LILLY ELI & CO
Form 10-Q
October 29, 2014

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
Quarterly Report Under Section 13 or 15(d) of the
Securities Exchange Act of 1934
FOR THE QUARTER ENDED SEPTEMBER 30, 2014
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 of principal executive offices)
Registrant's telephone number, including area code (317) 276-2000

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 and (2) has been subject to such filing requirements for the past 90 days.
Yes ý No o

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of a "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting Company o

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).
Yes ý No o

The number of shares of common stock outstanding as of October 20, 2014:

Class	Number of Shares Outstanding
Common	1,113,429,817

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). Forward-looking statements include all statements that do not relate solely to historical or current facts, and can generally be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue” expressions.

In particular, information appearing under “Management's Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those projected in these statements. Where, in any forward-looking statement, we ("Lilly" or the "company") 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.

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 Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2013, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2014 and June 30, 2014, particularly under the captions “Forward-Looking Statements” and “Risk Factors.”

All forward-looking statements speak only as of the date of this report and are expressly qualified in their entirety by the cautionary statements included in or incorporated by reference into this report. 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 report.

PART I. Financial Information
Item 1. Financial Statements
Consolidated Condensed Statements of Operations
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars and shares in millions, except per-share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	$4,875.6	$5,772.6	$14,494.3	$17,304.3
Cost of sales	1,267.0	1,198.1	3,679.4	3,521.6
Research and development	1,243.2	1,377.4	3,547.9	4,055.9
Marketing, selling, and administrative	1,672.1	1,652.4	4,820.9	5,172.0
Acquired in-process research and development (Note 3)	95.0	—	95.0	—
Asset impairment, restructuring, and other special charges (Note 5)	36.3	—	67.7	85.2
Other–net, (income) expense (Note 13)	(93.5)	31.3	(203.3)	(509.8)
	4,220.1	4,259.2	12,007.6	12,324.9
Income before income taxes	655.5	1,513.4	2,486.7	4,979.4
Income taxes (Note 9)	154.9	310.3	524.7	1,022.1
Net income	$500.6	$1,203.1	$1,962.0	$3,957.3
Basic earnings per share:				
Weighted-average number of common shares outstanding, including incremental shares	1,069.6	1,080.2	1,071.4	1,082.8
Basic earnings per share	$0.47	$1.11	$1.83	$3.65
Diluted earnings per share:				
Weighted-average number of common shares outstanding, including incremental shares and stock options	1,074.4	1,084.2	1,075.7	1,086.7
Diluted earnings per share	$0.47	$1.11	$1.82	$3.64
Dividends paid per share	$0.49	$0.49	$1.47	$1.47

See Notes to Consolidated Condensed Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net income	$500.6	$1,203.1	$1,962.0	$3,957.3
Other comprehensive income (loss), net of tax (Note 12)	(616.3)	384.6	(548.9)	233.0
Comprehensive income (loss)	$(115.7)	$1,587.7	$1,413.1	$4,190.3

See Notes to Consolidated Condensed Financial Statements.

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

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	$3,165.8	$3,830.2
Short-term investments (Note 6)	1,644.1	1,567.1
Accounts receivable, net of allowances for doubtful accounts of $55.2 (2014) and $62.2 (2013)	3,053.5	3,434.4
Other receivables	581.1	588.4
Inventories	2,844.5	2,928.8
Prepaid expenses and other	821.5	755.8
Total current assets	12,110.5	13,104.7
Other Assets		
Investments (Note 6)	7,405.5	7,624.9
Goodwill and other intangibles, net (Notes 3 and 4)	4,750.8	4,331.1
Sundry	2,338.7	2,212.5
Total other assets	14,495.0	14,168.5
Property and Equipment		
Land, buildings, equipment, and construction in progress	16,081.5	15,646.7
Accumulated depreciation	(8,038.2)	(7,671.2)
Property and equipment, net	8,043.3	7,975.5
Total assets	$34,648.8	$35,248.7
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	$313.0	$1,012.6
Accounts payable	1,023.3	1,119.3
Employee compensation	701.1	943.9
Sales rebates and discounts	1,970.6	1,941.7
Dividends payable	—	523.5
Income taxes payable	153.5	254.4
Deferred income taxes	1,352.5	792.8
Other current liabilities	2,060.6	2,328.4
Total current liabilities	7,574.6	8,916.6
Other Liabilities		
Long-term debt	5,292.6	4,200.3
Accrued retirement benefits (Note 10)	1,524.1	1,549.4
Long-term income taxes payable	932.8	1,078.7
Other noncurrent liabilities	1,642.2	1,863.0
Total other liabilities	9,391.7	8,691.4
Commitments and Contingencies (Note 11)		
Eli Lilly and Company Shareholders' Equity (Notes 7 and 8)		
Common stock	696.6	698.5
Additional paid-in capital	5,222.0	5,050.0
Retained earnings	17,406.9	16,992.4
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 12)	(2,551.6)	(2,002.7)

Cost of common stock in treasury	(91.4)	(93.6)
Total Eli Lilly and Company shareholders' equity	17,669.3	17,631.4
Noncontrolling interests	13.2	9.3
Total equity	17,682.5	17,640.7
Total liabilities and equity	$34,648.8	$35,248.7

See Notes to Consolidated Condensed Financial Statements.

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

	Nine Months Ended September 30,	
	2014	2013
Cash Flows from Operating Activities		
Net income	$1,962.0	$3,957.3
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	1,039.6	1,094.4
Change in deferred income taxes	185.1	807.6
Stock-based compensation expense	115.4	105.1
Net realized investment gains	(153.4)	(29.9)
Proceeds from terminations of interest rate swaps	252.5	—
Acquired in-process research and development, net of tax	61.8	—
Income related to termination of the exenatide collaboration (Note 4)	—	(495.4)
Other changes in operating assets and liabilities, net of acquisitions and divestitures	(548.3)	(1,498.3)
Other operating activities, net	102.8	67.4
Net Cash Provided by Operating Activities	3,017.5	4,008.2
Cash Flows from Investing Activities		
Net purchases of property and equipment	(753.8)	(548.1)
Proceeds from sales and maturities of short-term investments	2,661.6	2,378.1
Purchases of short-term investments	(1,401.8)	(778.6)
Proceeds from sales of noncurrent investments	7,355.5	8,482.9
Purchases of noncurrent investments	(8,636.7)	(10,239.5)
Cash paid for acquisitions, net of cash acquired	(551.4)	(43.7)
Purchase of in-process research and development	(45.0)	—
Purchase of product rights	(308.2)	—
Other investing activities, net	(50.4)	(91.5)
Net Cash Used for Investing Activities	(1,730.2)	(840.4)
Cash Flows from Financing Activities		
Dividends paid	(1,576.0)	(1,591.8)
Net change in short term borrowings	304.9	—
Proceeds from issuance of long-term debt	992.9	—
Repayment of long-term debt	(1,034.3)	(3.0)
Purchases of common stock	(500.0)	(1,198.1)
Other financing activities, net	109.0	—
Net Cash Used for Financing Activities	(1,703.5)	(2,792.9)
Effect of exchange rate changes on cash and cash equivalents	(248.2)	(24.8)
Net increase (decrease) in cash and cash equivalents	(664.4)	350.1
Cash and cash equivalents at January 1	3,830.2	4,018.8
Cash and Cash Equivalents at September 30	$3,165.8	$4,368.9

See Notes to Consolidated Condensed Financial Statements

6

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 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, revenues, 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, 2013. We issued our financial statements by filing with the Securities and Exchange Commission (SEC) and have evaluated subsequent events up to the time of the filing.

Certain reclassifications have been made to prior periods in the consolidated condensed financial statements and accompanying notes to conform with the current presentation.

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 outstanding common shares plus the effect of dilutive stock options and other incremental shares.

Note 2: Implementation of New Financial Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a final standard on revenue recognition. Under the new standard, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In order to do so, an entity would follow the five-step process for in-scope transactions: 1) identify the contract with a customer, 2) identify the separate performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the separate performance obligations in the contract, and 5) recognize revenue when (or as) the entity satisfies a performance obligation. For public entities, the provisions of the new standard are effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. We are in the process of determining our approach to the adoption of this new revenue recognition standard, as well as the anticipated impact to our consolidated condensed financial statements.

In July 2013, the FASB issued a clarification regarding the presentation of an unrecognized tax benefit related to a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. Under this new standard, the liability related to an unrecognized tax benefit, or a portion thereof, should be presented in the financial statements as a reduction to a deferred tax asset if available under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position. Otherwise, the unrecognized tax benefit should be presented in the financial statements as a separate liability. The assessment is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date. The provisions of the new standard are effective on a prospective basis beginning in 2014 for annual and interim reporting periods. Adoption of this standard in the first quarter of 2014 resulted in an immaterial impact to our consolidated condensed balance sheet and did not affect our consolidated condensed statements of operations.

Note 3: Acquisitions

In April 2014, we announced an agreement to acquire Novartis Animal Health (NAH) in an all-cash transaction for approximately $5.4 billion. NAH has a global commercial presence in both the companion and food animal markets. Under the terms of the agreement, we will acquire manufacturing sites, research and development facilities, a global commercial infrastructure and portfolio of products, a pipeline of projects in development, and employees. The transaction is expected to close by the end of the first quarter of 2015, subject to clearance under the Hart-

7

Scott-Rodino Antitrust Improvements Act, similar requirements outside the U.S., and other customary closing conditions.

We have agreed to divest the U.S. assets related to two major parasiticides for dogs, Sentinel® Flavor Tabs and Sentinel® Spectrum, currently marketed in the U.S. by NAH, in connection with the U.S. Federal Trade Commission's (FTC) review of the pending acquisition of NAH. We have entered into an agreement to sell these assets to Virbac Corporation, subject to approval from the FTC and the closing of our acquisition of NAH.

On April 30, 2014, we acquired Lohmann SE (Lohmann Animal Health), a privately-held company headquartered in Cuxhaven, Germany, through a stock purchase for a total purchase price of $591.2 million, comprised of $551.4 million of net cash plus $39.8 million of assumed debt. Lohmann Animal Health is a global leader in poultry vaccines. As part of this transaction, we acquired the rights to a range of vaccines, commercial capabilities, and manufacturing sites in Germany and the United States. This acquisition was accounted for as a business combination under the acquisition method of accounting. The assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. 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 has been recorded as goodwill. The results of operations of this acquisition are included in our consolidated condensed financial statements from the date of acquisition. The acquisition is not material to our consolidated financial statements. Preliminary amounts currently recorded in connection with this acquisition include $275.4 million of marketed product assets, $23.9 million of other intangible assets, $89.8 million of property and equipment, $248.2 million of goodwill, and $93.7 million of deferred tax liabilities, with $47.6 million of other net assets. The final determination may result in asset and liability fair values that differ from the preliminary estimates, but it is not expected that these differences will be material to our consolidated financial statements. Goodwill associated with this acquisition is not deductible for tax purposes.

Product and Other Acquisitions

In connection with the arrangements described below, our partners may be entitled to future royalties based on sales should these products be approved for commercialization and/or milestones based on the successful progress of the drug candidate through the development process.

In July 2014, we entered into a co-discovery and co-development collaboration with Immunocore Limited to research and potentially develop pre-clinical novel T cell-based cancer therapies. Upon entering the agreement, we paid an upfront fee of $45.0 million in cash. At that time, we determined that the rights acquired had no alternative future use. The related $45.0 million charge for acquired in-process research and development (IPR&D) was included as expense in the third quarter of 2014.

