LILLY ELI & CO
Form 10-Q
October 30, 2013

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, 2013
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	Smaller reporting Company o
		(Do not check if a smaller reporting company)	

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 23, 2013:

Class	Number of Shares Outstanding
Common	1,126,649,615

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, 2012 and all subsequently filed Quarterly Reports on Form 10-Q, 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 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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(Dollars in millions, except per-share data)			
Revenue	$5,772.6	$5,443.3	$17,304.3	$16,646.0
Cost of sales	1,198.1	1,203.6	3,521.6	3,548.2
Research and development	1,377.4	1,342.8	4,055.9	3,815.0
Marketing, selling, and administrative	1,652.4	1,757.4	5,172.0	5,536.0
Asset impairments, restructuring, and other special charges (Note 5)	—	53.3	85.2	77.1
Other – net, (income) expense (Note 14)	31.3	(788.5)	(509.8)	(726.0)
	4,259.2	3,568.6	12,324.9	12,250.3
Income before income taxes	1,513.4	1,874.7	4,979.4	4,395.7
Income taxes (Note 10)	310.3	548.1	1,022.1	1,134.4
Net income	$1,203.1	$1,326.6	$3,957.3	$3,261.3
Earnings per share – basic (Note 9)	$1.11	$1.18	$3.65	$2.92
Earnings per share – diluted (Note 9)	$1.11	$1.18	$3.64	$2.92
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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(Dollars in millions)			
Net income	$1,203.1	$1,326.6	$3,957.3	$3,261.3
Other comprehensive income, net of tax (Note 13)	384.6	398.3	233.0	322.7
Comprehensive income	$1,587.7	$1,724.9	$4,190.3	$3,584.0

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Balance Sheets
ELI LILLY AND COMPANY AND SUBSIDIARIES

	September 30, 2013	December 31, 2012
	(Dollars in millions) (Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	$4,368.9	$4,018.8
Short-term investments (Note 6)	1,010.4	1,665.5
Accounts receivable, net of allowances of $106.3 (2013) and $108.5 (2012)	3,445.0	3,336.3
Other receivables	550.4	552.0
Inventories	2,974.1	2,643.8
Prepaid expenses and other	853.4	822.3
Total current assets	13,202.2	13,038.7
Other Assets		
Investments (Note 6)	7,220.2	6,313.3
Goodwill and other intangibles, net (Note 3)	4,455.1	4,752.7
Sundry	1,320.7	2,534.0
Total other assets	12,996.0	13,600.0
Property and Equipment		
Land, buildings, equipment, and construction-in-progress	15,343.0	14,918.0
Less accumulated depreciation	(7,575.6)	(7,157.8)
Property and equipment, net	7,767.4	7,760.2
Total assets	$33,965.6	$34,398.9
Liabilities and Shareholders' Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	$1,019.1	$11.9
Accounts payable	1,247.4	1,188.3
Employee compensation	805.2	940.3
Sales rebates and discounts	2,014.1	1,777.2
Dividends payable	—	541.4
Income taxes payable	37.5	143.5
Deferred income taxes	841.9	1,048.0
Other current liabilities	2,110.9	2,738.9
Total current liabilities	8,076.1	8,389.5
Other Liabilities		
Long-term debt	4,263.8	5,519.4
Accrued retirement benefits (Note 11)	2,607.9	3,012.4
Long-term income taxes payable (Note 10)	853.5	1,334.3
Other noncurrent liabilities	1,268.2	1,369.4
Total other liabilities	8,993.4	11,235.5
Shareholders' Equity (Notes 7 and 8)		
Common stock	704.7	716.6
Additional paid-in capital	5,042.3	4,963.1
Retained earnings	17,811.0	16,088.2
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 13)	(3,564.1)	(3,797.1)
Noncontrolling interests	9.0	8.7

Cost of common stock in treasury	(93.6)	(192.4)
Total shareholders' equity	16,896.1	14,773.9
Total liabilities and shareholders' equity	$33,965.6	$34,398.9

See Notes to Consolidated Condensed Financial Statements.

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

	Nine Months Ended September 30,	
	2013	2012
	(Dollars in millions)	
Cash Flows from Operating Activities		
Net income	$3,957.3	$3,261.3
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	1,094.4	1,117.6
Change in deferred income taxes	807.6	206.2
Stock-based compensation expense	105.1	100.3
Income related to termination of the exenatide collaboration (Note 4)	(495.4)	(787.8)
Other changes in operating assets and liabilities, net of acquisitions and divestitures	(1,498.3)	(271.5)
Other operating activities, net	37.5	76.7
Net Cash Provided by Operating Activities	4,008.2	3,702.8
Cash Flows from Investing Activities		
Net purchases of property and equipment	(548.1)	(492.2)
Proceeds from sales and maturities of short-term investments	2,378.1	2,125.8
Purchases of short-term investments	(778.6)	(1,868.5)
Proceeds from sales and maturities of noncurrent investments	8,482.9	3,557.4
Purchases of noncurrent investments	(10,239.5)	(5,506.8)
Purchase of product rights	—	(102.0)
Cash paid for acquisitions, net of cash acquired	(43.7)	(199.3)
Net change in loan to collaboration partner (Note 4)	—	165.0
Proceeds from prepayment of revenue-sharing obligation (Note 4)	—	1,212.1
Other investing activities, net	(91.5)	(61.8)
Net Cash Used for Investing Activities	(840.4)	(1,170.3)
Cash Flows from Financing Activities		
Dividends paid	(1,591.8)	(1,639.2)
Net change in short-term borrowings	—	(6.7)
Repayment of long-term debt	(3.0)	(1,508.5)
Purchases of common stock	(1,198.1)	—
Net Cash Used for Financing Activities	(2,792.9)	(3,154.4)
Effect of exchange rate changes on cash and cash equivalents	(24.8)	18.6
Net increase (decrease) in cash and cash equivalents	350.1	(603.3)
Cash and cash equivalents at January 1	4,018.8	5,922.5
Cash and Cash Equivalents at September 30	$4,368.9	$5,319.2

