July 2018 ruling and requested restrictions on Lilly Brasil's assets in Brazil. In July 2019, the labor court issued a ruling requiring either a freeze of Lilly Brasil's immovable property or, alternatively, a security deposit or lien of 500 million Brazilian real. Lilly Brasil filed a writ of mandamus challenging this ruling, but the court has stayed its decision on this writ and instead directed the parties to attend conciliation hearings, a process that concluded unsuccessfully in September 2020. Consequently, the partial stay of the proceedings relating to Lilly Brasil's application to appeal in the main proceedings has been lifted and in June 2021, the court reduced the security deposit or lien to 100 million Brazilian real from the 500 million Brazilian real referred to above**.** In addition, the Labor Attorney's application for preliminary enforcement of the July 2018 healthcare coverage ruling was granted. As the conciliation hearings have been unsuccessful, we have filed a brief to strike the Labor Attorney's application to enforce the previous healthcare coverage. Lilly Brasil is currently awaiting a determination as to whether its application seeking leave to appeal to the superior labor court has been successful.

Individual Former Employee Litigation

We are also named in approximately 30 lawsuits filed in the same labor court by individual former employees making similar claims. These lawsuits are each at various stages in the litigation process, with judgments being handed down in approximately half of the lawsuits, nearly all of which are on appeal in the labor courts.

China NDRC Antitrust Matter

The competition authority in China has investigated our distributor pricing practices in China in connection with a broader inquiry into pharmaceutical industry pricing. We have cooperated with this investigation.

Eastern District of Pennsylvania Pricing (Average Manufacturer Price) Inquiry

In November 2014, we, along with another pharmaceutical manufacturer, are 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. Trial is scheduled for February 2022.

Health Choice Alliance

We are named as a defendant in a lawsuit filed in June 2017 in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain patient support programs related to our products Humalog, Humulin, and Forteo. In September 2019, the U.S. District Court granted the U.S. Department of Justice's motion to dismiss the relator's second amended complaint. In January 2020, the relator appealed the District Court's dismissal to the U.S. Court of Appeals for the Fifth Circuit. In July 2021, the U.S. Court of Appeals for the Fifth Circuit affirmed the dismissal of the lawsuit. We are also named as a defendant in two similar 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. In November 2020, the Texas state court action was stayed pending a final determination with respect to the aforementioned federal lawsuit. In April 2021, the New Jersey state court action was dismissed with prejudice and in June 2021, the relator filed a notice of appeal to the Appellate Division of the New Jersey Superior Court, appealing the state court's decision.

Pricing Litigation, Investigations, and Inquiries

Litigation

In December 2017, we, along with Sanofi-Aventis U.S. LLC (Sanofi) and Novo Nordisk, Inc. (Novo Nordisk) were named as defendants in a consolidated purported class action lawsuit, *In re. Insulin Pricing Litigation*, in the U.S. District Court for the District of New Jersey relating to insulin pricing seeking damages under various state consumer protection laws and the Federal Racketeer Influenced and Corrupt Organization Act (federal RICO Act). Separately, in February 2018, we, along with Sanofi and Novo Nordisk, were named as defendants in *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.*, in the same court, seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. In both *In re. Insulin Pricing Litigation* and the *MSP Recovery Claims* litigation, the court dismissed claims under the federal RICO Act and certain state laws. In April 2021, the plaintiffs in *In re. Insulin Pricing Litigation* amended their complaint to allege additional state law claims for civil conspiracy and violations of state RICO statutes. Also, filed in the same court in November 2020, we, along with Sanofi, Novo Nordisk, CVS, Express Scripts, and Optum, have been sued in a purported class action, *FWK Holdings, LLC v. Novo Nordisk Inc., et al.*, for alleged violations of the federal RICO Act as well as the New Jersey RICO Act and antitrust law. That same group of defendants, along with Medco Health and United Health Group, also have been sued in other purported class actions in the same court, *Rochester Drug Co-Operative Inc. v. Eli Lilly & Co. et al.* and *Value Drug Co. v. Eli Lilly & Co. et al.* both initiated in March 2020, for alleged violations of the federal RICO Act. In September 2020, the U.S. District Court for the District of New Jersey granted plaintiffs' motion to consolidate *FWK Holdings, LLC v. Novo Nordisk Inc., et al.*, *Rochester Drug Co-Operative Inc. v. Eli Lilly & Co. et al.*, and *Value Drug Co. v. Eli Lilly & Co. et al.* In July 2021, the U.S. District Court for the District of New Jersey dismissed the three antitrust claims alleged by plaintiffs in the consolidated litigation and denied dismissal of the RICO claims.

In October 2018, the Minnesota Attorney General's Office initiated litigation against us, Sanofi, and Novo Nordisk, *State of Minnesota v. Sanofi-Aventis U.S. LLC et al.,* in the U.S. District Court for the District of New Jersey, alleging unjust enrichment, violations of various Minnesota state consumer protection laws, and the federal RICO Act. In March 2021, the U.S. District Court for the District of New Jersey dismissed with prejudice the Minnesota Attorney General's federal RICO claims and false advertising claims under state law; the consumer fraud and other related state law claims remain ongoing. Additionally, in May 2019, the Kentucky Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, *Commonwealth of Kentucky v. Novo Nordisk, Inc. et al.*, in Kentucky state court, alleging violations of the Kentucky consumer protection law, false advertising, and unjust enrichment. In November 2019, Harris County in Texas initiated litigation against us, Sanofi, Novo Nordisk, Express Scripts, CVS, Optum, and Aetna, *County of Harris Texas v. Eli Lilly & Co., et al.*, in federal court in the Southern

District of Texas alleging violations of the federal RICO Act, federal and state antitrust law, and the state deceptive trade practices-consumer protection act. Harris County also alleges common law claims such as fraud, unjust enrichment, and civil conspiracy. This lawsuit relates to our insulin products as well as Trulicity.

In June 2021, the City of Miami, Florida initiated litigation against us, Sanofi, Novo Nordisk, ESI, CVS/Caremark/Aetna, and Optum, asserting state law antitrust, common law fraud, money had and received, unjust enrichment, and civil conspiracy claims. In June 2021, the Mississippi Attorney General's Office initiated litigation against us, Sanofi, Novo Nordisk, Evernorth/ESI, CVS/Caremark, and United/Optum in the Hinds County, Mississippi Chancery Court, alleging state law consumer protection, unjust enrichment, and civil conspiracy claims.

Investigations, Subpoenas, and Inquiries

We received a subpoena from the New York and Vermont Attorney General Offices and civil investigative demands from the Washington, New Mexico, and Colorado Attorney General Offices relating to the pricing and sale of our insulin products. The Offices of the Attorney General in Mississippi, Washington D.C., California, Florida, Hawaii, and Nevada have requested information relating to the pricing and sale of our insulin products. We also received interrogatories and a subpoena from the California Attorney General's Office regarding our competition in the long-acting insulin market, which was subsequently withdrawn in June 2021.

We received two requests from the House of Representatives' Committee on Energy and Commerce and a request from the Senate's Committee on Health, Education, Labor, and Pensions seeking certain information related to the pricing of insulin products, among other issues. We also received requests from the House of Representatives' Committee on Oversight and Reform and the Senate's Committee on Finance, which seek detailed commercial information and business records. In January 2021, the Senate's Committee on Finance released a report summarizing the findings of its investigation.

We are cooperating with all of these 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. A trial date has not been set.