In September 2014, we entered into a collaboration agreement with AstraZeneca UK Limited (AstraZeneca) for the worldwide co-development and co-commercialization of AstraZeneca's oral beta-secretase cleaving enzyme (BACE) inhibitor known as AZD3293, a compound being investigated for the potential treatment of Alzheimer's disease. AZD3293 has completed Phase 1 testing and we and AstraZeneca will progress AZD3293 into a Phase 2/3 clinical trial in patients with early Alzheimer's disease. We will be responsible for leading development efforts, while AstraZeneca will be responsible for manufacturing efforts. If successful, both parties will take joint responsibility for commercialization of AZD3293. Under the agreement, both parties will share equally in the ongoing development costs, gross margins and certain other costs associated with the commercialization of the compound. Upon execution of the agreement, we immediately recorded, as an acquired IPR&D charge, our obligation associated with a payment of $50.0 million which we expect to pay to AstraZeneca in 2015.

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 and 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 or payments to the collaboration partner. Elements within a collaboration are separated into individual units of accounting if they have standalone value from other elements within the arrangement. In these situations, the arrangement consideration is allocated to the elements on a relative

selling price basis. Revenues related to products we sell pursuant to these arrangements are included in net product sales, while other sources of revenue (e.g., royalties and profit-sharing due from our partner) are included in collaboration and other revenue. We recognized collaboration and other revenue of $204.0 million and $183.4 million for the three months ended September 30, 2014 and 2013, respectively, and $593.9 million and $506.7 million for the nine months ended September 30, 2014 and 2013, respectively. 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.

Diabetes Collaboration

We and Boehringer Ingelheim have a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Currently, the compounds included in the collaboration are Boehringer Ingelheim's two oral diabetes agents, linagliptin (trade name Trajenta®) and empagliflozin (trade name Jardiance®), and our new insulin glargine product. The agreement also provided Boehringer Ingelheim with the ability to opt in to the Phase III development and potential commercialization of our anti-TGF-beta monoclonal antibody. However, we made the decision in April 2014 to discontinue development of the molecule, which had been in Phase II clinical testing.

Trajenta was approved in 2011 and launched in the U.S., Japan, certain countries in Europe, and other countries. Jardiance was approved in Europe and the U.S. in May and August 2014, respectively, and has been submitted to regulatory authorities in Japan. The product was launched in certain European countries and the U.S. in the third quarter of 2014. Our new insulin glargine product was approved by the European Commission in Europe in September 2014, received tentative approval in the U.S. in August 2014, and has been submitted to regulatory authorities in Japan. The U.S. Food and Drug Administration (FDA) has determined that our new insulin glargine product (tradename Basaglar™ in the U.S.) meets all regulatory requirements for approval, but final approval is subject to a delay of up to 30 months as a result of patent infringement litigation filed by Sanofi, which makes Lantus®, the only currently marketed insulin glargine. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), the FDA may not give final approval until the end of the 30-month period in mid-2016, unless the court determines that the patent is not infringed, invalid, or unenforceable prior to that start time.

In connection with the approval of Trajenta in the U.S., Japan, and Europe, we paid $478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales.

In connection with the approval of Jardiance in the U.S. and Europe, we paid success-based regulatory milestones of $286.5 million, which were capitalized as intangible assets and will be amortized to cost of sales. We incurred milestone-related expenses of $97.2 million in connection with regulatory submissions for Jardiance in the U.S., Europe, and Japan during 2013. These regulatory submission milestones were recorded as research and development expenses. We may also pay up to 11.3 million euro in additional success-based regulatory milestones for Jardiance.

Upon the approval of our new insulin glargine product in Europe during the third quarter of 2014, we recorded, as deferred revenue, a $50.0 million milestone which will be amortized to collaboration and other revenue upon product launch in Europe through the term of the collaboration (2029). During 2013, we earned $50.0 million in milestones for the regulatory submissions of our new insulin glargine product in the U.S., Europe, and Japan. These submission milestones were recorded as income in other–net, (income) expense. In the future, we will be eligible to receive up to $200.0 million in success-based regulatory milestones on our new insulin glargine product.

In October 2014, we and Boehringer Ingelheim agreed upon certain changes to the operational structure of our diabetes collaboration. Under the revised agreement the companies will continue their co-promotion work in 17 countries, representing over 90 percent of the collaboration's anticipated market opportunity. In the other countries, the companies will exclusively commercialize the respective molecules they brought to the collaboration. The modifications become effective on December 31, 2014, and will change the financial terms related to the modified countries; however, the financial impact resulting from the revised terms of the agreement in these countries is not anticipated to be material. As a result of these changes, in the fourth quarter of 2014, we expect to record a gain of approximately $90 million related to the transfer of our license rights to co-promote Trajenta and Jardiance in these countries, as well as a charge of approximately $55 million related to the transfer to us of Boehringer Ingelheim's rights to co-promote our new insulin glargine product in countries where it is not yet approved, which will be recorded as acquired IPR&D expense.

With the exception of the countries affected by the amendment to the collaboration agreement, the companies share equally the ongoing development costs and, if successful, commercialization costs and gross margin for any product resulting from the collaboration. We record our portion of the gross margin associated with Boehringer Ingelheim's

compounds as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Our revenue related to

Trajenta was $78.9 million and $64.7 million for the three months ended September 30, 2014 and 2013, respectively, and $246.1 million and $162.1 million for the nine months ended September 30, 2014 and 2013, respectively. Our revenue related to Jardiance was not material for the three and nine months ended September 30, 2014.

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) to develop, market, and promote Effient. We and Daiichi Sankyo co-promote Effient in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. Daiichi Sankyo has exclusive marketing rights in Japan and certain other territories. The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. We record product sales in our exclusive and co-promotion territories. In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. Profit-share payments due to Daiichi Sankyo are recorded as marketing, selling, and administrative expenses. All royalties due to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales. Effient sales were $131.5 million and $124.9 million for the three months ended September 30, 2014 and 2013, respectively, and $384.4 million and $378.1 million for the nine months ended September 30, 2014 and 2013, respectively.

Erbitux®

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Canada, and Japan (Bristol-Myers Squibb Company); and worldwide except the U.S. and Canada (Merck KGaA). Upon expiration of the agreements, all of the rights to Erbitux in the U.S. and Canada return to us and certain rights to Erbitux outside the U.S. and Canada will remain with Merck KGaA (Merck).

The following table summarizes our revenue recognized with respect to Erbitux:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net product sales	$8.8	$6.2	$34.5	$43.8
Collaboration and other revenue	84.1	81.0	242.8	229.9
Total revenue	$92.9	$87.2	$277.3	$273.7

Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), we are co-developing Erbitux in the U.S. and Canada with BMS through September 2018, exclusively, and in Japan with BMS and Merck through 2032. Under these arrangements, Erbitux research and development and other costs are shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties under the agreements. Collaborative reimbursements due to us for supply of clinical trial materials; for research and development; and for a portion of marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in collaboration and other revenue. Royalties due to third parties are recorded as a reduction of collaboration and other revenue, net of any royalty reimbursements due from third parties.

We are responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in the U.S. and Canada, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. Sales of Erbitux to BMS for commercial use are reported in net product sales.

Merck KGaA

A development and license agreement grants Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and expires in December 2018. A separate agreement grants co-exclusive rights among Merck, BMS, and us in Japan and expires in 2032.

Merck manufactures Erbitux for supply in its territory as well as for Japan. We receive a royalty on the sales of Erbitux outside of the U.S. and Canada, which is included in collaboration and other revenue as earned. Royalties due to third parties are recorded as a reduction of collaboration and other revenue, net of any royalty reimbursements due from third parties.

Exenatide

In November 2011, we agreed with Amylin Pharmaceuticals, Inc. (Amylin) to terminate our collaborative arrangement for the joint development, marketing, and selling of Byetta® (exenatide injection) and other forms of exenatide such as Bydureon® (exenatide extended-release for injectable suspension). Under the terms of the termination agreement, Amylin made a one-time, upfront payment to us of $250.0 million. Amylin also agreed to make future revenue-sharing payments to us in an amount equal to 15.0 percent of its global net sales of exenatide products until Amylin made aggregate payments to us of $1.20 billion plus interest, which would accrue at 9.5 percent. Upon completion of the acquisition of Amylin by Bristol-Myers Squibb Company in August 2012, Amylin's obligation of $1.26 billion, including accrued interest, was paid in full, with $1.21 billion representing a prepayment of the obligation. We would also receive a $150.0 million milestone payment contingent upon FDA approval of a once-monthly suspension version of exenatide.

Commercial operations were transferred to Amylin in the U.S. in late 2011. Outside the U.S., we transferred to Amylin exenatide commercial rights and control in all markets during the first quarter of 2013. We were responsible for certain development costs related to certain clinical trials outside the U.S. that we were conducting as of the date of the termination agreement as well as commercialization costs outside the U.S. until the commercial rights were transferred to Amylin.

Payments received from Amylin were allocated 65 percent to the U.S., which was treated as a contract termination, and 35 percent to the business outside the U.S., which was treated as the disposition of a business. The allocation was based upon relative fair values. The revenue-sharing income allocated to the U.S. was recognized as collaboration and other revenue, consistent with our policy for royalty revenue, while the income related to the prepayment of Amylin's obligation allocated to the U.S. was recognized in other–net, (income) expense. All income allocated to the business outside the U.S. that was transferred during the first quarter of 2013 was recognized as a gain on the disposition of a business in other–net, (income) expense, net of the goodwill allocated to the business transferred.

Under the terms of our prior arrangement, we reported as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. We paid Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs were recorded in cost of sales. This arrangement for the commercial operations outside the U.S. continued until those rights were transferred to Amylin during the first quarter of 2013.

In accordance with the prior arrangement and pursuant to Amylin’s request, we loaned Amylin $165.0 million in the second quarter of 2011. This loan and related accrued interest were paid in full in August 2012.

We recognized net product sales of $28.6 million and $113.7 million with respect to exenatide for the three and nine months ended September 30, 2013, respectively. Net product sales of exenatide were insignificant in 2014.

We recognized income of $495.4 million in other-net, (income) expense related to termination of the exenatide collaboration with Amylin during the first quarter of 2013.

Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby TPG funded a portion of the Phase III development of solanezumab. Under the agreement, TPG’s obligation to fund solanezumab costs was not material and ended in 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately $70 million and mid-single digit royalties contingent upon the successful development of solanezumab. The royalties would be paid for approximately 10 years after launch of a product.

Baricitinib

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 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 future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these

compounds on an indication-by-indication basis by funding 30 percent of the associated development costs

from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. The agreement also provides Incyte with an option to co-promote in the U.S. and calls for payments associated with certain development, success-based regulatory, and sales-based milestones. Upon initiation of Phase III trials for the treatment of rheumatoid arthritis in the fourth quarter of 2012, we incurred a milestone-related expense of $50.0 million which was recorded as research and development expense. As of September 30, 2014, Incyte is eligible to receive up to $415.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones as well as an additional $150.0 million of potential sales-based milestones.

Tanezumab

In October 2013, we entered into a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the potential treatment of osteoarthritis pain, chronic low back pain and cancer pain. Tanezumab is currently in Phase III development and is subject to a partial clinical hold by the FDA pending submission of nonclinical data to the FDA. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and certain commercialization expenses. Contingent upon the parties continuing in the collaboration after receipt of the FDA's response to the submission of the nonclinical data, we will be obligated to pay an upfront fee of $200.0 million. This payment would be immediately expensed. In addition to this fee, we may pay up to $350.0 million in success-based regulatory milestones and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab. Both parties have the right to terminate the agreement under certain circumstances.

Summary of Commission and Profit-Share Payments

The aggregate amount of marketing, selling, and administrative expense associated with our commission and profit-sharing obligations for the collaborations and other arrangements described above was $53.5 million and $50.5 million for the three months ended September 30, 2014 and 2013, respectively, and $155.4 million and $151.0 million for the nine months ended September 30, 2014 and 2013, respectively.