See Notes to Consolidated Condensed Financial Statements

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

Note 1: Basis of Presentation

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the 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, 2012. We issued our financial statements by filing with the 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.

Note 2: Implementation of New Financial Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board 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. Early adoption is permitted. While we are still determining the impact of this standard on the presentation of both our deferred tax assets and income taxes payable, implementation of the standard will have no impact on our consolidated statements of operations.

Note 3: Acquisitions

On February 17, 2012, we acquired all of the outstanding stock of ChemGen Corporation, a privately-held bioscience company specializing in the development and commercialization of innovative feed-enzyme products that improve the efficiency of poultry, egg, and meat production, for total purchase consideration of $206.9 million in cash. In connection with this acquisition, we recorded $151.5 million of intangible assets related to marketed products and $55.4 million of other net assets.

Note 4: Collaborations

We often enter into collaborative 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 collaborations 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 third party. 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-share payments) are included in collaboration and other revenue. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments made to or reimbursements received from our collaboration partners. Each collaboration is unique in nature, and our more significant arrangements are discussed below.

The following table summarizes the composition of our total revenue recognized from all transactions, including collaboration activity:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net product sales	$5,589.2	$5,301.2	$16,797.6	$16,170.5
Collaboration and other revenue	183.4	142.1	506.7	475.5
Total revenue	$5,772.6	$5,443.3	$17,304.3	$16,646.0

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. Amylin will also pay a $150.0 million milestone to us contingent upon the U.S. Food and Drug Administration (FDA) approval of a once-monthly suspension version of exenatide that is currently in Phase II clinical trials.

Commercial operations were transferred to Amylin in the U.S. at the end of November 2011. Outside the U.S., we transferred to Amylin exenatide commercial rights and control in all markets during the first quarter of 2013. 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.

Prior to termination of the collaboration, we and Amylin were co-promoting Byetta in the United States. Amylin was responsible for manufacturing and primarily utilized third-party contract manufacturers to supply Byetta. We supplied Byetta pen delivery devices for Amylin and will continue to do so for a period that will not extend substantially beyond December 31, 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.

Under the terms of our prior arrangement, we reported as collaboration and other revenue our 50 percent share of gross margin on Amylin’s net product sales in the United States. 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. Prior to termination of the agreement, under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide’s gross margin, we also recorded approximately 50 percent of U.S.-related research and development costs and marketing and selling costs in the respective line items on the consolidated condensed statements of operations.

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.

The following table summarizes the revenue and other income recognized with respect to exenatide:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net product sales	$28.6	$49.5	$113.7	$151.1
Collaboration and other revenue	—	4.7	—	70.1
Total revenue	$28.6	$54.2	$113.7	$221.2
Income related to termination of the exenatide collaboration with Amylin [1]	$—	$787.8	$495.4	$787.8

[1] Presented in other-net, (income) expense

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (Daiichi Sankyo) to develop, market, and promote Effient. We and Daiichi Sankyo have agreed to co-promote 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 made to Daiichi Sankyo are recorded as marketing, selling, and administrative expenses. All royalties paid to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales. Effient sales were $124.9 million and $109.7 million for the quarters ended September 30, 2013 and 2012, respectively, and $378.1 million and $336.6 million for the nine months ended September 30, 2013 and 2012, respectively.

Erbitux®

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Japan, and Canada (Bristol-Myers Squibb Company); and worldwide except the U.S. and Canada (Merck KGaA). The agreements are expected to expire in 2018, upon which all of the rights with respect to Erbitux in the U.S. and Canada return to us and certain rights with respect to Erbitux outside the U.S. and Canada (excluding Japan) remain with Merck KGaA (Merck).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net product sales	$6.2	$6.2	$43.8	$69.0
Collaboration and other revenue	81.0	80.4	229.9	241.0
Total revenue	$87.2	$86.6	$273.7	$310.0

Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, we are co-developing Erbitux in the U.S. and Canada with BMS, exclusively, and in Japan with BMS and Merck. 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 received by 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. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.

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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 in the agreement. Sales of Erbitux to BMS for commercial use are reported in net product sales.