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 June 30, 2021 and 2020:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at April 1, 2021	**$ (1,677.2)**	**$ 4.5**	**$ (4,646.3)**	**$ (76.6)**	**$ (6,395.6)**
Other comprehensive income (loss) before reclassifications	**161.0**	**4.4**	**(10.2)**	**(136.8)**	**18.4**
Net amount reclassified from accumulated other comprehensive loss	**—**	**0.2**	**86.6**	**3.3**	**90.1**
Net other comprehensive income (loss)	**161.0**	**4.6**	**76.4**	**(133.5)**	**108.5**
Balance at June 30, 2021	**$ (1,516.2)**	**$ 9.1**	**$ (4,569.9)**	**$ (210.1)**	**$ (6,287.1)**

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at April 1, 2020	$ (1,804.5)	$ 5.8	$ (4,530.3)	$ (556.9)	$ (6,885.9)
Other comprehensive income (loss) before reclassifications	82.0	5.8	(6.7)	33.0	114.1
Net amount reclassified from accumulated other comprehensive loss	—	3.5	82.1	3.3	88.9
Net other comprehensive income (loss)	82.0	9.3	75.4	36.3	203.0
Balance at June 30, 2020	$ (1,722.5)	$ 15.1	$ (4,454.9)	$ (520.6)	$ (6,682.9)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the six months ended June 30, 2021 and 2020:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2021	**$ (1,427.5)**	**$ 14.8**	**$ (4,751.0)**	**$ (332.7)**	**$ (6,496.4)**
Other comprehensive income (loss) before reclassifications	**(88.7)**	**(6.4)**	**8.6**	**116.0**	**29.5**
Net amount reclassified from accumulated other comprehensive loss	**—**	**0.7**	**172.5**	**6.6**	**179.8**
Net other comprehensive income (loss)	**(88.7)**	**(5.7)**	**181.1**	**122.6**	**209.3**
Balance at June 30, 2021	**$ (1,516.2)**	**$ 9.1**	**$ (4,569.9)**	**$ (210.1)**	**$ (6,287.1)**

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2020	$ (1,678.0)	$ 4.9	$ (4,638.6)	$ (211.9)	$ (6,523.6)
Other comprehensive income (loss) before reclassifications	(44.5)	6.8	24.2	(315.2)	(328.7)
Net amount reclassified from accumulated other comprehensive loss	—	3.4	159.5	6.5	169.4
Net other comprehensive income (loss)	(44.5)	10.2	183.7	(308.7)	(159.3)
Balance at June 30, 2020	$ (1,722.5)	$ 15.1	$ (4,454.9)	$ (520.6)	$ (6,682.9)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Tax benefit (expense)	**2021**	**2020**	**2021**	**2020**
Foreign currency translation gains/losses	**$ (21.9)**	$ 27.4	**$ (53.3)**	$ (11.1)
Unrealized net gains/losses on securities	**(1.3)**	(2.4)	**3.1**	(2.8)
Defined benefit pension and retiree health benefit plans	**(20.2)**	(18.9)	**(51.5)**	(44.6)
Effective portion of cash flow hedges	**35.5**	(9.7)	**(32.6)**	82.0
Benefit (provision) for income taxes allocated to other comprehensive income (loss) items	**$ (7.9)**	$ (3.6)	**$ (134.3)**	$ 23.5

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 June 30,		Six Months Ended June 30,		Affected Line Item in the Consolidated Condensed Statements of Operations
	2021	**2020**	**2021**	**2020**	
Amortization of retirement benefit items:					
Prior service benefits, net	**$ (13.8)**	$ (13.8)	**$ (27.6)**	$ (27.6)	Other–net, (income) expense
Actuarial losses, net	**123.4**	117.7	**246.0**	229.5	Other–net, (income) expense
Total before tax	**109.6**	103.9	**218.4**	201.9	
Tax benefit	**(23.0)**	(21.8)	**(45.9)**	(42.4)	Income taxes
Net of tax	**86.6**	82.1	**172.5**	159.5	
Other, net of tax	**3.5**	6.8	**7.3**	9.9	Other–net, (income) expense
Total reclassifications, net of tax	**$ 90.1**	$ 88.9	**$ 179.8**	$ 169.4	

Note 11: Other–Net, (Income) Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Interest expense	**$ 86.9**	$ 88.3	**$ 174.7**	$ 180.8
Interest income	**(5.4)**	(7.1)	**(10.9)**	(21.4)
Net investment gains on equity securities	**(215.4)**	(576.8)	**(517.0)**	(763.4)
Retirement benefit plans	**(71.1)**	(35.9)	**(144.5)**	(80.5)
Other (income) expense	**14.5**	84.6	**(13.9)**	148.5
Other–net, (income) expense	**$ (190.5)**	$ (446.9)	**$ (511.6)**	$ (536.0)

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

Results of Operations

(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 the results of operations and financial position of our consolidated company. 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, 2020, 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, recent product and late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data are presented on a diluted basis.

COVID-19 Pandemic

In response to the COVID-19 pandemic, we have focused on maintaining a reliable supply of our medicines; reducing the strain on the medical system; developing treatments for COVID-19; protecting the health, safety, and well-being of our employees; supporting our communities; and ensuring affordability of and access to our medicines, particularly insulin.

We have experienced negative impacts to our underlying business due to the COVID-19 pandemic, including decreases in new prescriptions as a result of fewer patient visits to physician's offices to begin or change treatment, changes in payer segment mix, and the use of patient affordability programs in the United States (U.S.) due to increased unemployment. Additionally, we have experienced, and may continue to experience if the COVID-19 pandemic undergoes resurgent or more severe waves, decreased demand as a result of lack of normal access and fewer in-person interactions by patients and our employees with the healthcare system. In certain locations in the U.S. and around the world with COVID-19 outbreaks, we temporarily halted in-person interactions by our employees with healthcare providers and increased virtual interactions. Prescriptions in most of our therapeutic areas have returned to pre-COVID-19 pandemic levels in the U.S., and healthcare systems in most of our major markets have largely resumed normal operations as of June 30, 2021. While a majority of our in-person interactions have resumed, we may decide to halt such activity in the future and, in those cases, expect to resume such interactions as it is safe to do so and in compliance with applicable guidance and requirements. We may experience additional pricing pressures resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.

We remain committed to discovering and developing new treatments for the patients we serve. At the beginning of the COVID-19 pandemic, we paused new clinical trial starts and enrollment in new trials in order to reduce the strain on the medical system, and we have resumed this activity in our clinical trials. However, significant delays or unexpected issues, such as higher discontinuation rates or delays accumulating data, affecting the timing, conduct, or regulatory review of our clinical trials, could adversely affect our ability to commercialize some assets in our product pipeline if the COVID-19 pandemic experiences resurgent or more severe waves.

Since the start of the pandemic we have worked with a variety of organizations, including governmental agencies, to facilitate access to our COVID-19 therapies in various countries. The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for bamlanivimab and bamlanivimab and etesevimab administered together for higher-risk patients who have been recently diagnosed with mild-to-moderate COVID-19 and for baricitinib for treatment with or without remdesivir in hospitalized COVID-19 patients. In April 2021, the FDA subsequently revoked the EUA for bamlanivimab alone. In June 2021, the Office of the Assistant Secretary for Preparedness and Response halted shipment of bamlanivimab and etesevimab administered together in the U.S. This was due to the prevalence of the Gamma and Beta variants in the U.S. at that time and the fact that bamlanivimab and etesevimab administered together do not retain neutralization effects against those variants. The COVID-19 pandemic has involved, and may continue to involve, the spread of variants, including the Delta variant which is currently estimated to be the most dominant variant in the U.S. Preclinical data demonstrate that bamlanivimab and etesevimab administered together retain neutralization activity against the variants currently in circulation in many countries, including Delta and Alpha. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for bamlanivimab alone and for bamlanivimab and etesevimab administered together for patients that do not require supplemental oxygen and who are at high risk of progressing to severe COVID-19.