Amortization of Intangible Assets

We record, as finite-lived intangible assets, the cost of milestone payments associated with products approved for marketing, as well as the cost of rights to assets approved for marketing that were acquired in business combinations. We also record finite-lived intangible assets for the cost of licensed platform technologies that have alternative future uses in research and development; manufacturing technologies; and customer relationships from business combinations. Amortization expense related to these finite-lived intangibles was $134.0 million and $132.2 million for the three months ended September 30, 2014 and 2013, respectively, and $399.9 million and $423.5 million for the nine months ended September 30, 2014 and 2013, respectively.

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

We recognized $36.3 million of asset impairment, restructuring, and other special charges during the three months ended September 30, 2014, with no comparable charges during the same period in 2013. For the nine months ended September 30, 2014, we recognized $67.7 million of asset impairment, restructuring, and other special charges compared to $85.2 million during the same period in 2013. The 2014 charges related primarily to severance associated with ongoing cost containment efforts and costs related to the pending acquisition of NAH. The 2013 charges related primarily to costs associated with the decision to close a packaging and distribution facility in Germany and severance costs for actions taken to reduce the company's cost structure.

In October 2014, we approved a plan to close and sell a manufacturing plant located in Puerto Rico. As a result of this action, we expect to record an asset impairment charge of approximately $170 million in the fourth quarter of 2014.

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-sciences products account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by 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. Major financial institutions represent the largest component of our investments in corporate

12

debt securities. In accordance with documented corporate 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.

Accounting Policy for Risk-Management Instruments

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the assets, liabilities, and transactions being hedged. Management reviews the correlation and effectiveness of our derivatives that are designated as hedges on a quarterly basis.

For derivative contracts 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 contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in current earnings during the period of change.

We may enter into foreign currency forward contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the 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 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 contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At September 30, 2014, we had outstanding foreign currency forward commitments to purchase 547.5 million U.S. dollars and sell 428.1 million euro, commitments to purchase 737.6 million euro and sell 953.3 million U.S. dollars, commitments to purchase 429.7 million U.S. dollars and sell 46.21 billion Japanese yen, and commitments to purchase 159.0 million British pounds and sell 199.5 million euro, which will all settle within 30 days.

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 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 within our Consolidated Condensed Statement of Cash Flows. At September 30, 2014, substantially all of our total debt is at a fixed rate. We have converted approximately 50 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

Investments in debt securities are subject to different interest rate risks based on their maturities. We may manage the average maturity of our investments in debt securities to achieve economic returns using interest rate contracts, none of which are designated as hedging instruments. As of September 30, 2014, the total notional amounts of fixed-interest rate contracts not designated as hedging instruments were $876.0 million, which will all settle within six months.

We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities.

We may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. Upon completion of a debt issuance and termination of the swap, the change in fair value of these instruments is recorded as part of other comprehensive income (loss) and is amortized to interest expense over the life of the debt agreement. As of September 30, 2014, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.35 billion, which will all settle within six months.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Fair value hedges:				
Effect from hedged fixed-rate debt	$(7.7)	$(31.3)	$86.0	$(244.6)
Effect from interest rate contracts	7.7	31.3	(86.0)	244.6
Cash flow hedges:				
Effective portion of losses on equity contracts reclassified from accumulated other comprehensive loss[(1)]	20.2	—	87.6	—
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.3	2.3	6.7	6.7
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	(8.3)	33.9	12.7	26.4
Net gains on interest rate contracts not designated as hedging instruments	(2.4)	—	(1.3)	—

[1] Realized gains on the sale of the underlying equity securities recognized in other–net, (income) expense for the three and nine months ended September 30, 2014 were $56.8 million and $183.1 million, respectively.

The effective portion of net (losses) gains on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $(11.8) million and $(33.0) million for the three months ended September 30, 2014 and 2013, respectively, and $108.7 million and $(41.9) million for the nine months ended September 30, 2014 and 2013, respectively. During the next three months, we expect to sell the underlying equity securities in designated cash flow hedging relationships that were outstanding at September 30, 2014, and will reclassify to earnings the accumulated other comprehensive loss related to the cash flow hedges and the unrealized gains on the underlying equity securities. As of September 30, 2014, the unrealized gains are in excess of the losses on the cash flow hedges.

In August 2014, we terminated certain interest rate swaps designated as fair value hedges with an aggregate notional amount of $900.0 million. As a result of the termination, we received cash of $252.5 million, which represented the fair value of the interest rate swaps at the time of termination. The related fair value adjustment was recorded as an increase to the carrying value of the underlying fixed-rate debt and will be amortized into earnings as a reduction of interest expense over the remaining life of the underlying debt.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings $9.0 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.

During the nine months ended September 30, 2014 and 2013, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 2014 and December 31, 2013 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:

Description	Carrying Amount	Amortized Cost	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
September 30, 2014						
Cash and cash equivalents	$3,165.8	$3,165.8	$2,932.1	$233.7	$	$3,165.8
Short-term investments:						
Government-related debt securities:						
U.S. government and agencies	$251.1	$251.0	$227.5	$23.6		$251.1
Corporate debt securities	1,295.2	1,293.0		1,295.2		1,295.2
Asset-backed	3.0	3.0		3.0		3.0
Other securities	0.3	0.3		0.3		0.3
Marketable equity	94.5	17.5	94.5			94.5
Short-term investments	$1,644.1	$1,564.8				
Noncurrent investments:						
Government-related debt securities:						
U.S. government and agencies	$1,697.4	$1,698.8	$1,633.3	$64.1	$	$1,697.4
Foreign and other	0.4	0.4		0.4		0.4
Corporate debt securities	4,359.8	4,356.5		4,359.8		4,359.8
Mortgage-backed	285.3	291.4		285.3		285.3
Asset-backed	583.9	586.4		583.9		583.9
Other securities	7.6	8.2		7.6		7.6
Marketable equity	84.0	29.0	84.0			84.0
Equity method and other investments[(1)]	387.1	387.1				
Noncurrent investments	$7,405.5	$7,357.8				
December 31, 2013						
Cash and cash equivalents	$3,830.2	$3,830.2	$3,772.6	$57.6	$	$3,830.2
Short-term investments:						
U.S. government and agencies	$276.4	$276.6	$276.4	$	$	$276.4
Corporate debt securities	931.7	929.8		931.7		931.7
Other securities	2.7	2.7		2.7		2.7
Marketable equity	356.3	75.0	356.3			356.3
Short-term investments	$1,567.1	$1,284.1				
Noncurrent investments:						
U.S. government and agencies	$1,115.6	$1,126.1	$1,035.6	$80.0	$	$1,115.6

Corporate debt securities	4,940.5	4,933.7		4,940.5	4,940.5
Mortgage-backed	636.0	652.4		636.0	636.0
Asset-backed	490.0	494.5		490.0	490.0
Other securities	7.3	8.3		7.3	7.3
Marketable equity	81.2	22.8	81.2		81.2
Equity method and other investments[1]	354.3	354.3			
Noncurrent investments	$7,624.9	$7,592.1			

[1] Fair value not applicable

Description	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
Short-term borrowings[1]					
September 30, 2014	$(300.0)	$—	$(300.0)	$—	$(300.0)
December 31, 2013	—	—	—	—	—
Long-term debt, including current portion					
September 30, 2014	$(5,305.6)	$—	$(5,648.2)	$—	$(5,648.2)
December 31, 2013	(5,212.9)	—	(5,490.9)	—	(5,490.9)

[1] Represents commercial paper borrowings

Description	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
September 30, 2014					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	$143.5		$143.5		$143.5
Other current liabilities	(36.7)		(36.7)		(36.7)
Other noncurrent liabilities	(25.9)		(25.9)		(25.9)
Interest rate contracts not designated as hedging instruments:					
Other current assets	1.3		1.3		1.3
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	22.0		22.0		22.0
Other current liabilities	(17.5)		(17.5)		(17.5)
Equity contracts designated as hedging instruments:					
Other current liabilities	(40.9)		(40.9)		(40.9)
December 31, 2013					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Other receivables	20.1		20.1		20.1
Sundry	278.7		278.7		278.7
Other noncurrent liabilities	(0.9)		(0.9)		(0.9)

Foreign exchange contracts not designated as hedging instruments:			
Other receivables	6.7	6.7	6.7
Other current liabilities	(7.1)	(7.1)	(7.1)
Equity contracts designated as hedging instruments:			
Other current liabilities	(149.6)	(149.6)	(149.6)

Risk-management instruments above are disclosed on a gross basis. There are various rights of setoff associated with certain of the risk-management instruments above that are subject to an enforceable master netting arrangement 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 fair values 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. The fair value of equity method investments and other investments is not readily available.

In August 2014, we refinanced our bank credit facilities and entered into a $1.20 billion credit facility with a five-year term and a $2.00 billion credit facility with a 364-day term, resulting in $3.20 billion of unused committed bank credit facilities, all of which backs our commercial paper program. As of September 30, 2014, we had $300.0 million outstanding under our commercial paper program.

In February 2014, we issued $600.0 million of 1.95% and $400.0 million of 4.65% fixed-rate notes with interest to be paid semi-annually and maturity dates of March 15, 2019, and June 15, 2044, respectively. Current maturities of long-term debt of $1.00 billion were repaid in March 2014.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of September 30, 2014:

	Maturities by Period				
	Total	Less Than 1 Year	2-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$8,484.0	$1,549.6	$6,263.1	$346.1	$325.2

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 (pretax) in accumulated other comprehensive loss follows:

	September 30, 2014	December 31, 2013
Unrealized gross gains	$153.6	$375.6
Unrealized gross losses	26.6	59.8
Fair value of securities in an unrealized gain position	4,139.3	4,982.7
Fair value of securities in an unrealized loss position	3,980.8	3,664.7

Other-than-temporary impairment losses on investment securities of $3.6 million and $11.0 million were recognized in the consolidated condensed statement of operations for the three and nine months ended September 30, 2014. Other-than-temporary impairment losses on investment securities of $5.2 million were recognized in the consolidated condensed statement of operations for the nine months ended September 30, 2013. No charges were recognized during the third quarter of 2013. For fixed-income securities, the amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position include fixed-rate debt securities of varying maturities. The value of fixed-income securities is sensitive to changes in the yield curve and other market conditions. Approximately 85 percent of the securities in a loss position are investment-grade debt securities. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. 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 we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of September 30, 2014.

Activity related to our investment portfolio, substantially all of which related to available-for-sale securities, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Proceeds from sales	$2,491.2	$2,785.5	$9,680.4	$10,230.6
Realized gross gains on sales	92.7	3.6	257.3	41.8
Realized gross losses on sales	1.1	4.2	16.2	12.1

Realized gains and losses on sales of 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.

Note 7: Stock-Based Compensation

Our stock-based compensation expense consists of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognized pretax stock-based compensation expense of $38.5 million and $36.2 million for the three months ended September 30, 2014 and 2013, respectively, and $115.4 million and $105.1 million for the nine months ended September 30, 2014 and 2013, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain pre-established earnings-per-share targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of September 30, 2014, the total remaining unrecognized compensation cost related to nonvested PAs was $29.8 million, which will be amortized over the weighted-average remaining requisite service period of 13 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued, if any, varies depending on our stock price at the end of the three-year vesting period compared to pre-established target stock prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of September 30, 2014, the total remaining unrecognized compensation cost related to nonvested SVAs was $68.4 million, which will be amortized over the weighted-average remaining requisite service period of 22 months.

RSUs are granted to certain employees and are payable in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of grant. The corresponding expense is amortized over the vesting period, typically three years. As of September 30, 2014, the total remaining unrecognized compensation cost related to nonvested RSUs was $102.3 million, which will be amortized over the weighted-average remaining requisite service period of 28 months.