Merck KGaA

A development and license agreement with Merck with respect to Erbitux granted Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and a separate agreement grants co-exclusive rights with BMS and us in Japan. Merck also 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. Collaborative reimbursements received for research and development and for marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. Royalty expense paid to third parties, net of any royalty reimbursements received, is recorded as a reduction of collaboration and other revenue.

Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim entered into 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 and empagliflozin, and our new insulin glargine product. Additionally, Boehringer Ingelheim may elect to opt in to the Phase III development and potential commercialization of our anti-TGF-beta monoclonal antibody. Under the terms of the global agreement, we made an initial one-time payment to Boehringer Ingelheim of $388.0 million and recorded an acquired in-process research and development (IPR&D) charge, which was included as expense in the first quarter of 2011 and was deductible for tax purposes.

Linagliptin was subsequently approved in 2011 and launched in the U.S. (trade name Tradjenta®), Japan (trade name Trazenta™), certain countries in Europe (trade name Trajenta®), and other countries. Currently, empagliflozin is under regulatory review in the U.S. and Europe, the new insulin glargine product is under regulatory review in Europe, and the anti-TGF-beta monoclonal antibody is in Phase II clinical testing.

In connection with the approval of linagliptin in the U.S., Japan, and Europe, in 2011 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. We incurred milestone-related expenses of $92.2 million in connection with regulatory submissions for empagliflozin in the U.S. and Europe during the first quarter of 2013. These regulatory submission milestones were recorded as research and development expenses. We may also pay up to 228.8 million euro in additional regulatory milestones for empagliflozin. In the future, we will be eligible to receive up to $290.0 million in success-based regulatory milestones on our new insulin glargine product. Should Boehringer Ingelheim elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to $525.0 million in opt-in and success-based regulatory milestone payments. The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin 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. Revenue related to this collaboration was $64.7 million and $22.8 million for the quarters ended September 30, 2013 and 2012, respectively, and $162.1 million and $48.7 million for the nine months ended September 30, 2013 and 2012, respectively.

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 the first half of 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately $70 million and mid-single digit royalties that are contingent upon the successful development of solanezumab. The royalties relating to solanezumab would be paid for approximately 10 years after launch of a product.

Baricitinib

In December 2009, we entered into a worldwide license and collaboration agreement with Incyte Corporation (Incyte) to acquire development and commercialization rights to its JAK inhibitor compound, now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. The agreement calls for payments of up to $515.0 million associated with certain development and regulatory

milestones as well as an additional $150.0 million of potential sales-based milestones. Incyte also 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. The agreement also provides Incyte with an option to co-promote in the United States. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. 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.

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, chronic low back pain and cancer pain. Tanezumab is currently in Phase III clinical trials and is subject to a partial clinical hold by the FDA pending submission of nonclinical data to the FDA. Pfizer anticipates submitting that data in the first half of 2014. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and commercialization expenses. We will be obligated to pay an upfront fee of $200.0 million contingent upon the parties continuing in the collaboration after receipt of the FDA's response to the submission of the nonclinical data. 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 Collaboration-Related Commission and Profit-Share Payments

The aggregate amount of commission and profit-share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was $50.5 million and $45.3 million for the quarters ended September 30, 2013 and 2012, respectively, and $151.0 million and $138.0 million for the nine months ended September 30, 2013 and 2012, 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 $132.2 million and $140.8 million for the quarters ended September 30, 2013 and 2012, respectively, and $423.5 million and $421.7 million for the nine months ended September 30, 2013 and 2012, respectively.

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

There were no asset impairments, restructuring, and other special charges recognized in the quarter ended September 30, 2013 compared to $53.3 million during the same period in 2012. For the nine months ended September 30, 2013, we recognized $85.2 million of asset impairments, restructuring, and other special charges compared to $77.1 million during the same period in 2012. The 2013 charges related primarily to costs associated with the anticipated closure of a packaging and distribution facility in Germany and severance costs for actions the company is taking, primarily outside the U.S., to reduce its cost structure and global workforce. The 2012 charges related primarily to the recognition of an asset impairment resulting from the decision to stop development of a delivery device platform during the third quarter, and a charge in the first quarter of 2012 resulting from a change in our estimates of returned product related to the withdrawal of Xigris™ from the market during the fourth quarter of 2011.

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 debt securities. In accordance with documented corporate policies, we limit 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. As derivative contracts are initiated, we designate the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of our derivatives 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 currently in 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, 2013, we had outstanding foreign currency forward commitments to purchase 872.3 million U.S. dollars and sell 651.7 million euro, commitments to purchase 287.3 million euro and sell 388.6 million U.S. dollars, commitments to purchase 362.3 million U.S. dollars and sell 35.83 billion Japanese yen, which will all settle within 30 days.

In the normal course of business, our operations are exposed to fluctuations in interest rates. These fluctuations 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. At September 30, 2013, substantially all of our total debt is at a fixed rate. We have converted approximately 60 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

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 as part of any anticipated future debt issuances. 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. During the third quarter of 2013, in order to reduce the risk of cash flow volatility from future changes in interest rates, we entered into forward-starting interest rate swaps with a notional amount of $400.0 million and maturities not exceeding 30 years to hedge a portion of the cash flows associated with the planned refinancing of our $1.00 billion March 2014 debt maturity.