We have, and will continue to, face unique risks and uncertainties in our development, manufacture, and uptake of potential treatments for COVID-19, including vulnerability to supply chain disruptions, higher manufacturing costs, difficulties in manufacturing appropriate quantities of our therapies, heightened regulatory scrutiny of our manufacturing practices, restrictions on administration that limit widespread and timely access to our therapies, and risks related to handling, return, and/or refund of product after delivery by us. Expedited authorization processes, including our EUA for bamlanivimab and etesevimab administered together, have allowed restricted distribution of products with less than typical safety and efficacy data, and additional data that become available have and may further call into question the safety or effectiveness of our COVID-19 therapies. Additionally, the availability of superior or competitive therapies, or preventative measures, such as vaccines, coupled with the transient nature of pandemics, have and could further negatively impact or eliminate demand for our COVID-19 therapies. Mutations or the spread of other variants of the coronavirus have in some cases reduced the effectiveness of our COVID-19 therapies, and may further render our therapies less effective or ineffective. We may also be required to accept returns of certain bamlanivimab and etesevimab previously supplied together in the U.S. if the relevant EUA is revoked or terminated due to safety and efficacy concerns. In addition, evolving regulatory priorities have intensified governmental scrutiny of our operations, including our compliance with Good Manufacturing Practices (cGMP), quality assurance, and similar regulations relating to our manufacture of COVID-19 therapies and other medicines. Any of these risks could prevent us from recouping our substantial investments in the research, development, and manufacture of our COVID-19 therapies. These risks could also affect other aspects of our business, including potentially resulting in delays or denials in the approval or launch of other products.

Our ability to continue to operate without significant negative impacts will in part depend on our ability to protect our employees and our supply chain. We have taken steps to protect our employees worldwide, with particular measures in place for those working in our manufacturing sites and distribution facilities. We have been able to largely maintain our normal operations. However, uncertainty resulting from the COVID-19 pandemic could have an adverse impact on our manufacturing operations, global supply chain, and distribution systems, which could impact our ability to produce and distribute our products and the ability of third parties on which we rely to fulfill their obligations to us, and could increase our expenses if the COVID-19 pandemic experiences resurgent or more severe waves.

Although the COVID-19 pandemic has affected our operations and demand for our products, it has not negatively impacted our liquidity position. We expect to continue to generate cash flows to meet our short-term liquidity needs and to have access to liquidity via the short-term and long-term debt markets. As part of our response to the COVID-19 pandemic, and at the request of the U.S. and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic has continued to evolve during 2021, we have incurred inventory charges related to our COVID-19 antibodies during the three and six months ended June 30, 2021, primarily due to the combination of changes to current and forecasted demand from the U.S. and international governments, including changes to our agreement with the U.S. government, and near-term expiry dates of COVID-19 antibodies. We could experience additional impairments of our assets, including inventory related to our COVID-19 antibodies, or significant changes in the fair value of our assets due to the COVID-19 pandemic, including as a result of the factors discussed above.

See “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020 for additional information on risk factors that could impact our results.

Financial Results

The following table summarizes our key operating results:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021	2020	Percent Change	2021	2020	Percent Change
Revenue	**$ 6,740.1**	$ 5,499.4	23	**$ 13,545.7**	$ 11,359.2	19
Gross margin	**4,786.9**	4,277.4	12	**9,713.9**	8,922.1	9
Gross margin as a percent of revenue	**71.0 %**	77.8 %		**71.7 %**	78.5 %	
Operating expenses	**$ 3,358.5**	$ 2,838.8	18	**$ 6,619.3**	$ 5,780.5	15
Acquired in-process research and development (IPR&D)	**25.0**	241.8	(90)	**324.3**	294.1	10
Asset impairment, restructuring, and other special charges	**—**	—	NM	**211.6**	59.9	NM
Net income	**1,390.2**	1,412.0	(2)	**2,745.5**	2,868.5	(4)
EPS	**1.53**	1.55	(1)	**3.01**	3.15	(4)

NM - not meaningful

Revenue increased for the three and six months ended June 30, 2021 driven by increased volume and the favorable impact of foreign exchange rates, partially offset by lower realized prices. We estimate that the COVID-19 pandemic negatively impacted revenue for the three months ended June 30, 2020 by approximately $250 million of decreased customer buying that largely offset product stocking that occurred in the first quarter of 2020. Operating expenses, defined as the sum of research and development and marketing, selling, and administrative expenses, increased for the three and six months ended June 30, 2021, primarily due to higher development expenses for late-stage assets and higher research and development expenses for COVID-19 therapies, as well as higher marketing and selling expenses. The increase in marketing and selling expenses for the three and six months ended June 30, 2021 was driven by lower marketing and selling expenses in the same periods in 2020 due to pandemic-related spending reductions. The decrease in net income and EPS for the three and six months ended June 30, 2021 was primarily driven by higher operating expenses, largely offset by higher gross margin.

The following highlighted items also affect comparisons of our financial results for the three and six months ended June 30, 2021 and 2020:

2021

Cost of Sales (See Note 5 to the consolidated condensed financial statements)

- We recognized inventory impairment charges of $423.0 million and $504.5 million for the three and six months ended June 30, 2021, respectively, for excess inventory related to our COVID-19 antibodies. As part of our response to the COVID-19 pandemic, and at the request of the U.S. and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic has continued to evolve during 2021, we incurred excess inventory charges primarily due to the combination of changes to current and forecasted demand from U.S. and international governments, including changes to our agreement with the U.S. government, and near-term expiry dates of COVID-19 antibodies.

Acquired IPR&D (See Note 3 to the consolidated condensed financial statements)

- We recognized acquired IPR&D charges of $25.0 million and $324.3 million for the three and six months ended June 30, 2021, respectively. The charges for the three months ended June 30, 2021 were related to a business development transaction with MiNA Therapeutics Limited (MiNA). The charges for the six months ended June 30, 2021 also included charges related to business development transactions with Rigel Pharmaceuticals, Inc. (Rigel), Precision BioSciences, Inc. (Precision), Merus N.V. (Merus), and Asahi Kasei Pharma Corporation (Asahi).

Asset Impairment, Restructuring, and Other Special Charges (See Note 5 to the consolidated condensed financial statements)

- We recognized charges of $211.6 million for the six months ended June 30, 2021 primarily related to an intangible asset impairment resulting from the sale of the rights to Qbrexza®, as well as acquisition and integration costs associated with the acquisition of Prevail Therapeutics Inc. (Prevail).

Other-Net, (Income) Expense (See Note 6 to the consolidated condensed financial statements)

- We recognized other income of $215.4 million and $517.0 million of net investment gains on equity securities for the three and six months ended June 30, 2021, respectively.

2020

Acquired IPR&D (See Note 3 to the consolidated condensed financial statements)

- We recognized acquired IPR&D charges of $241.8 million and $294.1 million for the three and six months ended June 30, 2020, respectively. The charges for the three months ended June 30, 2020 were related to the acquisition of a pre-clinical stage company, as well as business development transactions with AbCellera Biologics Inc. (AbCellera), Evox Therapeutics Limited (Evox), and Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences). The charges for the six months ended June 30, 2020 also included a charge related to a business development transaction with Sitryx Therapeutics Limited (Sitryx).

Asset Impairment, Restructuring, and Other Special Charges (See Note 5 to the consolidated condensed financial statements)

- We recognized charges of $59.9 million for the six months ended June 30, 2020 primarily related to acquisition and integration costs associated with the acquisition of Dermira, Inc. (Dermira).

Other-Net, (Income) Expense (See Note 6 to the consolidated condensed financial statements)

- We recognized other income of $576.8 million and $763.4 million of net investment gains on equity securities for the three and six months ended June 30, 2020, respectively.

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 candidates in clinical development or under regulatory review, and a larger number of projects in the discovery phase.

The following new molecular entities (NMEs) are currently in Phase III clinical trials or have been submitted for regulatory review or have received first regulatory approval in the U.S., Europe, or Japan in 2021. In addition, the following table includes certain NMEs currently in Phase I or Phase II clinical trials. The following table reflects the status of these NMEs, including certain other developments since January 1, 2021.