Note 8: Shareholders' Equity

During the nine months ended September 30, 2014, we purchased $500.0 million of shares associated with our $5.00 billion share repurchase program announced in October 2013. During the first quarter of 2013, we purchased the remaining $1.10 billion of shares associated with our $1.50 billion share repurchase program announced in December 2012.

Note 9: Income Taxes

During the third quarter of 2013, we reached resolution on the remaining matters related to tax years 2008-2009 that were not settled as part of a previous examination. As a result of this resolution, our gross unrecognized tax benefits were reduced by approximately $630 million. Considering the impact of this resolution on periods that have not yet been examined, as well as its impact on tax asset carryforwards, there was an immaterial benefit to our consolidated condensed results of operations during the third quarter of 2013. We made cash payments of approximately $135 million related to tax years 2008-2009 after application of available tax credit carryforwards and carrybacks in the third quarter of 2013.

The U.S. examinations related to tax years 2010-2012 commenced during the fourth quarter of 2013. Because the examination of tax years 2010-2012 still largely remains in the informational stage, the resolution of matters in this audit period will likely extend beyond the next 12 months.

Note 10: Retirement Benefits

Net pension and retiree health benefit expense included the following components:

	Defined Benefit Pension Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Components of net periodic benefit cost:				
Service cost	$65.4	$71.5	$195.7	$212.3
Interest cost	118.3	110.0	355.5	328.3
Expected return on plan assets	(188.9)	(176.1)	(567.3)	(525.8)
Amortization of prior service cost	0.9	1.0	2.7	3.0
Recognized actuarial loss	68.8	103.8	207.3	302.2
Net periodic benefit cost	$64.5	$110.2	$193.9	$320.0

	Retiree Health Benefit Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Components of net periodic benefit (income) cost:				
Service cost	$10.3	$15.0	$33.2	$45.2
Interest cost	20.9	23.4	64.7	70.1
Expected return on plan assets	(36.0)	(32.8)	(107.9)	(98.3)
Amortization of prior service benefit	(7.4)	(9.2)	(22.0)	(22.0)
Recognized actuarial loss	5.0	25.7	15.1	71.9
Net periodic benefit (income) cost	$(7.2)	$22.1	$(16.9)	$66.9

Contributions to our global defined benefit pension and retiree health benefit plans to satisfy minimum funding requirements as well as additional discretionary funding in the aggregate were not material during the nine months ended September 30, 2014, and are not expected to be material for the remainder of 2014.

Note 11: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. 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, except as noted below with respect to the Alimta® patent litigation and administrative proceedings, 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.

Alimta Patent Litigation and Administrative Proceedings

A number of generic manufacturers are seeking approvals in various countries to market generic forms of Alimta prior to the expiration of our vitamin dosage regimen patents, alleging that those patents are invalid, not infringed, or both. We believe our Alimta vitamin dosage patents are valid and enforceable against these generic manufacturers and we expect to prevail in these proceedings. However, it is not possible to determine the ultimate outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect that a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

U.S. Patent Litigation

We are engaged in various U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984. Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); Barr Laboratories, Inc. (Barr); Pliva Hrvatska D.O.O. (Pliva); Accord Healthcare Inc. (Accord), Apotex Inc. (Apotex), Sun Pharmaceutical Industries, Ltd. (Sun); Sun Pharma Global FZE (Sun Global); and Glenmark Generics Inc., USA (Glenmark), and Nan Kuang Pharmaceutical Co., Ltd. (Nan Kuang) each submitted Abbreviated New Drug Applications (ANDAs) seeking approval to market generic versions of Alimta prior to the expiration of our vitamin dosage regimen patent (expiring in 2021 plus pediatric exclusivity expiring in 2022) and alleging the patent is invalid.

In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP, Pliva, and Barr seeking rulings that the U.S. vitamin dosage regimen patent is valid and infringed (the Teva/APP litigation). Teva and APP stipulated to infringement of our vitamin dosage regimen patent, with the contingency that Teva and APP would be permitted to litigate the issue of infringement if the U.S. Supreme Court vacated an en banc decision of the Federal Circuit that dealt with the issues of liability related to infringement (Akamai v. Limelight Networks). Thus, the sole issue before the district court was to determine the issue of patent validity.

Trial in the Teva/APP litigation occurred in August 2013. In March 2014, the court ruled that the asserted claims of the vitamin dosage patent are valid. The defendants filed their notice of appeal in April 2014. In January 2012 and April 2012, we filed similar lawsuits in the same court against Accord and Apotex, respectively. We filed a second lawsuit against Accord in February 2013. The Accord and Apotex cases have been consolidated and stayed by the court and the parties have agreed to be bound by the outcome of the Teva/APP litigation. In September 2013, we filed a similar lawsuit in the same court against Sun and Sun Global seeking a ruling that our patent is valid and infringed. This case has been stayed, and we and Sun have agreed to be bound by the outcome of the Teva/APP litigation. In January 2014, we filed a similar lawsuit in the same court against Glenmark seeking a ruling that our patent is valid and infringed. That case was amended in March 2014 to add two related Glenmark companies. This case has been stayed, and Lilly and Glenmark have agreed to be bound by the outcome of the Teva/APP litigation. In October 2014, we filed a lawsuit against Nan Kuang in the same court, seeking a ruling that our patent is valid and infringed.

In June of 2014, the U.S. Supreme Court vacated the Akamai decision. In July of 2014, the court of appeals in the Teva/APP litigation entered an order remanding the case back to the district court to consider the issue of infringement. A hearing has been scheduled for January 29, 2015.

European Patent Litigation and Administrative Proceedings

Generic manufacturers filed an opposition to the European Patent Office's decision to grant us a vitamin dosage regimen patent. The Opposition Division of the European Patent Office upheld the patent and the generic manufacturers lodged an appeal. In addition, in the UK, Actavis Group ehf and other Actavis companies filed litigation asking for a declaratory judgment that commercialization of certain salt forms of pemetrexed (the active ingredient in Alimta) would not infringe the vitamin dosage regimen patents in the UK, Italy, France, and Spain. This trial occurred in April 2014. In May 2014, the court ruled that the vitamin dosage patents for Alimta would not be infringed by the defendants' commercialization of alternative salt forms of pemetrexed, after expiration of the compound patents in December 2015. We filed a motion to appeal the court's ruling in June 2014, and a hearing is scheduled to occur in March 2015.

We commenced separate infringement proceedings against certain Actavis companies in Germany. The German case was heard by the trial court in March 2014. In April 2014, the German trial court ruled in our favor. The defendants filed their notice of appeal in May 2014, and a hearing is scheduled to occur in March 2015.

Japanese Administrative Proceedings

Sawai Pharmaceutical Company Limited, has filed a demand for invalidation of our vitamin dosage regimen patents with the Japanese Patent Office. No hearing dates have been set.

Actos® Product Liability Litigation

We are named along with Takeda Chemical Industries, Ltd., and Takeda affiliates as a defendant in approximately 4,900 product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until September 2006. Our agreement with Takeda calls for Takeda to defend and indemnify us against our losses and expenses with respect to the U.S. product liability litigation and other related expenses in accordance with the terms of the agreement.

In general, plaintiffs in these actions allege that Actos caused or contributed to their bladder cancer. Almost all of the active cases have been consolidated in federal multi-district litigation in the Western District of Louisiana or are pending in a coordinated state court proceeding in California or a coordinated state court proceeding in Illinois. We believe these lawsuits are without merit, and we and Takeda are prepared to defend against them vigorously.

On April 7, 2014, a jury in the Western District of Louisiana found in favor of the plaintiffs in the case of Terrence Allen, et al. v. Takeda Pharmaceuticals, et al., no. 6:12-md-00064. Because of the existence of the indemnification agreement, Lilly tendered its defense of the case to Takeda. After the jury reached its verdict in Allen, Takeda notified us that it was reserving its right to challenge its obligations to defend and indemnify us with respect to the Allen case. We believe we are entitled to full indemnification of our losses and expenses in Allen and all other U.S. cases; however, there can be no guarantee we will ultimately be successful in obtaining full indemnification.

On September 3, 2014, judgment was entered awarding approximately $1.3 million in compensatory damages to plaintiffs (allocated 75 percent to Takeda and 25 percent to us) and punitive damages of $6.00 billion against Takeda and $3.00 billion against us. On October 27, 2014, the judge issued an order substantially reducing the amount of punitive damages awarded to approximately $30 million against Takeda and approximately $9 million against us. We continue to believe the evidence did not support plaintiffs' claims and strongly disagree with the verdict. We and Takeda intend to vigorously challenge this outcome through all available legal means.

We are also named along with Takeda as a defendant in three purported product liability class actions in Canada related to Actos, including one in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.), one in Quebec (Whyte et al. v. Eli Lilly et al.), and one in Alberta (Epp v. Takeda Canada et al.). We promoted Actos in Canada until 2009. We believe these claims are without merit and are prepared to defend against them vigorously.

Byetta Product Liability Litigation

We are named as a defendant in approximately 390 Byetta product liability lawsuits involving approximately 880 plaintiffs. Approximately 95 of these lawsuits, covering about 500 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 290 lawsuits, covering about 330 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation in the Southern District of California. The remaining approximately 10 lawsuits, representing about 60 plaintiffs, are in various state courts. Approximately 330 of the lawsuits, involving approximately 500 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer). We are aware of approximately 400 additional claimants who have not yet filed suit. The majority of these additional claims allege damages for pancreatitis. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

Prozac® Product Liability Litigation

We are named as a defendant in approximately 10 U.S. lawsuits primarily related to allegations that the antidepressant Prozac caused or contributed to birth defects in the children of women who ingested the drug during pregnancy. We are aware of approximately 500 additional claims related to birth defects, which have not yet been filed. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

Brazil–Employee Litigation

Our subsidiary in Brazil, Eli Lilly do Brasil (Lilly Brasil), is named in a lawsuit brought by the Labor Attorney for 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 manufacturing facility in Cosmopolis, Brazil,

operated by the company between 1977 and 2003. The plaintiffs allege that some employees at the facility were exposed to benzene and heavy metals; however, Lilly Brasil maintains that these alleged contaminants were never

used in the facility. In May 2014, the labor court judge ruled against Lilly Brasil. The judge's ruling orders Lilly Brasil to undertake several actions of unspecified financial impact, including paying lifetime medical insurance for the employees and contractors who worked at the Cosmopolis facility more than 6 months during the affected years and their children born during and after this period. While we cannot currently estimate the range of reasonably possible financial losses that could arise in the event we do not ultimately prevail in the litigation, the judge has estimated the total financial impact of the ruling to be approximately $450 million plus interest. We strongly disagree with the decision and filed an appeal in May 2014. We are also named in approximately 30 lawsuits filed in the same court by individual former employees making similar claims. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of 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 marketed products.