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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,	
	2013	2012	2013	2012
Fair value hedges:				
Effect from hedged fixed-rate debt	$31.3	$12.1	$244.6	$43.8
Effect from interest rate contracts	(31.3)	(12.1)	(244.6)	(43.8)
Cash flow hedges:				
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	33.9	(23.7)	26.4	(38.5)

For equity contracts in designated cash flow hedging relationships, the effective portion of net losses recorded in other comprehensive income (loss) was $33.0 million and $41.9 million for the three and nine months ended September 30, 2013, respectively. There were no equity contracts in designated cash flow hedging relationships in 2012.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings $8.8 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.

During the three and nine months ended September 30, 2013 and 2012, 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, 2013 and December 31, 2012 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, 2013						
Cash and cash equivalents	$4,368.9	$4,368.9	$4,315.2	$53.7	$	$4,368.9
Short-term investments:						
U.S. government and agencies	$162.2	$162.1	$162.2	$	$	$162.2
Corporate debt securities	843.2	841.2		843.2		843.2
Other securities	5.0	5.0		5.0		5.0
Short-term investments	$1,010.4	$1,008.3				
Noncurrent investments:						
U.S. government and agencies	$1,131.9	$1,138.6	$1,045.6	$86.3	$	$1,131.9
Corporate debt securities	4,508.1	4,513.4		4,508.1		4,508.1
Mortgage-backed	588.1	603.5		588.1		588.1
Asset-backed	359.0	363.6		359.0		359.0
Other securities	7.4	8.2		7.4		7.4
Marketable equity	370.8	139.8	370.8			370.8
Equity method and other investments[1]	254.9	254.9				
Noncurrent investments	$7,220.2	$7,022.0				
December 31, 2012						
Cash and cash equivalents	$4,018.8	$4,018.8	$3,964.4	$54.4	$	$4,018.8
Short-term investments:						
U.S. government and agencies	$150.2	$150.2	$150.2	$	$	$150.2
Corporate debt securities	1,503.5	1,501.5		1,503.5		1,503.5
Other securities	11.8	11.8		11.8		11.8
Short-term investments	$1,665.5	$1,663.5				
Noncurrent investments:						
U.S. government and agencies	$1,362.7	$1,360.3	$1,122.4	$240.3	$	$1,362.7
Corporate debt securities	3,351.3	3,322.9		3,351.3		3,351.3
Mortgage-backed	668.1	677.7		668.1		668.1
Asset-backed	519.0	523.5		519.0		519.0
Other securities	3.3	3.3		3.3		3.3
Marketable equity	175.8	83.0	175.8			175.8
	233.1	233.1				

Equity method and other investments[1]		
Noncurrent investments	$6,313.3	$6,203.8

[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
Long-term debt, including current portion					
September 30, 2013	$(5,282.9)	$	$(5,570.2)	$	$(5,570.2)
December 31, 2012	(5,531.3)		(5,996.6)		(5,996.6)

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, 2013					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Other receivables	$11.3	$	$11.3	$	$11.3
Sundry	336.6		336.6		336.6
Other current liabilities	(4.3)		(4.3)		(4.3)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	3.7		3.7		3.7
Other current liabilities	(15.4)		(15.4)		(15.4)
Equity contracts designated as hedging instruments:					
Other current liabilities	(37.5)		(37.5)		(37.5)
Other noncurrent liabilities	(4.4)		(4.4)		(4.4)
December 31, 2012					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	$589.4	$	$589.4	$	$589.4
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	11.0		11.0		11.0
Other current liabilities	(17.5)		(17.5)		(17.5)

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.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of September 30, 2013:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$7,600.5	$1,010.4	$5,437.4	$451.0	$701.7

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, 2013	December 31, 2012
Unrealized gross gains	$259.6	$140.5
Unrealized gross losses	59.3	29.0
Fair value of securities in an unrealized gain position	4,289.1	5,246.0
Fair value of securities in an unrealized loss position	3,435.9	2,102.0

Other-than-temporary impairment losses on investment securities of $5.2 million were recognized in the statement of operations for the nine months ended September 30, 2013. No charges were recognized during the third quarter of 2013. Other-than-temporary impairment losses on investment securities of $0.8 million and $8.2 million were recognized in the statement of operations for the third quarter and first nine months of 2012, respectively. 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 90 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 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, 2013.

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,	
	2013	2012	2013	2012
Proceeds from sales	$2,785.5	$1,698.8	$10,230.6	$5,334.1
Realized gross gains on sales	3.6	43.1	41.8	70.0
Realized gross losses on sales	4.2	2.2	12.1	7.4

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 primarily of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognized pretax stock-based compensation expense of $36.2 million and $34.4 million for the quarters ended September 30, 2013 and 2012, respectively. During the first nine months of 2013 and 2012, we recognized pretax stock-based compensation expense of $105.1 million and $100.3 million, 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 earnings per share targets over a

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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 period. As of September 30, 2013, the total remaining unrecognized compensation cost related to nonvested PAs amounted to $27.7 million, which will be amortized over the weighted-average remaining requisite service period of approximately 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 varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation 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, 2013, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to $64.5 million, which will be amortized over the weighted-average remaining requisite service period of approximately 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, 2013, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to $70.9 million, which will be amortized over the weighted-average remaining requisite service period of 23 months.