Compound	Indication	Status	Developments
COVID-19 Therapies			
Bamlanivimab administered alone	COVID-19	Emergency Use Authorization[(1)]	Announced in the first quarter of 2021 that a Phase III trial met the primary and all key secondary endpoints. The EMA's CHMP issued a positive scientific opinion in the first quarter of 2021. In the second quarter of 2021 the FDA revoked the EUA for bamlanivimab alone in the U.S.
Bamlanivimab and etesevimab administered together	COVID-19	Emergency Use Authorization	Announced in the first quarter of 2021 that Phase III trials met the primary and all key secondary endpoints. Additional Phase III trial is ongoing. The FDA granted EUA for higher-risk patients recently diagnosed with mild-to-moderate COVID-19 in the first quarter of 2021. The EMA's CHMP issued a positive scientific opinion in the first quarter of 2021. Submitted in Europe in the first quarter of 2021.
Bamlanivimab, etesevimab and bebtelovimab (LY-CoV1404) administered together	COVID-19	Phase II	Phase II trial initiated in the second quarter of 2021.
VIR-7831 and bamlanivimab administered together[(2)]	COVID-19	Phase II	Phase II trial initiated in the first quarter of 2021.

Compound	Indication	Status	Developments
Endocrinology			
Tirzepatide	Heart failure with preserved ejection fraction	Phase III	Phase III trial initiated in the second quarter of 2021.
	Obesity		Phase III trials are ongoing.
	Type 2 diabetes		Announced in the first and second quarters of 2021 that Phase III trials met the primary and key secondary endpoints. We intend to submit to regulatory authorities for approval by the end of 2021. Additional Phase III trials are ongoing.
	Nonalcoholic steatohepatitis	Phase II	Phase II trial is ongoing.
Basal Insulin-Fc	Type 1 and 2 diabetes	Phase II	Phase II trials are ongoing.
GGG Tri-Agonist	Obesity	Phase II	Phase II trials initiated in the second quarter of 2021.
	Type 2 diabetes		
Immunology			
Lebrikizumab[3]	Atopic dermatitis	Phase III	Granted FDA Fast Track designation[4]. Phase III trials are ongoing.
Mirikizumab	Crohn's disease	Phase III	Phase III trials are ongoing.
	Ulcerative colitis		Announced in the first quarter of 2021 that a Phase III trial met the primary and key secondary endpoints. Additional Phase III trials are ongoing.
	Psoriasis	Not pursuing submission	Announced in the second quarter of 2021 that we do not plan to pursue submission.
CXCR1/2 Ligands Monoclonal Antibody	Hidradenitis suppurativa	Phase II	Phase II trial is ongoing.
IL-2 Conjugate	Systemic lupus erythematosus	Phase II	Phase II trial is ongoing.
	Ulcerative colitis		Phase II trial initiated in the second quarter of 2021.
PD-1 MAB Agonist	Rheumatoid arthritis	Phase II	Phase II trial initiated in the first quarter of 2021.
Neuroscience			
Tanezumab[5]	Osteoarthritis pain	Submitted	In the first quarter of 2021 an Advisory Committee to the FDA concluded that the proposed risk evaluation and mitigation strategy will not ensure that the benefits outweigh the risks. In collaboration with Pfizer, we plan to continue to work with the FDA as it continues to review the submission.
	Cancer pain	Phase III	In collaboration with Pfizer, announced in July 2021 that a Phase III trial met the primary endpoint.
Donanemab	Early Alzheimer’s disease	Phase III	Announced in the first quarter of 2021 that a Phase II trial met the primary endpoint and that we expanded a Phase II trial to become a Phase III trial. Granted FDA Breakthrough Therapy designation[6] in the second quarter of 2021. We intend to submit to the FDA under the accelerated approval pathway by the end of 2021.
Solanezumab	Preclinical Alzheimer's disease	Phase III	Phase III trial is ongoing.
Epiregulin/TGFα MAB	Chronic pain	Phase II	Phase II trials are ongoing.

Compound	Indication	Status	Developments
GBA1 Gene Therapy (PR001)	Parkinson's disease	Phase II	Acquired in the Prevail acquisition in the first quarter of 2021. Granted FDA Fast Track designation[4]. Phase II trials are ongoing.
GRN Gene Therapy (PR006)	Frontotemporal dementia	Phase II	
PACAP38 Antibody	Chronic pain	Phase II	Phase II trial is ongoing.
SSTR4 Agonist	Chronic pain	Phase II	Phase II trials are ongoing.
Zagotenemab	Alzheimer's disease	Phase II	Phase II trial is ongoing.
Oncology			
Selpercatinib (Retevmo®)	Thyroid cancer	Launched[7]	Granted conditional marketing authorisation[7] in Europe in the first quarter of 2021. Phase III trials are ongoing.
	Lung cancer		
Sintilimab injection[8]	Lung cancer	Submitted	In collaboration with Innovent, submitted in the U.S. in the second quarter of 2021.
Pirtobrutinib (LOXO-305)	Chronic lymphocytic leukemia	Phase III	Phase III trial initiated in the first quarter of 2021.
	Mantle cell lymphoma	Phase III	Phase III trial initiated in the second quarter of 2021.
	B-cell malignancies	Phase II	Phase II trial initiated in the second quarter of 2021.

[1] EUAs remain active for certain countries outside of the U.S.

[2] In collaboration with Vir Biotechnology, Inc. and GlaxoSmithKline plc.

[3] In collaboration with Almirall, S.A. (Almirall) in Europe.

[4] Fast Track designation is designated to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

[5] In collaboration with Pfizer, Inc (Pfizer).

[6] 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.

[7] Continued approval may be contingent on verification and description of clinical benefit in confirmatory Phase III trials.

[8] In collaboration with Innovent Biologics, Inc. (Innovent).

Our pipeline also contains several new indication line extension (NILEX) products. The following certain NILEX products are currently in Phase II or Phase III clinical testing, have been submitted for regulatory review, or have received first regulatory approval in the U.S., Europe, or Japan for use in the indication described in 2021. The following table reflects the status of certain NILEX products, including certain other developments since January 1, 2021:

Compound	Indication	Status	Developments
Endocrinology			
Empagliflozin (Jardiance®)[1]	Heart failure with reduced ejection fraction	Approved	Granted FDA Fast Track designation[2]. Granted marketing authorisation in Europe in the second quarter of 2021.
	Chronic kidney disease	Phase III	Granted FDA Fast Track designation[2]. Phase III trials are ongoing.
	Heart failure with preserved ejection fraction		Granted FDA Fast Track designation[2]. Announced in July 2021 that a Phase III trial met the primary endpoint.
Immunology			
Baricitinib (Olumiant®)	Atopic dermatitis	Approved	Approved in Europe and Japan. Announced in July 2021 that the FDA will not meet the Prescription Drug User Fee Act action date for the submission in the U.S.
	COVID-19	Emergency Use Authorization[3]	Announced in the second quarter of 2021 that a Phase III trial evaluating baricitinib 4 mg once daily plus standard of care did not meet the primary endpoint, but did result in a significant reduction in death. In July 2021, the FDA broadened the EUA for baricitinib to allow for treatment with or without remdesivir.
	Alopecia areata	Submitted	Granted FDA Breakthrough Therapy designation[4]. Announced in the first and second quarters of 2021 that Phase III trials met the primary endpoints. Submitted in Japan in July 2021.
	Systemic lupus erythematosus	Phase III	Phase III trials are ongoing.
Oncology			
Abemaciclib (Verzenio®)	HR+, HER2- Adjuvant breast cancer	Submitted	Announced in the first quarter of 2021 patient-reported outcomes in combination with standard adjuvant endocrine therapy. Submitted in Japan in the first quarter of 2021.
	HR+, HER2+ Adjuvant breast cancer	Phase III	Phase III trial initiated in the second quarter of 2021.
	Prostate cancer	Phase III	Phase III trial initiated in July 2021.

[1] In collaboration with Boehringer Ingelheim.

[2] Fast Track designation is designated to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

[3] The FDA granted EUA for treatment with or without remdesivir in hospitalized COVID-19 patients.

[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.