Note 12: Other Comprehensive Income (Loss)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the three months ended September 30, 2014 and September 30, 2013:

(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 July 1, 2014	$ 467.9	$124.7	$ (2,403.3)	$(124.6)	$ (1,935.3)
Other comprehensive income (loss) before reclassifications	(635.4)	17.3	36.5	(34.5)	(616.1)
Net amount reclassified from accumulated other comprehensive loss	—	(59.5)	44.7	14.6	(0.2)
Net other comprehensive income (loss)	(635.4)	(42.2)	81.2	(19.9)	(616.3)
Balance at September 30, 2014	$ (167.5)	$82.5	$ (2,322.1)	$(144.5)	$ (2,551.6)

(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 July 1, 2013	$ 92.9	$67.0	$ (4,005.2)	$(103.4)	$ (3,948.7)
Other comprehensive income (loss) before reclassifications	289.7	62.8	(27.5)	(22.7)	302.3
Net amount reclassified from accumulated other comprehensive loss	—	0.4	80.4	1.5	82.3
Net other comprehensive income (loss)	289.7	63.2	52.9	(21.2)	384.6
Balance at September 30, 2013	$ 382.6	$130.2	$ (3,952.3)	$(124.6)	$ (3,564.1)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the nine months ended September 30, 2014 and 2013:

(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, 2014	$ 463.0	$205.2	$ (2,489.1)	$(181.8)	$ (2,002.7)
Other comprehensive income (loss) before reclassifications	(630.5)	34.0	30.0	(23.8)	(590.3)
Net amount reclassified from accumulated other comprehensive loss	—	(156.7)	137.0	61.1	41.4
Net other comprehensive income (loss)	(630.5)	(122.7)	167.0	37.3	(548.9)
Balance at September 30, 2014	$ (167.5)	$82.5	$ (2,322.1)	$(144.5)	$ (2,551.6)

(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, 2013	$ 426.8	$72.5	$ (4,195.2)	$(101.2)	$ (3,797.1)
Other comprehensive income (loss) before reclassifications	(44.2)	61.1	10.2	(27.8)	(0.7)
Net amount reclassified from accumulated other comprehensive loss	—	(3.4)	232.7	4.4	233.7
Net other comprehensive income (loss)	(44.2)	57.7	242.9	(23.4)	233.0
Balance at September 30, 2013	$ 382.6	$130.2	$ (3,952.3)	$(124.6)	$ (3,564.1)

The tax effect on the unrealized net gains (losses) on securities was a benefit of $22.8 million and an expense of $32.9 million for the three months ended September 30, 2014 and 2013, respectively, and a benefit of $66.3 million and an expense of $31.1 million for the nine months ended September 30, 2014 and 2013, respectively.

The tax effect related to our defined benefit pension and retiree health benefit plans was an expense of $30.8 million and $48.1 million for the three months ended September 30, 2014 and 2013, respectively, and an expense of $70.8 million and $137.2 million for the nine months ended September 30, 2014 and 2013, respectively.

The tax effect on the effective portion of cash flow hedges was a benefit of $10.7 million and $11.4 million for the three months ended September 30, 2014 and 2013, respectively, and an expense of $19.9 million and a benefit of$12.7 million for the nine months ended September 30, 2014 and 2013, respectively. Income taxes are not provided for foreign currency translation.

Details about Accumulated Other Comprehensive Loss Components	Reclassifications Out of Accumulated Other Comprehensive Loss				
	Three Months Ended September 30,		Nine Months Ended September 30,		Affected line Item in the Consolidated Condensed Statements of Operations
	2014	2013	2014	2013	
Amortization of retirement benefit items:					
Prior service benefits, net	$(6.5)	$(8.2)	$(19.3)	$(19.0)	[1]
Actuarial losses	73.8	129.5	222.4	374.1	[1]
Total before tax	67.3	121.3	203.1	355.1	
Tax benefit	(22.6)	(40.9)	(66.1)	(122.4)	
Net of tax	44.7	80.4	137.0	232.7	
Unrealized gains/losses on available-for-sale securities:					
Realized gains, net	(91.6)	0.6	(241.1)	(7.7)	Other–net, (income) expense
Impairment losses	—	—	—	2.5	Other–net, (income) expense
Total before tax	(91.6)	0.6	(241.1)	(5.2)	
Tax expense	32.1	(0.2)	84.4	1.8	
Net of tax	(59.5)	0.4	(156.7)	(3.4)	
Other, net of tax	14.6	1.5	61.1	4.4	Other–net, (income) expense
Total reclassifications for the period (net of tax)	$(0.2)	$82.3	$41.4	$233.7	

[1] These accumulated other comprehensive loss components are included in the computation of net periodic benefit (see Note 10).

Note 13: Other–Net, (Income) Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Interest expense	$38.1	$39.8	$111.4	$120.4
Interest income	(28.8)	(32.2)	(96.8)	(85.5)
Income related to termination of the exenatide collaboration with Amylin (Note 4)	—	—	—	(495.4)
Other	(102.8)	23.7	(217.9)	(49.3)
Other–net, (income) expense	$(93.5)	$31.3	$(203.3)	$(509.8)

Other–net, income for the three and nine months ended September 30, 2014 is primarily related to gains on sales of investment securities and income from milestones earned. Other–net, income of $509.8 million for the first nine months of 2013 is primarily related to the income recognized from the termination of the exenatide collaboration with Amylin. See Note 4 for additional information.

Note 14: Segment Information

We operate in two business segments—human pharmaceutical products and animal health. Our business segments are distinguished by the ultimate end user of the product—humans or animals. Performance is evaluated based on profit or loss from operations before income taxes.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Segment revenue—to unaffiliated customers:				
Human pharmaceutical products:				
Endocrinology	$1,708.3	$1,764.7	$5,087.0	$5,273.9
Neuroscience	869.9	1,878.1	2,727.9	5,731.5
Oncology	882.4	821.8	2,505.1	2,394.1
Cardiovascular	757.2	715.6	2,235.3	2,140.9
Other pharmaceuticals	73.1	62.1	225.7	190.8
Total human pharmaceutical products	4,290.9	5,242.3	12,781.0	15,731.2
Animal health	584.7	530.3	1,713.3	1,573.1
Total segment revenue	$4,875.6	$5,772.6	$14,494.3	$17,304.3
Segment profits:				
Human pharmaceutical products[1]	$760.0	$1,362.5	$2,350.8	$4,141.4
Animal health[2]	145.8	150.9	417.6	427.8
Total segment profits	$905.8	$1,513.4	$2,768.4	$4,569.2
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	$905.8	$1,513.4	$2,768.4	$4,569.2
Other profits (losses):				
Income related to termination of the exenatide collaboration with Amylin (Note 4)	—	—	—	495.4
Acquired in-process research and development (Note 3)	(95.0)	—	(95.0)	—
Asset impairment, restructuring, and other special charges (Note 5)	(36.3)	—	(67.7)	(85.2)
Incremental U.S. Branded Prescription Drug Fee due to issuance of final tax regulations	(119.0)	—	(119.0)	—
Total consolidated income before taxes	$655.5	$1,513.4	$2,486.7	$4,979.4

1 Human pharmaceutical products segment profit includes total depreciation and amortization expense of $315.0 million and $323.1 million for the three months ended September 30, 2014 and 2013, respectively, and $956.2 million and $1.02 billion for the nine months ended September 30, 2014 and 2013, respectively.

2 Animal health segment profit includes total depreciation and amortization expense of $27.4 million and $25.9 million for the three months ended September 30, 2014 and 2013, respectively, and $83.4 million and $72.4 million for the nine months ended September 30, 2014 and 2013, respectively.

For internal management reporting presented to the chief operating decision maker, certain costs are fully allocated to our human pharmaceutical products segment and therefore are not reflected in the animal health segment's profit. Such items include costs associated with treasury-related financing, global administrative services, certain acquisition-related transaction costs, and certain manufacturing costs.

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

Results of Operations

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and legal, regulatory, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data is presented on a diluted basis.

Financial Results

Worldwide total revenue decreased 16 percent to $4.88 billion and decreased 16 percent to $14.49 billion in the third quarter and first nine months of 2014, respectively. The declines were primarily driven by decreases in volume which were primarily the result of the loss of U.S. patent exclusivity for Cymbalta® in December 2013 and to a lesser extent Evista® in March 2014, partially offset by volume growth in most other products. The decreases in revenue and gross margin were partially offset in both periods by a decrease in research and development expenses, and in the first nine months of 2014, a decrease in marketing, selling, and administrative expenses. As a result, net income for the third quarter and first nine months of 2014 decreased 58 percent to $500.6 million and 50 percent to $1.96 billion, respectively. EPS for the third quarter and first nine months of 2014 decreased 58 percent to $0.47 per share and 50 percent to $1.82, respectively. EPS for both periods benefited from a lower number of shares outstanding compared to the same respective periods in 2013 as a result of our share repurchase programs.

The following highlighted items affect comparisons of our financial results for the three and nine months ended September 30, 2014 and 2013:

2014

Acquired In-Process Research & Development (IPR&D) (Note 3)

- We recognized expense in the third quarter of $95.0 million (pretax), or $0.06 per share, related to IPR&D from the collaboration agreements with Immunocore Limited and AstraZeneca UK Limited.

Asset Impairment, Restructuring, and Other Special Charges (Note 5)

- We recognized charges in the third quarter of $36.3 million (pretax), or $0.02 per share, related primarily to severance associated with our ongoing cost containment efforts and costs related to the pending acquisition of Novartis Animal Health (NAH).
- We recognized charges in the first quarter of $31.4 million (pretax), or $0.02 per share, related to restructuring costs for actions being taken to reduce our cost structure.

Other

- We recognized a marketing, selling, and administrative expense in the third quarter of $119.0 million (non-tax deductible), or $0.11 per share, for an extra year of the U.S. Branded Prescription Drug Fee due to final regulations issued by the Internal Revenue Service (IRS).

2013

Collaborations (Note 4)

- We recognized income in the first quarter of $495.4 million (pretax), or $0.29 per share, related to the termination of the exenatide collaboration with Amylin.

Asset Impairment, Restructuring, and Other Special Charges (Note 5)

- We recognized charges in the second quarter of $63.5 million (pretax), or $0.04 per share, primarily related to costs associated with the decision to close a packaging and distribution facility in Germany.
- We recognized charges in the first quarter of $21.7 million (pretax), or $0.01 per share, related to severance costs for actions taken to reduce our cost structure.

Late-Stage Pipeline

Our long-term success depends to a great extent on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on molecules currently in development by other biotechnology

or pharmaceutical companies. We currently have approximately 55 potential new drugs in human testing or under regulatory review, and a larger number of projects in preclinical research.

The following new molecular entities (NMEs) are currently in Phase III clinical trial testing for potential use in the diseases described. The quarter in which the NME initially entered Phase III for any indication is shown in parentheses:

Abemaciclib (Q3 2014)—a small molecule cell-cycle inhibitor, selective for cyclin-dependent kinases 4 and 6 (CDK 4/6 inhibitor) for the treatment of metastatic breast cancer and non-small-cell lung cancer.

Baricitinib (Q4 2012)—a Janus tyrosine kinase (JAK 1 and JAK 2) inhibitor for the treatment of rheumatoid arthritis (in collaboration with Incyte Corporation).

Basal insulin peglispro* (Q4 2011)—a novel basal insulin for the treatment of type 1 and type 2 diabetes.

Evacetrapib (Q4 2012)—a cholesteryl ester transfer protein (CETP) inhibitor for the treatment of high-risk vascular disease.

Ixekizumab* (Q4 2011)—a neutralizing monoclonal antibody to interleukin-17A (IL-17) for the treatment of psoriasis and psoriatic arthritis.

Necitumumab* (Q4 2009)—an anti-epidermal growth factor receptor (EGFR) monoclonal antibody for the treatment of squamous NSCLC.

Solanezumab* (Q2 2009)—an anti-amyloid beta (Aß) monoclonal antibody for the treatment of mild Alzheimer’s disease.

Tanezumab* (Q3 2008)—an anti-nerve growth factor monoclonal antibody for the treatment of osteoarthritis pain, chronic low back pain and cancer pain (in collaboration with Pfizer Inc. (Pfizer)). Tanezumab is currently subject to a partial clinical hold by the U.S. Food and Drug Administration (FDA) (see Note 4).

*Biologic molecule subject to the U.S. Biologics Price Competition and Innovation Act

The following are late-stage pipeline updates since January 1, 2014:

Abemaciclib—In August 2014, we initiated a Phase III study of abemaciclib in combination with fulvestrant as a potential treatment of metastatic breast cancer.