Note 8: Shareholders' Equity

During the first quarter of 2013, we purchased the remaining $1.10 billion of shares associated with our previously announced $1.50 billion share repurchase program. In October 2013, we announced a new $5.00 billion share repurchase program.

Note 9: Earnings Per Share

Unless otherwise noted in the footnotes, all per-share amounts are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares plus the effect of all potentially dilutive common shares (primarily contingently issuable shares and unexercised stock options).

Note 10: Income Taxes

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in most major taxing jurisdictions for years before 2007.

During the third quarter, 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. We made cash payments of approximately $135 million related to tax years 2008–2009 after application of available tax credit carryforwards and carrybacks.

We expect the U.S. examinations related to tax years 2010-2012 will commence during the fourth quarter of 2013.

Note 11: 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,	
	2013	2012	2013	2012
Components of net periodic benefit cost:				
Service cost	$71.5	$66.7	$212.3	$193.8
Interest cost	110.0	113.0	328.3	338.7
Expected return on plan assets	(176.1)	(171.2)	(525.8)	(512.6)
Amortization of prior service cost	1.0	0.8	3.0	2.5
Recognized actuarial loss	103.8	71.4	302.2	213.3
Net periodic benefit cost	$110.2	$80.7	$320.0	$235.7

	Retiree Health Benefit Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Components of net periodic benefit cost:				
Service cost	$15.0	$16.1	$45.2	$48.4
Interest cost	23.4	28.6	70.1	85.6
Expected return on plan assets	(32.8)	(31.8)	(98.3)	(95.4)
Amortization of prior service cost	(9.2)	(8.8)	(22.0)	(26.3)
Recognized actuarial loss	25.7	24.6	71.9	72.9
Net periodic benefit cost	$22.1	$28.7	$66.9	$85.2

On a global basis, we have contributed approximately $55 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2013. In addition, we have contributed approximately $300 million of discretionary funding to our global post-retirement benefit plans in 2013. During the remainder of 2013, we expect to make contributions to our defined benefit pension plans of approximately $5 million to satisfy minimum funding requirements. We do not anticipate making any additional discretionary contributions in 2013.

Note 12: 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® Hatch-Waxman patent challenges, 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

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 (the Hatch-Waxman Act). Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); Barr Laboratories, Inc. (Barr); Pliva Hrvatska D.O.O. (Pliva); Accord Healthcare Inc. (Accord); and Apotex Inc. (Apotex) 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 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 patent is valid and infringed. The trial occurred in August 2013, and we are awaiting a decision. In January 2012 and April 2012, we filed similar lawsuits in the same court against Accord and Apotex, respectively. A second lawsuit against Accord was filed in February 2013. In September 2013, we filed a

similar lawsuit in the same court against Sun Pharmaceutical Industries, Ltd. and Sun Pharma Global seeking a ruling that Lilly's patent is valid and infringed. 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 June 2013, Accord filed a petition requesting review of the patent by the U.S. Patent and Trademark Office, which was denied in October 2013. In addition, generic manufacturers have opposed the European Patent Office's decision to grant a vitamin dosage regimen patent, and are seeking revocation of that patent.

We believe the challenges to these patents are without merit and expect to prevail. However, it is not possible to determine the outcome of the challenges, 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.

Byetta Product Liability Litigation

We have been named as a defendant in approximately 235 Byetta product liability lawsuits involving approximately 650 plaintiffs. Approximately 85 of these lawsuits, covering about 455 plaintiffs, are filed in California and coordinated in a Los Angeles Superior Court. We are aware of approximately 460 additional claimants who have not yet filed suit. The majority of the claims allege damages for pancreatitis. Approximately 150 lawsuits have been filed involving approximately 210 plaintiffs who have alleged that Byetta caused or contributed to their cancer. We believe these claims are without merit and are prepared to defend against them vigorously.

Diethylstilbestrol Product Liability Litigation

We have been named as a defendant in fewer than 10 U.S. lawsuits involving fewer than 10 claimants seeking to recover damages for health issues experienced by children or grandchildren of women who were prescribed diethylstilbestrol (DES) during pregnancy in the 1950s and 1960s. We believe these claims are without merit and are prepared to defend against them vigorously.

Prozac® Product Liability Litigation

We have been 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 410 additional claims related to birth defects, which have not yet been filed. We believe these claims are without merit and are prepared to defend against them vigorously.

Brazil–Employee Litigation

We have been 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. Final arguments were submitted in September and we are awaiting a decision. We have also been 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. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for product liability losses. The DES claims are covered by insurance, subject to deductibles and coverage limits. There is no assurance that we will be able to fully collect from our insurance carriers in the future.