Other Matters

Patent Matters

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

Our vitamin regimen patents for Alimta® expired in major European countries and Japan in June 2021. In the U.S., we expect the vitamin regimen patent for Alimta to provide us with patent protection through May 2022. However, we and Eagle Pharmaceuticals, Inc. (Eagle) reached an agreement in December 2019 to settle all pending U.S. patent litigation, allowing Eagle a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition in the U.S., major European countries, and Japan following the loss of patent exclusivity will cause a rapid and severe decline in revenue, and we expect that the entry of generic competition in the U.S. will have a material adverse effect on our consolidated results of operations and cash flows. See Note 9 to the consolidated condensed financial statements for a more detailed account of the legal proceedings currently pending regarding, among others, our Alimta patents.

Our compound patent for Humalog® (insulin lispro) has expired in major markets. Global regulators have different legal pathways to approve similar versions of insulin lispro. A competitor launched a similar version of insulin lispro in certain European markets in 2017 and in the U.S. in the second quarter of 2018. While it is difficult to estimate the severity of the impact of insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time.

Our formulation and use patents for Forteo® have expired in major markets. We expect further decline in revenue as a result of the anticipated entry of generic and biosimilar competition due to the loss of patent exclusivity in major markets.

Our compound patent for Cymbalta® expired in Japan in January 2020. Two generic competitors entered the market in June 2021. We expect that the entry of generic competition will cause a rapid and severe decline in revenue.

Foreign Currency Exchange Rates

As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro and Japanese yen. While we manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a substantial impact, either positive or negative, on our revenue, cost of sales, and operating expenses. While there is uncertainty in the future movements in foreign exchange rates, fluctuations in these rates could adversely impact our future consolidated results of operations and cash flows.

Trends Affecting Pharmaceutical Pricing, Reimbursement, Access, and Other Regulatory Matters

U.S.

In the U.S., public concern over access to and affordability of pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates, or other cost control measures may be enacted to manage federal and state budgets. Evolving regulatory priorities could further intensify these efforts and otherwise increase regulatory scrutiny over our operations. Key health policy initiatives affecting biopharmaceuticals include:

- the Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent stimulus bills that focus on ensuring availability and access to lifesaving drugs during a public health crisis,
- foreign reference pricing in Medicare and private insurance,
- modifications to Medicare Parts B and D,
- provisions that would allow the Department of Health and Human Services (HHS) to negotiate prices for biologics and drugs in Medicare,
- a reduction in biologic data exclusivity,
- proposals related to Medicaid prescription drug coverage and manufacturer drug rebates,
- proposals that would require biopharmaceutical manufacturers to disclose proprietary drug pricing information,

- state-level proposals related to prescription drug prices and reducing the cost of pharmaceuticals,
- federal and state proposals to permit importation of pharmaceuticals, including insulin, intended for sale in foreign markets, and
- the Biden administration's regulatory rule freeze affecting all federal agency rules that had not gone into effect as of January 20, 2021, impacting the implementation or effectiveness, as applicable, of final rules related to the 340B prescription drug program, rebate reform in Medicare Part D, drug importation including insulin, and foreign reference pricing in Medicare Parts B and D.

On September 1, 2020, we announced we would distribute all 340B ceiling priced products directly to covered entities and their child sites only. We provide 340B discounts to a contract pharmacy only if it is a wholly owned subsidiary of a covered entity, if a covered entity does not have an in-house retail pharmacy or, in the case of insulin, if the subject covered entity and its contract pharmacies agree to pass along the discount to patients without any markup for dispensing fees and without billing insurance or collecting duplicate discounts. We have been transparent with regulators on our distribution activity and continue to comply with all 340B program requirements. Certain covered entities and their trade associations have initiated litigation questioning whether our program, and similar actions by other manufacturers, violate 340B program requirements. We are engaged in a number of legal proceedings related to our decision to distribute all 340B ceiling priced products directly to covered entities and their child sites only. See Note 9 to the consolidated condensed financial statements for additional information regarding our ongoing 340B legal proceedings.

California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the effect this legislation or future legislation will have on our business. Several states have also passed importation legislation, including Colorado, Florida, Maine, New Hampshire, New Mexico, and Vermont. As of late 2020 several of these states were actively working with the former presidential administration to implement an importation program from Canada. On November 22, 2020, Florida announced it submitted a proposed importation plan to the U.S. In 2020, HHS and the FDA also took several actions to advance state importation initiatives, including issuing requests for proposals (RFPs) for personal importation and reimportation of insulin and a final rule on the Importation of Prescription Drugs. On July 9, 2021, the FDA and HHS announced the withdrawal of the RFPs. We continue to review these state proposals and legislation, as well as federal rules, commentary to the rulemaking, and guidance published by HHS and the FDA, the impact of which is uncertain at this time. On July 9, 2021, the Biden administration released its Executive Order on "Promoting Competition in the American Economy" (EO). The EO supports the importation of prescription drugs from Canada, requests that HHS develop a drug pricing plan within 45 days, and includes provisions to increase the availability of generics and biosimilars. We will continue to monitor and assess these developments.

In the private sector, consolidation and integration among healthcare providers significantly affects the competitive marketplace for pharmaceuticals. Health plans, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, typically maintain formularies that specify coverage (the conditions under which drugs are included on a plan's formulary) and reimbursement (the associated out-of-pocket cost to the consumer) to control costs by negotiating discounts, rebates and other price concessions in exchange for formulary inclusion. Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations that result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles. Consequently, pharmaceutical companies compete for formulary placement not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates. Value-based agreements, where the amount of rebates is based on achievement (or not) of specified outcomes, are another tool that may be utilized between payers and pharmaceutical companies as formulary placement and pricing are negotiated. Price is an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. We anticipate these downward pricing pressures will continue to negatively affect our consolidated results of operations. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost-sharing through high deductible plans and higher co-insurance or co-pays. We continue to invest in patient affordability solutions (resulting in lower revenue) in an effort to assist patients in affording their medicines.

The main coverage expansion provisions of the Affordable Care Act (ACA) are currently in effect through both state-based exchanges and the expansion of Medicaid. A trend has been the prevalence of benefit designs containing high out-of-pocket costs for patients, particularly for pharmaceuticals. In addition to the coverage expansions, many employers in the commercial market continue to evaluate strategies such as private exchanges and wider use of consumer-driven health plans to reduce their healthcare liabilities over time. Federal legislation, litigation, or administrative actions to repeal or modify some or all of the provisions of the ACA could have a material adverse effect on our consolidated results of operations and cash flows. At the same time, the broader paradigm shift towards performance-based reimbursement and the launch of several value-based purchasing initiatives have placed demands on the pharmaceutical industry to offer products with proven real-world outcomes data and a favorable economic profile.

On December 31, 2020, the Centers for Medicare and Medicaid Services published in the Federal Register a final regulation impacting the rules for calculating Medicaid rebate amounts, though the provision most likely to have a material impact on us relates to the inclusion of copayment assistance programs in best price and will take effect January 1, 2023. We are evaluating the impact of this regulation. We do not anticipate the changes related to "line extensions," which are scheduled to take effect January 1, 2022, to be material.

On March 11, 2021, President Biden signed into law the American Rescue Plan Act of 2021 (ARP). Section 9816 of the ARP removed Medicaid's maximum rebate percentage effective January 1, 2024. We are evaluating the impact of this legislation. We expect to see continued focus on regulating pricing, potentially resulting in additional legislation and regulation under the newly elected Congress and the Biden administration.

In addition, evolving regulatory priorities have intensified governmental scrutiny of our operations, including our compliance with cGMP, quality assurance, and similar regulations. Any regulatory issues concerning these matters could 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, delays or denials in the approvals of new products pending resolution of the issues, and reputational harm, any of which would adversely affect our business. See “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020. See also Note 9 to the consolidated condensed financial statements.