Basal insulin peglispro—In May 2014, we announced positive top-line results of three completed Phase III clinical trials studying basal insulin peglispro in patients with type 2 diabetes. The primary efficacy endpoint of non-inferior reduction in hemoglobin A1c (HbA1c) compared to insulin glargine was met in all three trials. Having met the primary endpoints, superiority for HbA1c lowering was examined and, in all three trials, basal insulin peglispro showed a statistically superior reduction in HbA1c compared with insulin glargine.

In September 2014, we announced positive top-line results of two completed Phase III clinical trials studying basal insulin peglispro in patients with type 1 diabetes. We intend to submit the first application to regulatory authorities by the end of the first quarter of 2015.

Dulaglutide—In February 2014, we announced positive top-line results of the sixth Phase III AWARD trial studying dulaglutide as a once-weekly treatment for type 2 diabetes. In the AWARD-6 study, once-weekly dulaglutide 1.5 mg achieved the primary endpoint of non-inferiority to once-daily liraglutide 1.8 mg, as measured by the reduction of hemoglobin A1c (HbA1c) from baseline at 26 weeks.

In September 2014, Trulicity™ (dulaglutide) received FDA approval and a positive opinion from the Committee for Medicinal Products for Human Use (CHMP). The European Commission typically follows the committee's recommendation and is expected to make its final decision on marketing authorization for the product in the fourth quarter of 2014. Dulaglutide was submitted to regulatory authorities in Japan in the third quarter of 2014. Trulicity was launched in the U.S. in October 2014.

Empagliflozin—In April 2014, we and Boehringer Ingelheim announced the FDA accepted the filing of the New Drug Application (NDA) for the investigational combination tablet of empagliflozin and linagliptin (Trajenta®) for the treatment of adults with type 2 diabetes.

In May 2014, we and Boehringer Ingelheim announced the European Commission granted marketing authorization for Jardiance® (empagliflozin) for the treatment of type 2 diabetes to improve glycemic control

in adults. In August 2014, Jardiance was also approved in the U.S. We and Boehringer Ingelheim launched the product in the U.S. and certain European countries in the third quarter of 2014.

Ixekizumab—In August 2014, we announced positive top-line results of three completed Phase III trials studying skin clearance measures in patients with moderate-to-severe plaque psoriasis. Ixekizumab met all primary and secondary objectives and was superior to etanercept and placebo on all measures of skin clearance in both active comparator studies. We intend to submit the first application to regulatory authorities in the first half of 2015.

Necitumumab—In the fourth quarter of 2014, with the FDA having granted Fast Track status to necitumumab as a first-line treatment for squamous non-small-cell lung cancer, we have initiated our rolling submission. The FDA Fast Track status is a designation that facilitates the development, and expedites the review, of drugs which treat a serious or life-threatening condition and fill an unmet medical need. We expect to complete our rolling submission to the FDA before the end of 2014.

New insulin glargine product—In January 2014, Sanofi-Aventis U.S. LLC (Sanofi) filed a lawsuit against us in the U.S. District Court for the District of Delaware alleging patent infringement with respect to our insulin glargine product for which we are seeking approval from the FDA. Sanofi asserts infringement of three patents relating to pen injector devices and two patents relating to insulin glargine formulations. Under the Hatch-Waxman Act, the initiation of the lawsuit automatically invokes a stay of FDA approval of the product for a period of 30 months, which may be shortened in the event of an earlier decision in our favor. We believe the lawsuit is without merit, and we are prepared to vigorously defend against the allegations. In July 2014, Sanofi filed a second suit against us in the same court alleging infringement of patents relating to the use of our insulin glargine formulation in a cartridge. We are also involved in patent revocation and infringement actions related to the insulin glargine compound patent and certain device patents in the U.K. and France.

We do not believe the application infringes any of the asserted patents, and we believe we will prevail in the litigation. In August 2014, the FDA tentatively approved Basaglar™ (new insulin glargine), determining that it has met all regulatory requirements for approval, but it is subject to an automatic stay in the U.S. of up to 30 months as a result of the patent litigation filed by Sanofi.

In September 2014, the European Commission approved our new insulin glargine for the treatment of type 1 and type 2 diabetes. We will work with Boehringer Ingelheim to launch the new insulin glargine product in European countries on dates that do not infringe valid and enforceable patents.

Ramucirumab—In April 2014, we announced the FDA's approval of Cyramza® (ramucirumab), an anti-vascular endothelial growth factor receptor-2 (VEGFR-2) monoclonal antibody, as a single agent treatment for patients with advanced or metastatic gastric (stomach) cancer or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy. With this approval, Cyramza becomes the first FDA-approved treatment for patients in this setting. Product sales of Cyramza began in the U.S. during the second quarter of 2014.

In June 2014, we announced our submission to the FDA of a supplemental biologic license application for Cyramza in combination with paclitaxel for the treatment of second-line gastric cancer. We expect FDA action by the first quarter of 2015. We have also submitted for this indication in the EU and in September 2014, received a positive opinion from the CHMP for the use of Cyramza in adults in combination with paclitaxel for the treatment of advanced gastric or GEJ adenocarcinoma following prior chemotherapy and as a monotherapy in this setting for patients for whom treatment in combination with paclitaxel is not appropriate. The final decision from the European Commission is expected in the fourth quarter of 2014. In the third quarter of 2014, we also submitted a new drug application to regulatory authorities in Japan for Cyramza for its use in the treatment of second-line gastric cancer. We anticipate action in the first half of 2015.

In February 2014, we announced that the REVEL trial, a global Phase III study of Cyramza in combination with chemotherapy (docetaxel) in patients with second-line non-small cell lung cancer, met its primary endpoint of improved overall survival and a secondary endpoint of improved progression-free survival. In the third quarter of 2014, we announced the submission of the application for this indication to the FDA. We anticipate action before the end of 2014.

28

In June 2014, we announced that the Phase III REACH trial in patients with liver cancer did not meet its primary endpoint as overall survival favored the Cyramza arm, but was not statistically significant. We plan to discuss these results with regulatory authorities to inform future trials.

In September 2014, we announced that the RAISE trial, a global Phase III study of Cyramza in combination with chemotherapy in patients with metastatic colorectal cancer (mCRC), met its primary endpoint of overall survival. We intend to submit the first application for this indication to regulatory authorities in the first half of 2015.

Tabalumab—In October 2014, we announced the decision to stop development of tabalumab which was being studied as a treatment for lupus in Phase III trials due to lack of efficacy.

There are many difficulties and uncertainties inherent in pharmaceutical research and development (R&D) and the introduction of new products. A high rate of failure is inherent in new drug discovery and development. The process to bring a drug from the discovery phase to regulatory approval can take 12 to 15 years or longer and cost more than $1 billion. Failure can occur at any point in the process, including late in the process after substantial investment. As a result, most research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success. Delays and uncertainties in the regulatory approval processes in the U.S. and in other countries can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be approved and the sales growth of those products.

We manage R&D spending across our portfolio of molecules, and a delay in, or termination of, any one project will not necessarily cause a significant change in our total R&D spending. Due to the risks and uncertainties involved in the R&D process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our R&D projects, nor can we reliably estimate the future potential revenue that will be generated from a successful R&D project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated R&D expense. While we do accumulate certain R&D costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total R&D costs by project, by preclinical versus clinical spend, or by therapeutic category.

Legal, Regulatory, and Other Matters

In April 2014, we announced an agreement to acquire NAH in an all-cash transaction for approximately $5.4 billion. NAH, which operates in approximately 40 countries, generated revenue of approximately $1.1 billion in 2013. We will acquire NAH's nine manufacturing sites, six dedicated R&D facilities, a global commercial infrastructure with a portfolio of approximately 600 products, a pipeline with more than 40 projects in development, and more than 3,000 employees, subject to certain divestitures that will be required by global regulatory agencies. We expect that the acquisition will expand and complement Elanco's product portfolio, R&D and manufacturing capabilities, and commercial presence in key geographies. In particular, it is expected to provide Elanco with a greater commercial presence in the companion animal and swine markets, expand Elanco's presence in equine and vaccines areas, and create an entry into the aquaculture market. The transaction is expected to close by the end of the first quarter of 2015, subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act, similar requirements outside the U.S., and other customary closing conditions. The European antitrust regulators approved the NAH acquisition in October 2014. We have agreed to divest the U.S. assets related to two major parasiticides for dogs, Sentinel® Flavor Tabs and Sentinel® Spectrum, currently marketed in the U.S. by NAH, in connection with the U.S. Federal Trade Commission's (FTC) review of the pending acquisition of NAH. We have entered into an agreement to sell these assets to Virbac Corporation, subject to approval from the FTC and the closing of our acquisition of NAH. Total revenues of these products are expected to reach approximately $90 million to $100 million in 2014.

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. The loss of U.S. patent exclusivity for Cymbalta in December 2013 and Evista in March 2014, resulted in the immediate entry of generic competitors and a rapid and severe decline in revenue from the affected products, having a material adverse effect on our consolidated results of operations and cash flows. We lost our data package protection for Cymbalta in major European countries in 2014; however, we do not anticipate the entry of generic

competition in these countries until 2015. We will also lose patent exclusivity in December 2015 for Zyprexa® in Japan.

Additionally, as described in Note 11, the Alimta® vitamin dosage regimen patent, which provides us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the

United States, has been challenged in each of these jurisdictions. Our compound patent for Alimta will expire in the U.S. in January 2017, and in major European countries and Japan in December 2015.

We expect that the entry of generic competition for Cymbalta and Alimta into these markets would cause a rapid and severe decline in revenue from the affected products, having a material adverse effect on our consolidated results of operations and cash flows.

The U.S. compound patent for Humalog® expired in May 2013. The loss of compound patent protection for Humalog has not resulted in a rapid and severe decline in revenue. To date, no biosimilar version of Humalog has been approved in the U.S. or Europe; however, we are aware that other manufacturers have efforts underway to develop biosimilar forms of Humalog, and it is difficult to predict the likelihood, timing, and impact of biosimilars entering the market.

The continuing prominence of U.S. budget deficits as both a policy and political issue increases the risk that taxes, fees, rebates, or other federal measures that would further reduce pharmaceutical companies' revenue or increase expenses may be enacted. Certain federal and state health care proposals, including state price controls, continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These federal and state proposals, or state price pressures, could have a material adverse effect on our consolidated results of operations.

International operations also are generally subject to extensive price and market regulations. Proposals for cost-containment measures are pending in a number of countries, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual-property protection. Such proposals are expected to increase in both frequency and impact due to pressures on national and regional health care budgets resulting from governments managing health expenses carefully as economies continue to recover, and due to efforts in some countries to expand access to health care coverage while seeking savings from the biopharmaceutical sector.

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Changes in the relevant tax laws, regulations, administrative practices, principles, and interpretations could adversely affect our future effective tax rates. The U.S. and a number of other countries are actively considering changes in this regard. For example, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies, and other tax proposals under discussion or introduced in the U.S. Congress could change the tax rate and manner in which U.S. companies would be taxed. Additionally, the Organization for Economic Co-operation and Development launched and continues to advance an initiative to analyze and potentially influence international tax policy in major countries in which we operate. While outcomes of these initiatives are uncertain, changes to key elements of the U.S. or international tax framework could have a material effect on our consolidated operating results and cash flows in the period or periods in which the development occurs, as well as for subsequent periods.