Note 13: Other Comprehensive Income (Loss)

The following table summarizes the activity related to each component of other comprehensive income (loss) during the three months ended 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, 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 table summarizes the activity related to each component of other comprehensive income (loss) during the nine months ended 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 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 on securities was an expense of $32.9 million and $31.1 million for the third quarter and first nine months of 2013, respectively. The tax effect related to our defined benefit pension and retiree health benefit plans was an expense of $48.1 million and $137.2 million for the third quarter and first nine months of 2013, respectively. The tax effect on the effective portion of cash flow hedges was not significant for the third quarter and first nine months of 2013. Income taxes are not provided for foreign currency translation.

	Reclassifications Out of Accumulated Other Comprehensive Loss		
Details about Accumulated Other Comprehensive Loss Components	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013	Affected Line Item in the Consolidated Condensed Statements of Operations
Amortization of defined pension benefit items:			
Prior service costs	$8.2	$19.0	[1]
Actuarial gains (losses)	(129.5)	(374.1)	[1]

Total before tax	(121.3)	(355.1)	
Tax benefit	40.9	122.4	
Net of tax	(80.4)	(232.7)	
Other, net of tax	(1.9)	(1.0)	Other—net, (income) expense
Total reclassifications for the period (net of tax)	$ (82.3)	$ (233.7)	

[1] These accumulated other comprehensive loss components are included in the computation of net periodic pension cost (see Note 11).

Note 14: Other–Net, (Income) Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Income related to termination of the exenatide collaboration with Amylin (Note 4)	$—	$(787.8)	$(495.4)	$(787.8)
Interest expense	39.8	47.0	120.4	135.3
Interest income	(32.2)	(25.7)	(85.5)	(79.0)
Other	23.7	(22.0)	(49.3)	5.5
Other–net, (income) expense	$31.3	$(788.5)	$(509.8)	$(726.0)

Other–net, (income) expense was an expense of $31.3 million and income of $509.8 million for the third quarter and the first nine months of 2013, respectively. Comparisons to the same periods in 2012 are largely affected by income of $495.4 million and $787.8 million recognized in the first quarter of 2013 and the third quarter of 2012, respectively, related to the termination of the exenatide collaboration with Amylin. See Note 4 for additional information.

Note 15: 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,	
	2013	2012	2013	2012
Segment revenue — to unaffiliated customers:				
Human pharmaceutical products:				
Neuroscience	$1,878.1	$1,815.8	$5,731.5	$5,544.0
Endocrinology	1,764.7	1,646.1	5,273.9	5,041.2
Oncology	821.8	791.7	2,394.1	2,442.4
Cardiovascular	715.6	650.9	2,140.9	1,936.4
Other pharmaceuticals	62.1	59.4	190.8	199.6
Total human pharmaceutical products	5,242.3	4,963.9	15,731.2	15,163.6
Animal health	530.3	479.4	1,573.1	1,482.4
Total segment revenue	$5,772.6	$5,443.3	$17,304.3	$16,646.0
Segment profits:				
Human pharmaceutical products	$1,362.5	$1,034.2	$4,141.4	$3,315.0
Animal health	150.9	106.0	427.8	370.0
Total segment profits	$1,513.4	$1,140.2	$4,569.2	$3,685.0
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	$1,513.4	$1,140.2	$4,569.2	$3,685.0
Other profits (losses):				
Income related to termination of the exenatide collaboration with Amylin (Note 4)	—	787.8	495.4	787.8
Asset impairments, restructuring, and other special charges (Note 5)	—	(53.3)	(85.2)	(77.1)
Total consolidated income before taxes	$1,513.4	$1,874.7	$4,979.4	$4,395.7

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 service centers, certain acquisition-related transaction costs, and inventory valuation adjustments.

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 increased 6 percent to $5.77 billion and increased 4 percent to $17.30 billion in the third quarter and first nine months of 2013, respectively, primarily driven by growth in several products, including Cymbalta®, insulins, animal health products, Alimta, Cialis®, and Trajenta, partially offset by steep sales declines for Zyprexa® due to the loss of patent exclusivity in most major markets other than Japan. Net income for the third quarter and first nine months of 2013 decreased 9 percent to $1.20 billion and increased 21 percent to $3.96 billion, respectively. EPS for the third quarter and first nine months of 2013 decreased 6 percent to $1.11 per share and increased 25 percent to $3.64 per share, respectively, compared with the same periods of 2012. The decreases in net income and EPS during the third quarter were due primarily to income recognized in the third quarter of 2012 related to the early payment of the exenatide revenue-sharing obligation, partially offset by higher gross margin, lower marketing, selling, and administrative expenses, and a lower effective tax rate in 2013. The increases in net income and EPS for the first nine months of 2013 were driven by higher gross margin, lower marketing, selling, and administrative expenses, and a lower effective tax rate. EPS for both periods in 2013 also benefited from a lower number of shares outstanding compared to the same respective periods in 2012.

The following highlighted items affect comparisons of our financial results for the three and nine months ended September 30, 2013 and 2012:

2013

Collaborations (Note 4)

- We recognized income in the first quarter of $495.4 million (pretax), or $0.29 per share, related to the transfer to Amylin of exenatide commercial rights in all markets outside the United States.

Asset Impairments, 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 anticipated closure of 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 being taken, primarily outside the U.S., to reduce our cost structure and global workforce.