International

International operations also are generally subject to extensive price and market regulations. Cost-containment measures exist in a number of countries, including additional price controls and mechanisms to limit reimbursement for our products. Such policies are anticipated to increase in impact and reach, given the pressures on national and regional health care budgets that come from a growing, aging population and ongoing economic challenges. As additional reforms are finalized, we will assess their impact on future revenues. In addition, governments in many emerging markets are becoming increasingly active in expanding health care system offerings. Given the budget challenges of increasing health care coverage for citizens, policies may be proposed that promote generics and biosimilars only and reduce current and future access to branded pharmaceutical products. The COVID-19 pandemic is also creating additional pressure on health systems worldwide. As a result, cost containment and other measures may intensify as governments manage and emerge from the pandemic.

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 could affect our effective tax rate, results of operations, and cash flows. Countries around the world, including the U.S., are actively considering and enacting tax law changes. The Biden administration's tax proposal contains significant changes, including increases to the tax rates at which both domestic and foreign income of U.S. companies would be taxed. 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 policy in countries in which we operate. In addition, global tax authorities routinely examine our tax returns and are expected to become more aggressive in their examinations of profit allocations among jurisdictions, which could adversely impact our future consolidated results of operations and cash flows.

Acquisitions

We strategically invest in external research and technologies that we believe to complement and strengthen our own efforts. These investments can take many forms, including acquisitions, strategic alliances, collaborations, investments, and licensing arrangements. We view our business development activity as an important way to achieve our strategies, as we seek to bolster our pipeline and enhance shareholder value. We continuously evaluate business development transactions that have the potential to strengthen our business.

In February 2020, we acquired all shares of Dermira for a purchase price of $849.3 million, net of cash acquired. Under the terms of the agreement, we acquired lebrikizumab, a novel, investigational, monoclonal antibody being evaluated for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the FDA. We also acquired Qbrexza cloth, a medicated cloth for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating). During the six months ended June 30, 2021, we sold the rights to Qbrexza. See Note 5 to the consolidated condensed financial statements for additional information.

In January 2021, we acquired all shares of Prevail for a purchase price that included $22.50 per share in cash (or an aggregate of $747.4 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles Prevail stockholders to up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions, upon the first regulatory approval of a Prevail product in one of the following countries: U.S., Japan, United Kingdom, Germany, France, Italy, or Spain. Under the terms of the agreement, we acquired a gene therapy program for patients with neurodegenerative diseases.

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

Revenue

The following table summarizes our revenue activity by region:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021	2020	Percent Change	2021	2020	Percent Change
U.S.	**$ 3,704.2**	$ 3,144.8	18	**$ 7,645.5**	$ 6,473.6	18
Outside U.S.	**3,035.9**	2,354.6	29	**5,900.2**	4,885.6	21
Revenue	**$ 6,740.1**	$ 5,499.4	23	**$ 13,545.7**	$ 11,359.2	19

Numbers may not add due to rounding.

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

	Three Months Ended June 30, 2021 vs. 2020			Six Months Ended June 30, 2021 vs. 2020		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	18 %	26 %	22 %	21 %	17 %	20 %
Price	(1)	(4)	(2)	(3)	(3)	(3)
Foreign exchange rates	—	6	3	—	6	3
Percent change	18 %	29 %	23 %	18 %	21 %	19 %

Numbers may not add due to rounding.

We estimate that the COVID-19 pandemic negatively impacted worldwide revenue for the three months ended June 30, 2020 by approximately $200 million in the U.S. and approximately $50 million outside the U.S. as a result of decreased customer buying patterns that largely offset product stocking that occurred in the first quarter of 2020. We believe that this decrease in U.S. revenue in the second quarter of 2020 primarily impacted our diabetes portfolio, with estimated decreases of approximately $70 million to $80 million for insulin products and approximately $30 million to $40 million for Trulicity®. We also estimate that U.S. revenue for Taltz® in the second quarter of 2020 was negatively impacted by approximately $20 million to $25 million.

In the U.S. for the three months ended June 30, 2021, the increase in volume was primarily driven by Trulicity, Taltz, COVID-19 antibodies, Verzenio, and Jardiance. In The U.S. for the six months ended June 30, 2021, the increase in volume was primarily driven by COVID-19 antibodies, Trulicity, and Taltz. U.S. price performance was not a major driver during the three and six months ended June 30, 2021, as increased utilization in more highly-rebated government segments was offset by lower utilization in the 340B segment, primarily for the diabetes portfolio.

Outside the U.S. for the three and six months ended June 30, 2021, the increase in volume was primarily driven by increased volume for COVID-19 antibodies, Trulicity, Olumiant, Verzenio, and Taltz, as well as the sale of our rights to Cialis® in China.

The following table summarizes our revenue activity by product for the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,				
	2021			2020	
Product	**U.S.**	**Outside U.S.**	**Total**	**Total**	**Percent Change**
Trulicity	**$ 1,147.6**	**$ 388.0**	**$ 1,535.6**	$ 1,229.8	25
Alimta	**353.5**	**257.1**	**610.6**	539.1	13
Humalog [(1)]	**329.1**	**278.6**	**607.6**	555.1	9
Taltz	**399.8**	**169.3**	**569.1**	395.2	44
Jardiance [(2)]	**194.4**	**162.1**	**356.5**	262.0	36
Verzenio	**209.7**	**131.6**	**341.3**	208.6	64
Humulin®	**221.1**	**94.3**	**315.3**	313.6	1
Cialis	**(5.2)**	**286.3**	**281.0**	130.7	NM
Cyramza®	**101.4**	**167.3**	**268.7**	256.7	5
Forteo	**122.8**	**95.6**	**218.4**	252.7	(14)
Basaglar®	**133.4**	**77.3**	**210.7**	290.4	(27)
Olumiant	**17.8**	**190.6**	**208.4**	145.0	44
Cymbalta	**12.4**	**163.3**	**175.6**	179.9	(2)
Emgality®	**112.1**	**44.2**	**156.3**	87.4	79
COVID-19 antibodies [(3)]	**83.4**	**65.7**	**148.9**	—	NM
Erbitux®	**135.8**	**11.2**	**147.0**	129.5	14
Tyvyt®	**—**	**105.0**	**105.0**	64.1	64
Zyprexa®	**8.4**	**86.9**	**95.4**	96.6	(1)
Other products	**126.8**	**261.7**	**388.7**	363.0	7
Revenue	**$ 3,704.2**	**$ 3,035.9**	**$ 6,740.1**	$ 5,499.4	23

Numbers may not add due to rounding.

NM - not meaningful

[(1)] Humalog revenue includes insulin lispro.

[(2)] Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.

[(3)] COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to EUAs.

The following table summarizes our revenue activity by product for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,				
	2021			2020	
Product	**U.S. [1]**	**Outside U.S.**	**Total**	**Total**	**Percent Change**
Trulicity	**$ 2,264.3**	**$ 723.7**	**$ 2,988.1**	$ 2,459.1	22
Humalog [1]	**661.7**	**562.9**	**1,224.6**	1,250.8	(2)
Alimta	**614.6**	**554.9**	**1,169.6**	1,099.2	6
Taltz	**649.4**	**322.9**	**972.4**	838.7	16
COVID-19 antibodies [2]	**734.0**	**225.1**	**959.1**	—	NM
Jardiance [3]	**345.6**	**322.9**	**668.5**	529.5	26
Humulin	**440.1**	**196.9**	**637.0**	629.3	1
Verzenio	**382.5**	**227.8**	**610.3**	396.7	54
Cyramza	**181.5**	**327.7**	**509.2**	495.7	3
Basaglar	**308.6**	**148.7**	**457.3**	594.1	(23)
Forteo	**220.5**	**196.4**	**416.9**	525.0	(21)
Cialis	**3.4**	**404.4**	**407.8**	323.8	26
Olumiant	**42.5**	**359.7**	**402.2**	284.7	41
Cymbalta	**23.3**	**328.9**	**352.3**	390.3	(10)
Emgality	**213.6**	**62.2**	**275.7**	161.5	71
Erbitux	**243.7**	**25.7**	**269.4**	260.3	3
Tyvyt	**—**	**214.6**	**214.6**	121.5	77
Zyprexa	**15.3**	**175.8**	**191.1**	195.0	(2)
Other products	**300.6**	**518.9**	**819.6**	804.2	2
Revenue	**$ 7,645.5**	**$ 5,900.2**	**$ 13,545.7**	$ 11,359.2	19

Numbers may not add due to rounding.