On July 28, 2014, the IRS issued final regulations for the U.S. Branded Prescription Drug Fee, an annual non-tax deductible fee imposed on us and others engaged in the business of manufacturing or importing branded prescription drugs enacted by the Patient Protection and Affordable Care Act. The final regulations accelerated the expense recognition criteria for the fee obligation by one year, from the year in which the fee is paid to the year in which the sales used to calculate the fee occur. This change impacts all entities conducting covered activities in 2014 and results in the need to expense two years of the U.S. Branded Prescription Drug Fee in 2014 to account for the fee imposed and paid in 2014 and the fee that will be imposed and paid in 2015. We have recognized the additional expense in the third quarter of 2014. This additional fee will be paid, as scheduled, in 2015 and will not have a cash impact in 2014.

Information regarding contingencies relating to certain legal proceedings can be found in Note 11 and is incorporated here by reference.

Revenue

Worldwide total revenue decreased 16 percent to $4.88 billion for the third quarter of 2014 and decreased 16 percent to $14.49 billion for the first nine months of 2014, compared with the same periods of 2013. For the third quarter, the 16 percent worldwide revenue decline was due to decreased volume; the impact of changes in price and foreign exchange rates had a negligible effect. For the first nine months of 2014, the 16 percent worldwide revenue decline was comprised of 14 percent due to decreased volume, 1 percent due to lower prices, and 1 percent due to the

unfavorable impact of foreign exchange rates. The decreases in worldwide volume for both the third quarter and first nine months of 2014 were primarily driven by the loss of U.S. patent exclusivity for Cymbalta,

and to a lesser extent Evista, partially offset by volume growth in most other products. Total revenue in the U.S. decreased 33 percent to $2.22 billion for the third quarter of 2014 and decreased 32 percent to $6.68 billion for the first nine months of 2014, driven primarily by lower demand for Cymbalta and Evista following their patent expirations. Total revenue outside the U.S. increased 8 percent to $2.66 billion for the third quarter of 2014, primarily driven by increased volume. Total revenue outside the U.S. increased 5 percent to $7.81 billion for the first nine months of 2014, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates, primarily the Japanese yen, and lower prices.

The following tables summarize our revenue activity:

Product	Three Months Ended September 30, 2014 U.S.[1]	Outside U.S.	Total	Three Months Ended September 30, 2013 Total	Percent Change from 2013	
	(Dollars in millions)					
Alimta	$320.4	$403.0	$723.4	$690.5	5	%
Humalog	415.0	291.1	706.1	616.0	15	%
Cialis®	250.0	318.4	568.4	526.7	8	%
Cymbalta	69.4	298.6	368.0	1,375.8	(73	)%
Humulin®	165.8	170.1	335.9	307.0	9	%
Forteo®	127.2	205.0	332.2	306.7	8	%
Zyprexa	18.8	238.6	257.4	278.7	(8	)%
Strattera®	120.9	71.0	191.9	173.2	11	%
Effient®	99.6	31.9	131.5	124.9	5	%
Evista	34.8	54.7	89.5	255.3	(65	)%
Other human pharmaceutical products	162.9	219.7	382.6	404.1	(5	)%
Animal health products	312.9	271.8	584.7	530.3	10	%
Total net product sales	2,097.7	2,573.9	4,671.6	5,589.2	(16	)%
Collaboration and other revenue[2]	120.1	83.9	204.0	183.4	11	%
Total revenue	$2,217.8	$2,657.8	$4,875.6	$5,772.6	(16	)%

Product	Nine Months Ended September 30, 2014 U.S.[1]	Outside U.S.	Total	Nine Months Ended September 30, 2013 Total	Percent Change from 2013	
	(Dollars in millions)					
Alimta	$887.2	$1,179.8	$2,067.0	$1,976.8	5	%
Humalog	1,203.5	852.6	2,056.1	1,877.4	10	%
Cialis	722.0	946.6	1,668.6	1,571.1	6	%
Cymbalta	357.7	889.8	1,247.5	4,201.2	(70	)%
Humulin	502.2	502.3	1,004.5	946.3	6	%
Forteo	356.0	585.2	941.2	885.2	6	%
Zyprexa	85.6	698.6	784.2	846.7	(7	)%
Strattera	333.5	210.2	543.7	508.1	7	%
Effient	287.7	96.7	384.4	378.1	2	%
Evista	187.8	160.0	347.8	774.6	(55	)%
Other human pharmaceutical products	447.1	695.0	1,142.1	1,259.0	(9	)%
Animal health products	952.3	761.0	1,713.3	1,573.1	9	%
Total net product sales	6,322.6	7,577.8	13,900.4	16,797.6	(17	)%
Collaboration and other revenue[2]	358.9	235.0	593.9	506.7	17	%
Total revenue	$6,681.5	$7,812.8	$14,494.3	$17,304.3	(16	)%

[1] U.S. revenue includes revenue in Puerto Rico.

[2] Collaboration and other revenue consists primarily of royalties for Erbitux and revenue associated with Trajenta.

Sales of Alimta, a treatment for various cancers, increased 3 percent in the U.S. during the third quarter of 2014, driven primarily by higher prices. For the first nine months of 2014, sales in the U.S. increased 1 percent, driven by higher prices. Sales outside the U.S. increased 6 percent during the third quarter of 2014, driven by increased volume, partially offset by lower prices. For the first nine months of 2014, sales outside the U.S. increased 7 percent, driven by increased volume.

Sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 16 percent in the U.S. during the third quarter of 2014, driven by increased demand. For the first nine months of 2014, U.S. sales increased 11 percent driven by increased demand, partially offset by lower net effective selling prices and wholesaler buying patterns. Sales outside the U.S. increased 13 percent during the third quarter of 2014, driven primarily by increased volume. For the first nine months of 2014, sales outside the U.S. increased 8 percent, driven by increased volume.

Sales of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia (BPH), increased 7 percent in the U.S. during the third quarter of 2014, driven by higher prices, partially offset by decreased volume. For the first nine months of 2014, U.S. sales increased 9 percent, driven by higher prices, partially offset by wholesaler buying patterns. Sales outside the U.S. increased 9 percent during the third quarter of 2014, driven primarily by higher prices and increased volume. For the first nine months of 2014, sales outside the U.S. increased 4 percent, driven by higher prices and, to a lesser extent, increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the U.S. for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, decreased 94 percent in the U.S. for the third quarter of 2014 and decreased 89 percent in the U.S. for the first nine months of 2014, due to the loss of U.S. patent exclusivity in December 2013. Sales outside the U.S. increased 12 percent in the third quarter of 2014 and increased 9 percent for the first nine months of 2014, driven by increased volume.

Sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 3 percent in the U.S. in the third quarter of 2014, driven by increased volume. For the first nine months of 2014, U.S. sales increased 4 percent, driven by increased demand, partially offset by wholesaler buying patterns. Sales outside the U.S. increased 17 percent in the third quarter of 2014 and increased 8 percent in the first nine months of 2014, driven by increased volume, partially offset by lower prices. Sales of Humulin in the first nine months of 2014 were also negatively affected by the unfavorable impact of foreign exchange rates.

Sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, decreased 1 percent in the U.S. in the third quarter of 2014, driven by decreased volume, offset by higher prices. For the first nine months of 2014, U.S. sales remained flat as higher prices were largely offset by wholesaler and retailer buying patterns. Sales outside the U.S. increased 15 percent in the third quarter of 2014 due to increased volume. For the first nine months of 2014, sales outside the U.S. increased 10 percent due to increased volume, primarily in Japan, partially offset by the unfavorable impact of foreign exchange rates, primarily the Japanese yen.

Sales of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, were $18.8 million and $85.6 million in the U.S. in the third quarter and first nine months of 2014, respectively. Sales outside the U.S. decreased 3 percent in the third quarter of 2014, due to lower prices and the unfavorable impact of foreign exchange rates, partially offset by increased volume. For the first nine months of 2014, sales outside the U.S. decreased 8 percent, due to the unfavorable impact of foreign exchange rates, primarily the Japanese yen, and lower prices. We will lose patent exclusivity for Zyprexa in Japan in December 2015. Zyprexa sales in Japan were approximately $120 million and $345 million, for the third quarter and first nine months of 2014, respectively.

Sales of Strattera, a treatment for attention-deficit hyperactivity disorder, increased 9 percent in the U.S. in the third quarter of 2014, driven by higher prices. For the first nine months of 2014, U.S. sales increased 4 percent, as higher prices were partially offset by lower demand and wholesaler buying patterns. Sales outside the U.S. increased 15 percent during the third quarter of 2014 driven primarily by increased volume. For the first nine months of 2014, sales outside the U.S. increased 11 percent, driven by increased volume, primarily in Japan, partially offset by the unfavorable impact of foreign exchange rates, primarily the Japanese yen.

Sales of Effient, a product for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention, including patients undergoing angioplasty, atherectomy, or stent placement, increased 7 percent in the U.S. in the third quarter of 2014, driven primarily by higher prices. For the first nine months of 2014,

U.S. sales increased 3 percent driven by higher prices, partially offset by lower volume. Sales outside the U.S. decreased 1 percent in both the third quarter and first nine months of 2014, driven by lower volume, partially offset by the favorable impact of foreign exchange rates and higher prices.

Sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 82 percent in the U.S. in the third quarter of 2014 and decreased 67 percent in the U.S. for the first nine months of 2014, due to the loss of U.S. patent exclusivity in March 2014. Sales outside the U.S. decreased 14 percent in the third quarter of 2014, driven primarily by lower prices. For the first nine months of 2014, sales outside the U.S. decreased 24 percent, driven by lower prices and, to a lesser extent the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Sales of animal health products increased 3 percent in the U.S. in the third quarter of 2014, driven by higher prices, partially offset by lower volume for both food animal and companion animal products reflecting U.S. competitive challenges and market dynamics. For the first nine months of 2014, sales in the U.S. increased 3 percent, primarily driven by higher prices. Sales outside the U.S. increased 21 percent in the third quarter of 2014 and increased 17 percent for the first nine months of 2014, driven primarily by increased volume for food animal products, reflecting the acquisition of Lohmann Animal Health in the second quarter of 2014. Higher prices in both food animal and companion animal segments as well as increased volume for companion animal products also contributed to sales growth outside the U.S.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue decreased 5.2 percentage points to 74.0 percent for the third quarter of 2014 and decreased 5.0 percentage points to 74.6 percent for the first nine months of 2014, compared with the same periods in 2013, primarily due to lower sales of Cymbalta and Evista following U.S. patent expirations and, for the first nine months of 2014, the unfavorable impact of foreign exchange rates on international inventories sold.

Research and development expenses decreased 10 percent to $1.24 billion for the third quarter of 2014 and decreased 13 percent to $3.55 billion for the first nine months of 2014, driven primarily by lower late-stage clinical development costs, partially offset by a $63.0 million charge in the third quarter of 2014 associated with the termination of tabalumab development. In addition, the first nine months of 2013 included approximately $60 million in milestone payments and a charge for the discontinuation of the rheumatoid arthritis program for tabalumab taken in the first quarter of 2013.

Marketing, selling, and administrative expenses increased 1 percent to $1.67 billion for the third quarter of 2014 due primarily to a $119.0 million charge associated with the U.S. Branded Prescription Drug Fee, partially offset by a reduction in sales and marketing activities for Cymbalta, as well as ongoing cost containment efforts. For the first nine months of 2014, marketing, selling, and administrative expenses decreased 7 percent to $4.82 billion due primarily to the reduction in U.S. sales and marketing activities for Cymbalta and Evista, as well as ongoing cost containment efforts.

Acquired in-process research and development charges of $95.0 million related to collaboration agreements with Immunocore Limited and AstraZeneca were recognized in the third quarter and first nine months of 2014 compared to no charges for the same respective periods in 2013. See Note 3 for additional information.