2012

Collaborations (Note 4)

- We recognized income in the third quarter of $787.8 million (pretax), or $0.43 per share, related to the early payment of the exenatide revenue-sharing obligation following the completion of Amylin's acquisition by Bristol-Myers Squibb.

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

- We recognized asset impairments, restructuring, and other special charges in the third quarter of $53.3 million (pretax), or $0.04 per share, primarily related to asset impairments associated with the decision to stop development of a delivery device platform.

- We recognized asset impairments, restructuring, and other special charges in the first quarter of $23.8 million (pretax), or $0.01 per share, primarily related to changes in returns reserve estimates for the withdrawal of Xigris in the fourth quarter of 2011.

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 compounds currently in development by other biotechnology or pharmaceutical companies. We currently have approximately 60 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) have been submitted for regulatory review for potential use in the disease described. The quarter the NME initially was submitted for any indication is shown in parentheses:

Dulaglutide* (Q3 2013)—a long-acting analog of glucagon-like peptide 1 for the treatment of type 2 diabetes. Dulaglutide is protected in the U.S. by a compound patent expiring in July 2024, plus any potential patent extension.

Empagliflozin (Q1 2013)—a sodium glucose co-transporter-2 (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim). Empagliflozin is protected in the U.S. by a compound patent expiring in November 2025, plus any potential patent extension.

Liprotamase (Q1 2010)—a non-porcine pancreatic enzyme replacement therapy for the treatment of exocrine pancreatic insufficiency.

New insulin glargine product (Q2 2013 in Europe only)—a new insulin glargine product for the treatment of type 1 and type 2 diabetes (in collaboration with Boehringer Ingelheim). Lilly's new insulin glargine product has the same amino acid sequence as Sanofi-Aventis' Lantus® and is not covered by any patent protection.

Ramucirumab* (Q3 2013)—an anti-vascular endothelial growth factor receptor-2 (VEGFR-2) monoclonal antibody submitted for regulatory review for the treatment of gastric cancer. In addition, we are currently studying ramucirumab for the treatment of liver, non-small cell lung cancer (NSCLC), and colorectal cancers. Ramucirumab is protected in the U.S. by regulatory exclusivity until February 2026.

The following 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:

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

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

Edivoxetine (Q4 2010)—a norepinepherine reuptake inhibitor for the treatment of major depression

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 Alzheimer’s disease

Tabalumab* (Q4 2010)—an anti-B-cell activating factor (BAFF) monoclonal antibody for the treatment of systemic lupus erythematosus (lupus).

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

The following are late-stage pipeline updates since January 1, 2013:

Basal insulin peglispro—In January 2013, we announced plans for the 2013 and 2014 initiation of the remainder of the pre-planned clinical trials for the molecule. These studies will be conducted to support

regulatory submissions and evaluate safety, efficacy, and differentiation of the molecule. These studies are in addition to the five ongoing IMAGINE clinical trials.

Dulaglutide—In April 2013, we announced that the Phase III AWARD-2 and AWARD-4 trials studying dulaglutide as an investigational once-weekly treatment for type 2 diabetes met the primary endpoints related to reduction in hemoglobin A1c (HbA1c) compared to insulin glargine, and that the 1.5 mg dose demonstrated statistically superior reduction in HbA1c from baseline compared to insulin glargine in both trials. In the third quarter of 2013, we filed for regulatory review in both the U.S. and Europe.

Empagliflozin—In January 2013, we announced positive top-line results for four completed Phase III clinical trials studying empagliflozin for treatment of patients with type 2 diabetes. In all four studies, the primary efficacy endpoint, defined as significant change in HbA1c from baseline compared to placebo, was met with empagliflozin (10 and 25 mg) taken once daily. The pivotal studies for empagliflozin completed in 2012. In the first quarter of 2013, we and Boehringer Ingelheim filed for regulatory review in both the U.S. and Europe. In the fourth quarter of 2013, we and Boehringer Ingelheim filed for regulatory review in Japan.

Enzastaurin—In May 2013, we announced the decision to stop development of enzastaurin as a result of negative clinical trial results from the Phase III PRELUDE study, which explored the molecule as a monotherapy in the prevention of relapse for patients with diffuse large B-cell lymphoma.

Ixekizumab—In January 2013, we initiated Phase III clinical trial testing for ixekizumab as a potential treatment for psoriatic arthritis.

Necitumumab—In August 2013, we announced the Phase III study, SQUIRE, met its primary endpoint, finding that patients with stage IV metastatic squamous NSCLC experienced increased overall survival when administered necitumumab in combination with gemcitabine and cisplatin as a first-line treatment, as compared to chemotherapy alone. We anticipate filing for regulatory review before the end of 2014.

New insulin glargine product—In July 2013, we and Boehringer Ingelheim announced that the marketing authorization application for our new insulin glargine product, filed in June 2013 through the biosimilar pathway, was accepted for review by the European Medicines Agency. We anticipate filing for regulatory review in the U.S. in 2013.