NM - not meaningful

[1] Humalog revenue includes insulin lispro.

[2] COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to EUAs.

[3] Jardiance revenue includes Glyxambi, Synjardy, and Trijardy XR.

Revenue of Trulicity, a treatment for type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors, increased 20 percent in the U.S. during the three and six months ended June 30, 2021, driven by increased demand, partially offset by lower realized prices. Trulicity's lower realized prices in the U.S. during the three months ended June 30, 2021 were primarily due to higher contracted rebates, partially offset by modest list price increases. Trulicity's lower realized prices in the U.S. during the six months ended June 30, 2021 were primarily due to higher contracted rebates, partially offset by a favorable segment mix that reflected lower utilization in the 340B segment and modest list price increases. Revenue outside the U.S. increased 40 percent and 25 percent during the three and six months ended June 30, 2021, respectively, driven by increased volume and, to a lesser extent, the favorable foreign exchange rates, partially offset by lower realized prices.

Revenue of Humalog, an injectable human insulin analog for the treatment of diabetes, increased 17 percent in the U.S. during the three months ended June 30, 2021, driven by increased demand and higher realized prices due to changes to estimates in rebates and discounts. Revenue decreased 3 percent in the U.S. during the six months ended June 30, 2021, driven by lower realized prices, partially offset by increased demand. Humalog's lower realized prices in the U.S. during the six months ended June 30, 2021 were driven by higher contracted rebates and discounts, partially offset by changes to estimates in rebates and discounts and lower utilization in the 340B segment. Revenue outside the U.S. increased 2 percent during the three months ended June 30, 2021, driven by the favorable impact of foreign exchange rates, partially offset by decreased volume and, to a lesser extent, lower realized prices. Revenue outside the U.S. decreased 1 percent during the six months ended June 30, 2021, primarily driven by decreased volume, largely offset by the favorable impact of foreign exchange rates. While it is difficult to estimate the severity of the impact of insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue. However, due to the impact of competition and due to pricing pressure in the U.S. and some international markets, we expect some price decline and loss of market share to continue over time.

Revenue of Alimta, a treatment for various cancers, increased 11 percent in the U.S. during the three months ended June 30, 2021, primarily driven by higher volume as a result of customer buying patterns and, to a lesser extent, higher realized prices. Revenue decreased 4 percent in the U.S. during the six months ended June 30, 2021, primarily driven by lower demand. Revenue outside the U.S. increased 16 percent and 21 percent during the three and six months ended June 30, 2021, respectively, primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. We lost our patent protection for Alimta in Japan and major European countries in June 2021. We expect the limited entry of generic competition in the U.S. starting February 2022 and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition following the loss of exclusivity will cause a rapid and severe decline in revenue. See "Executive Overview - Other Matters- Patent Matters" for more information.

Revenue of Taltz, a treatment for moderate-to-severe plaque psoriasis, active psoriatic arthritis, ankylosing spondylitis, and active non-radiographic axial spondyloarthritis, increased 38 percent and 5 percent in the U.S. during the three and six months ended June 30, 2021, respectively, primarily driven by increased demand, partially offset by lower realized prices. Taltz's lower realized prices in the U.S. during the three and six months ended June 30, 2021 were driven by increased rebates to gain commercial access. Taltz's revenue increase in the U.S. for the three months ended June 30, 2021 was favorably impacted by inventory destocking in the three month ended June 30, 2020. Revenue outside the U.S. increased 60 percent and 45 percent during the three and six months ended June 30, 2021, respectively, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates.

Revenue of COVID-19 antibodies, treatments that were authorized pursuant to EUAs for mild to moderate COVID-19 for higher-risk patients, was $83.4 million and $734.0 million in the U.S. during the three and six months ended June 30, 2021, respectively. Revenue outside the U.S. was $65.7 million and $225.1 million during the three and six months ended June 30, 2021, respectively. The availability of superior or competitive therapies, or preventative measures, such as vaccines, coupled with the transient nature of pandemics, have and could further negatively impact or eliminate demand for these COVID-19 antibodies. In addition, mutations or the spread of other variants of the coronavirus have in some cases reduced the effectiveness of our COVID-19 antibodies, and may further render our antibodies less effective or ineffective.

Revenue of Jardiance, a treatment for type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease, increased 34 percent and 19 percent in the U.S. during the three and six months ended June 30, 2021, respectively, primarily driven by increased demand. Revenue outside the U.S. increased 39 percent and 35 percent during the three and six months ended June 30, 2021, respectively, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates. See Note 4 to the consolidated condensed financial statements for information regarding our collaboration with Boehringer Ingelheim involving Jardiance.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, increased 3 percent in the U.S. during the three months ended June 30, 2021, driven by increased volume, partially offset by lower realized prices. Revenue increased 3 percent in the U.S. during the six months ended June 30, 2021, driven by higher realized prices, and, to a lesser extent, increased demand. Revenue outside the U.S. decreased 5 percent and 2 percent during the three and six months ended June 30, 2021, respectively, driven by decreased volume, partially offset by the favorable impact of foreign exchange rates and higher realized prices.

Revenue of Verzenio, a treatment for HR+, HER2- metastatic breast cancer, increased 48 percent and 41 percent in the U.S. during the three and six months ended June 30, 2021, respectively, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 97 percent and 81 percent during the three and six months ended June 30, 2021, respectively, primarily driven by increased volume.

Revenue of Cyramza, a treatment for various cancers, increased 8 percent in the U.S. during the three months ended June 30, 2021, primarily driven by increased volume. Revenue decreased 1 percent in the U.S. during the six months ended June 30, 2021, driven by lower realized prices, partially offset by increased volume. Revenue outside the U.S. increased 3 percent for the three months ended June 30, 2021, primarily driven by increased volume. Revenue increased 5 percent for the six months ended June 30, 2021, driven by the favorable impact of foreign exchange rates and increased volume.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, decreased 42 percent and 33 percent in the U.S. during the three and six months ended June 30, 2021, respectively, driven by continued competitive pressures that resulted in lower realized prices and, to a lesser extent, decreased demand. Revenue outside the U.S. increased 27 percent during the three months ended June 30, 2021, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates. Revenue outside the U.S. increased 11 percent during the six months ended June 30, 2021, driven by increased volume and the favorable impact of foreign exchange rates, partially offset by lower realized prices. See Note 4 to the consolidated condensed financial statements for information regarding our collaboration with Boehringer Ingelheim involving Basaglar. A competitor launched a similar version of glargine in the U.S. in 2020. Due to competitive pressures, we expect some price decline and loss of market share in the U.S. over time.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue decreased 6.8 percentage points to 71.0 percent and 71.7 percent for the three and six months ended June 30 2021, respectively. The decrease in gross margin percent for the three and six months ended June 30, 2021 was primarily driven by $423.0 million and $504.5 million, respectively, of excess inventory charges related to our COVID-19 antibodies. As part of our response to the COVID-19 pandemic, and at the request of the U.S. and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic has continued to evolve during 2021, we incurred excess inventory charges primarily due to the combination of changes to current and forecasted demand from U.S. and international governments, including changes to our agreement with the U.S. government, and near-term expiry dates of COVID-19 antibodies. The decrease in gross margin percent for the six months ended June 30, 2021 was also due to the unfavorable effect of foreign exchange rates on international inventories sold.

Research and development expenses increased 20 percent to $1.67 billion and increased 21 percent to $3.36 billion for the three and six months ended June 30, 2021, respectively. The increase in research and development expenses for the three and six months ended June 30, 2021 was driven primarily by higher development expenses for late-stage assets, as well as higher research and development expenses for COVID-19 therapies.