In the third quarter of 2014, we recognized $36.3 million of asset impairment, restructuring, and other special charges, primarily severance, associated with ongoing cost containment efforts and costs related to the pending acquisition of NAH, compared to no charges for the third quarter of 2013. For the first nine months of 2014 and 2013, we recognized asset impairment, restructuring, and other special charges of $67.7 million and $85.2 million, respectively. See Note 5 for additional information.

Other–net, (income) expense was income of $93.5 million for the third quarter compared with expense of $31.3 million for the third quarter of 2013 and income of $203.3 million for the first nine months of 2014, compared with income of $509.8 million for the same respective period in 2013, driven primarily by gains on the sale of investment securities and income from milestones earned. The first quarter of 2013 benefited from income recognized related to the termination of the exenatide collaboration with Amylin. See Notes 4 and 13 for additional information.

The effective tax rate was 23.6 percent and 21.1 percent for the third quarter and first nine months of 2014, respectively, compared with 20.5 percent for the same respective periods in 2013. The effective tax rates in 2014 include the negative impact of the expiration of the R&D tax credit in the U.S. at the end of 2013. The effective tax rate for the first nine months of 2014 also includes a discrete tax benefit of approximately $30 million. For the first

nine months of 2013, the effective tax rate reflects the tax impact of the termination of the exenatide collaboration with Amylin, partially offset by the one-time impact of the R&D tax credit for full-year 2012, which was recorded in the first quarter of 2013.

Financial Condition

Cash and cash equivalents decreased to $3.17 billion as of September 30, 2014, compared with $3.83 billion as of December 31, 2013, as cash flow from operations of $3.02 billion was more than offset by dividends paid of $1.58 billion, net purchases of property and equipment of $753.8 million, cash paid for acquisitions (net of cash acquired) of $551.4 million, and share repurchases of $500.0 million. In addition to our cash and cash equivalents, we held total investments of $9.05 billion and $9.19 billion as of September 30, 2014 and December 31, 2013, respectively. See Note 6 for additional details.

Total debt increased to $5.61 billion as of September 30, 2014, compared with $5.21 billion as of December 31, 2013 primarily due to an increase of $300.0 million in commercial paper outstanding and, to a lesser extent, due to the increase in fair value of our hedged debt. During the first quarter of 2014, we issued $600.0 million of 1.95% and $400.0 million of 4.65% fixed-rate notes with interest to be paid semi-annually and maturity dates of March 2019 and June 2044, respectively. Proceeds from the new debt were used to repay $1.00 billion of debt that matured in March 2014. See Note 6 for additional details. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. In August 2014, we refinanced our bank credit facilities and entered into a $1.20 billion credit facility with a five-year term and a $2.00 billion credit facility with a 364-day term, resulting in $3.20 billion of unused committed bank credit facilities, all of which backs our commercial paper program.

During the nine months ended September 30, 2014, we purchased $500.0 million of shares associated with our previously announced $5.00 billion share repurchase program.

In April 2014, we announced an agreement to acquire NAH for approximately $5.4 billion in an all-cash transaction. See "Executive Overview—Legal, Regulatory, and Other Matters" for additional details. We anticipate funding this acquisition with approximately $3.4 billion of cash and investments (primarily outside the U.S.) and approximately $2.0 billion in debt to be issued. The acquisition is not expected to change our dividend policy or current share repurchase program.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including dividends, share repurchases, and capital expenditures, as well as certain potential business development activity. Various risks and uncertainties, including those discussed in "Forward-Looking Statements", may affect our operating results and cash generated from operations.

See "Executive Overview—Legal, Regulatory, and Other Matters" for information regarding recent and upcoming losses of patent protection for Cymbalta (U.S. and Europe), Evista (U.S.), Alimta (U.S., Europe, and Japan), and Zyprexa (Japan).

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 recent health care legislation; and various international government funding levels.

Financial Expectations for 2014

In October 2014, we revised certain elements of our 2014 financial guidance. Full-year 2014 earnings per share are now expected to be in the range of $2.36 to $2.44. Our 2014 financial guidance includes other income and IPR&D charges resulting from the revised agreement with Boehringer Ingelheim as well as expected impairment charges related to the planned closure of a manufacturing plant in Puerto Rico which are both fourth quarter events. Information regarding the revised agreement with Boehringer Ingelheim and the planned closure in Puerto Rico can be found in Note 4 and Note 5, respectively.

Due to the strengthening of the U.S. dollar, as well as competitive pressures and market dynamics in the U.S. animal health business, we now anticipate 2014 revenue between $19.4 billion and $19.8 billion. Patent expirations have led to a rapid and severe decline in U.S. Cymbalta and U.S. Evista sales. These revenue declines are expected to be partially offset by growth from a portfolio of other products including Humalog, Humulin, Trajenta, Cialis, Forteo and Alimta, as well as the animal health business and new product launches. In addition, strong revenue growth is

expected in China, while a weaker Japanese yen will dampen revenue growth in Japan.

We now anticipate gross margin as a percent of revenue will be approximately 74.5 percent in 2014 driven by recent strengthening of the U.S. dollar versus the euro. Gross margin in 2014 is now also expected to benefit from a decision to delay until 2015 the shutdown at one of our bulk insulin plants to implement production changes.

Total operating expenses in 2014 are still expected to decrease substantially compared to 2013. Marketing, selling and administrative expenses are now expected in the range of $6.4 billion to $6.6 billion, which includes the accelerated recognition of the U.S. Branded Prescription Drug Fee. Research and development expenses are now expected to be in the range of $4.6 billion to $4.8 billion.

Other income (expense) is now expected to be in the range of $300 million to $350 million of income, reflecting income from the revised agreement with Boehringer Ingelheim.

We now expect 2014 net income to be at least $2.6 billion. We still expect 2014 operating cash flow to be at least $4.0 billion. Operating cash flows are still expected to be sufficient to pay our dividend of approximately $2.1 billion, allow for capital expenditures that are still expected to be approximately $1.2 billion, and fund certain business development activity and share repurchases.

Our 2014 financial guidance assumes that the acquisition of NAH does not close during this calendar year. Should the acquisition close during 2014, we will revise our 2014 financial guidance, if necessary.

Available Information on our Website

We make available through our company website, free of charge, our company filings with the 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 http://investor.lilly.com/sec.cfm.

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 commission (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services, and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2014, and concluded that they are effective.

(b) Changes in Internal Controls. During the third quarter of 2014, 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

See Note 11: Contingencies to the Consolidated Condensed Financial Statements for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta.
- The product liability litigation involving Actos, Prozac, and Byetta.
- The employee litigation in Brazil.

That information is incorporated into this Item by reference.

This Item should be read in conjunction with the Legal Proceedings disclosures in our Annual Report on Form 10-K for the year ended December 31, 2013 (Part I, Item 3).

Other Product Liability Litigation

We are currently a defendant in a variety of other product liability lawsuits in the U.S. involving primarily Darvon®, Cymbalta, diethylstilbestrol (DES), and Zyprexa.

Along with several other manufacturers, we are named as a defendant in approximately 50 cases in the U.S. involving approximately 1,700 claimants related to the analgesics Darvon and related formulations of propoxyphene. Additionally, approximately 80 cases involving approximately 225 claimants were dismissed. Those dismissals were upheld by the Sixth Circuit and the time for appeal to the U.S. Supreme Court has passed, thus fully resolving those cases. Almost all of the active cases have been consolidated in a federal multi-district litigation in the Eastern District of Kentucky or are pending in a coordinated state court proceeding in California. We transferred the U.S. regulatory approvals and all marketing rights to our propoxyphene products in 2002 to NeoSan Pharmaceuticals, Inc. (an affiliate of aaiPharma, Inc.), which subsequently transferred all such approvals and marketing rights to Xanodyne Pharmaceuticals, Inc. We believe these claims are without merit and are prepared to defend against them vigorously.

In October 2012, we were named as a defendant in a purported class-action lawsuit in the U.S. District Court for the Central District of California (Saavedra et al v. Eli Lilly and Company) involving Cymbalta. The plaintiffs assert claims under the consumer protection statutes of four states and seek declaratory, injunctive, and monetary relief for various alleged injuries arising from discontinuing treatment with Cymbalta. The plaintiffs purport to represent a class of all persons within the U.S. who purchased and/or paid for Cymbalta. We believe these claims are without merit and are prepared to defend against them vigorously. Additionally, we have been named in approximately 30 individual lawsuits filed in various federal courts by claimants alleging injuries arising from discontinuation of treatment with Cymbalta. Counsel for plaintiffs have filed a petition seeking to have those cases and an unspecified number of future cases coordinated into a multi-district litigation in the Central District of California. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

Other Patent Litigation

We, along with Daiichi Sankyo Company, Limited (Daiichi Sankyo), Daiichi Sankyo, Inc., and Ube Industries (Ube) are engaged in various U.S. patent litigation matters involving Effient brought pursuant to procedures set out in the Hatch-Waxman Act. Accord Healthcare Inc., USA (Accord); Amneal Pharmaceuticals LLC (Amneal); Apotex Inc. (Apotex); Aurobindo Pharma Limited (Aurobindo); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's); First Time US Generics LLC (FTUG); Glenmark Generics Inc., USA (Glenmark); HEC Pharm Co., Ltd. (HEC); Hetero USA Inc. and Hetero Labs Limited Unit V (Hetero); Mylan Pharmaceuticals Inc. (Mylan); Panacea Biotec, Ltd. (Panacea); Par Pharmaceutical, Inc. (Par); Sun Pharma Global FZE (Sun); Teva Pharmaceuticals USA, Inc. (Teva); Watson Laboratories, Inc. (Watson); and Zydus Pharmaceuticals USA, Inc. (Zydus) each submitted Abbreviated New Drug Applications (ANDAs) seeking approval to market generic versions of Effient prior to the expiration of Daiichi Sankyo's and Ube's patents (expiring in 2022) covering methods of using Effient with aspirin, and alleging the patents are invalid. The ANDA filed by Mylan also alleges that the compound patent for Effient (expiring in 2017) is invalid.

In January 2014, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Par and its parent company seeking a ruling that the patents are valid and infringed. In March 2014, we filed a similar lawsuit in the same court against Accord, Amneal, Aurobindo, Dr. Reddy's, Glenmark, Hetero, Mylan, Par, Sun, Teva, Watson and Zydus, and their related companies, seeking a ruling that the patents are valid and infringed. In April 2014, we filed a similar lawsuit against Apotex in the same court. Similar lawsuits were filed in the same court against Panacea in June 2014, and against HEC and FTUG in July 2014. The lawsuits against Par and HEC were dismissed because those companies withdrew their patent challenges. In October 2014, the court consolidated the pending cases with the case filed in March 2014. The lawsuits against Aurobindo and FTUG have been stayed, and the parties have agreed to be bound by the outcome of the consolidated litigation.

We believe the Effient patents are valid and enforceable against these generic manufacturers and we expect to prevail in these proceedings. However, it is not possible to determine the outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. We expect a loss of exclusivity for Effient would result in a rapid and severe decline in future revenues for the product in the relevant market.

Other Matters

We are also a defendant in other litigation and investigations, including product liability, patent, employment, and premises liability litigation, of a character we regard as ordinary and incidental to our business.

Item 1A. Risk Factors

Our material risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013. There have been no material changes from the risk factors previously disclosed in our Annual Report.

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2014:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
July 2014	1,577.1	$63.39	1,577.1	$4,200.0
August 2014	—	—	—	4,200.0
September 2014	3,055.3	65.44	3,055.3	4,000.0
Total	4,632.4	64.74	4,632.4	

In October 2013, we announced a $5.00 billion share repurchase program. During the third quarter of 2014, we purchased $300.0 million of shares under the program.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data File

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: October 29, 2014

/s/James B. Lootens
James B. Lootens
Corporate Secretary

Date: October 29, 2014

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

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