Marketing, selling, and administrative expenses increased 16 percent to $1.69 billion and 9 percent to $3.26 billion for the three and six months ended June 30, 2021, respectively. The increase in marketing, selling, and administrative expenses for the three and six months ended June 30, 2021, was primarily due to lower marketing and selling expenses for the three and six months ended June 30, 2020 due to pandemic-related spending reductions.

We recognized $25.0 million and $324.3 million of acquired IPR&D charges for the three and six months ended June 30, 2021, respectively. The charge for the three months ended June 30, 2021 was related to a business development transaction with MiNA. The charges for the six months ended June 30, 2021 also included charges related to business development transactions with Rigel, Precision, Merus, and Asahi. We recognized $241.8 million and $294.1 million of acquired IPR&D charges for the three and six months ended June 30, 2020, respectively. The charges for the three months ended June 30, 2020 were related to the acquisition of a pre-clinical stage company, as well as business development transactions with AbCellera, Evox, and Junshi Biosciences. The charges for the six months ended June 30, 2020 also included a charge related to a business development transaction with Sitryx.

We recognized asset impairment, restructuring, and other special charges of $211.6 million for the six months ended June 30, 2021, primarily related to an intangible asset impairment resulting from the decision to sell the rights to Qbrexza, as well as acquisition and integration costs associated with the acquisition of Prevail. We recognized asset impairment, restructuring, and other special charges of $59.9 million for the six months ended June 30, 2020, primarily related to acquisition and integration costs associated with the acquisition of Dermira.

Other–net, (income) expense was income of $190.5 million and $511.6 million for the three and six months ended June 30, 2021, respectively, compared with income of $446.9 million and $536.0 million for the three and six months ended June 30, 2020, respectively. The decrease in other income for the three and six months ended June 30, 2021 was driven primarily by lower net investment gains on equity securities, partially offset by income from patent settlements in Europe for Alimta.

The effective tax rate was 12.8 percent for the three months ended June 30, 2021, compared with 14.1 percent for the three months ended June 30, 2020. The effective tax rate was 10.6 percent for the six months ended June 30, 2021, compared with 13.7 percent for the six months ended June 30, 2020. The lower effective tax rates for the three and six months ended June 30, 2021 were primarily due to the income tax impact of the excess inventory charges related to our COVID-19 antibodies and lower income tax expense related to lower net gains on investment securities compared to the same period in 2020, partially offset by a lower net discrete tax benefit compared to the same period in 2020 and a nondeductible acquired IPR&D charge in the second quarter of 2020.

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, 2020.

Cash and cash equivalents decreased to $3.22 billion as of June 30, 2021, compared with $3.66 billion as of December 31, 2020. Refer to the consolidated condensed statements of cash flows for additional information on the significant sources and uses of cash for the six months ended June 30, 2021 and 2020.

In addition to our cash and cash equivalents, we held total investments of $3.53 billion and $2.99 billion as of June 30, 2021 and December 31, 2020, respectively. See Note 6 to the consolidated condensed financial statements for additional information.

In January 2021, we acquired all shares of Prevail for a purchase price that included $22.50 per share in cash (or an aggregate of $747.4 million, net of cash acquired) plus one non-tradable CVR per share. The CVR entitles Prevail stockholders to up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions. The acquisition was funded primarily through cash on hand. See Note 3 to the consolidated condensed financial statements for additional information.

As of June 30, 2021, total debt was $16.52 billion, a decrease of $80.2 million compared with $16.60 billion as of December 31, 2020.

As of June 30, 2021, we had a total of $5.24 billion of unused committed bank credit facilities, $5.00 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 six months ended June 30, 2021, we repurchased $500.0 million of shares under our $8.00 billion share repurchase program authorized in June 2018. As of June 30, 2021, we had $500.0 million remaining under this program. In May 2021 we authorized an additional $5.00 billion share repurchase program. There were no shares repurchased under the $5.00 billion share repurchase program during the six months ended June 30, 2021.

During the six months ended June 30, 2021, we paid dividends of approximately $1.54 billion, or $1.70 per share, to our shareholders.

See "Executive Overview - Other Matters - Patent Matters" for information regarding recent and upcoming 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 health care 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 fair values of equity securities.

Financial Expectations

We have updated certain elements of our 2021 financial guidance on a reported basis. The update to our 2021 financial guidance reflects the excess inventory charges related to our COVID-19 antibodies and acquired IPR&D charge recognized during the three months ended June 30, 2021. The update also reflects acquired IPR&D charges for Protomer Technologies Inc. and Kumquat Biosciences Inc.

Earnings per share for 2021 are now expected to be in the range of $6.73 to $6.93.

We now anticipate 2021 revenue to be between $26.8 billion and $27.4 billion. This modest change reflects an increase of $200 million in estimated revenue from products in our core business, reflecting strong performance and, to a lesser extent, the favorable impact of foreign exchange rates, and a reduction in estimated revenue from COVID-19 therapies, which is now expected to be in the range of $1.0 billion to $1.1 billion.

Gross margin as a percent of revenue for 2021 is now expected to be approximately 75 percent, reflecting the impact of the excess inventory charges for our COVID-19 antibodies. Research and development expenses for 2021 are unchanged and remain in the range of $6.9 billion to $7.1 billion. Marketing, selling, and administrative expenses for 2021 are unchanged and remain in the range of $6.2 billion to $6.4 billion. Other—net, (income) expense for 2021 is now expected to be income in the range of $375 million to $475 million, reflecting the impact of net investment gains on equity securities and the income from patent settlements in Europe for Alimta recognized during the three months ended June 30, 2021. The 2021 effective tax rate is now expected to be approximately 12 percent, reflecting primarily the tax impact of the excess inventory charges related to our COVID-19 antibodies.

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**. The information contained in, or that can be accessed through, our website is not a part of, or incorporated by reference in, this Quarterly Report.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*. Under applicable 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 A. Ricks, president and chief executive officer, and Anat Ashkenazi, senior 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, 2020) as of June 30, 2021, and concluded that they were effective.

(b) *Changes in Internal Controls*. During the second quarter of 2021, 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.

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, 2020.

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, 2020. 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, 2020.

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, 2020.

The following table summarizes the activity related to repurchases of our equity securities during the three months ended June 30, 2021:

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)
April 2021	2,195	$ 202.67	2,195	$ 555.1
May 2021	—	—	—	5,555.1
June 2021	272	202.67	272	5,500.0
Total	2,467	—	2,467	

During the three months ended June 30, 2021, we repurchased $500.0 million of shares under our $8.00 billion share repurchase program authorized in June 2018. A $5.00 billion share repurchase program was authorized in May 2021. There were no shares repurchased under the $5.00 billion share repurchase program during the three months ended June 30, 2021.

Item 6. Exhibits

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

Exhibit	Description
EXHIBIT 3.1	Amended Articles of Incorporation are incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013
EXHIBIT 3.2	Bylaws, as amended, are incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2021
EXHIBIT 31.1	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Anat Ashkenazi, Senior Vice President and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data Files (embedded within the Inline XBRL document)
EXHIBIT 104.	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

(i) Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of our consolidated assets are not filed as exhibits to this Quarterly Report. We will furnish a copy of these agreements to the SEC 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: August 3, 2021

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

Date: August 3, 2021

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

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

CERTIFICATIONS

I, David A. Ricks, Chairman, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 3, 2021

By: /s/David A. Ricks
David A. Ricks
Chairman, President, and Chief Executive Officer

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

CERTIFICATIONS

I, Anat Ashkenazi, Senior 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 3, 2021

By: /s/Anat Ashkenazi

Anat Ashkenazi
Senior 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 June 30, 2021 (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: August 3, 2021

/s/David A. Ricks
David A. Ricks
Chairman, President, and Chief Executive Officer

Date: August 3, 2021

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