Ramucirumab—Our rolling submission to the FDA for ramucirumab as a single-agent biologic therapy in patients with advanced gastric cancer following progression on prior chemotherapy was completed in the third quarter of 2013, and received Priority Review status by the FDA in October 2013. Our regulatory submission in Europe for the same indication was also completed in the third quarter of 2013. In September 2013, we announced the RAINBOW trial, a global Phase III study of ramucirumab in combination with paclitaxel in patients with advanced gastric cancer, met its primary endpoint of improved overall survival and a secondary endpoint of improved progression-free survival. We intend to submit an application for ramucirumab in combination with paclitaxel to regulatory authorities. In September 2013, we also announced that a separate global Phase III study of ramucirumab in women with locally recurrent or metastatic breast cancer, ROSE, did not meet its primary endpoint of progression-free survival. We do not plan to submit an application to regulatory authorities for ramucirumab in the first-line treatment of locally recurrent or metastatic HER2-negative breast cancer based on the results from the ROSE study.

Tabalumab—In February 2013, we announced our decision to discontinue the Phase III rheumatoid arthritis program for tabalumab due to lack of efficacy. The decision was not based on safety concerns. The tabalumab Phase III program for lupus is ongoing and will continue as planned.

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 FDA approval process and the approval processes 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

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. Through 2014, we expect to lose U.S. patent protection for Cymbalta (December 2013) and Evista® (March 2014). The loss of exclusivity for Cymbalta and Evista will likely result in generic competition, generally causing a rapid and severe decline in revenue from the affected product, and having a material adverse effect on our results of operations. The U.S. compound patent for Humalog® expired in May 2013. We do not currently expect the loss of compound patent protection for Humalog to result 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 under way to develop biosimilar forms of Humalog, and it is difficult to predict the likelihood, timing, and impact of biosimilars entering the market. Our goal is to mitigate the effect of these exclusivity losses on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, in the emerging markets, in Japan, and in our animal health business. Our expected growth in the emerging markets and Japan is attributable to both the growth of these markets and launches of patent-protected products.

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, given the pressures on national and regional health care budgets as a result of continued austerity measures being pursued in a number of countries and the desire to manage health expenses carefully even as economies recover.

The Obama administration has proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. There also have been tax proposals under discussion or introduced in the U.S. Congress that could change the manner in which, and the rate at which, income of U.S. companies would be taxed. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, will continue to be a topic of discussion for Congress and the Obama administration. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations. In addition, the Organization for Economic Co-operation and Development has recently launched an initiative to analyze and potentially influence international tax policy in the major countries in which we operate. While the outcomes of this initiative are uncertain, significant changes to key elements of the global international tax framework could have a material adverse effect on our consolidated results of operations.

Revenue

Worldwide total revenue increased 6 percent to $5.77 billion for the third quarter of 2013 and increased 4 percent to $17.30 billion for the first nine months of 2013, compared with the same periods of 2012. For the third quarter, increases of 5 percent and 3 percent due to higher prices and increased volume, respectively, were partially offset by a decrease of 2 percent due to the unfavorable impact of foreign exchange rates. The increase in volume was driven by Humalog, Alimta, Trajenta, and Forteo®, as well as animal health products, partially offset by volume declines for Zyprexa and Cymbalta. For the first nine months of 2013, increases of 5 percent and 1 percent due to higher prices

and increased volume, respectively, were partially offset by a decrease of 2 percent due to the unfavorable impact of foreign exchange rates. Total revenue in the U.S. increased 11 percent to $3.31 billion for the third quarter of 2013 and increased 8 percent to $9.85 billion for the first nine months of 2013, driven by increased prices, primarily for Cymbalta. For the first nine months of 2013, the increased prices were partially offset by

continued volume declines of Zyprexa. Total revenue outside the U.S. remained relatively flat at $2.46 billion for the third quarter of 2013, as increased volume was largely offset by the unfavorable impact of the depreciation of the Japanese yen. Total revenue outside the U.S. decreased 1 percent to $7.46 billion for the first nine months of 2013, as the unfavorable impact of the depreciation of the Japanese yen, the loss of patent exclusivity for Zyprexa in most markets outside of Japan, and decreased prices, were partially offset by increased volume in other products.

The following table summarizes our revenue activity:

Product	Three Months Ended September 30, 2013 U.S.[1]	Outside U.S.	Total	Three Months Ended September 30, 2012 Total	Percent Change from 2012	
	(Dollars in millions)					
Cymbalta	$1,109.2	$266.6	$1,375.8	$1,235.8	11	%
Alimta	310.0	380.5	690.5	643.6	7	%
Humalog	357.8	258.2	616.0	575.8	7	%
Cialis	234.0	292.7	526.7	482.1	9	%
Humulin®	161.4	145.6	307.0	285.4	8	%
Forteo	127.9	178.8	306.7	288.7	6	%
Zyprexa	32.9	245.8	278.7	374.5	(26	)%
Evista	191.8	63.5	255.3	247.0	3	%
Strattera®	111.1	62.1	173.2	145.6	19	%
Effient	92.7	32.2	124.9	109.7	14	%
Other pharmaceutical products	154.6	249.5	404.1	433.6	(7	)%
Animal health products	305.0	225.3	530.3	479.4	11	%
Total net product sales	3,188.4	2,400.8	5,589.2	5,301.2	5	%
Collaboration and other revenue[2]	123.5	59.9	183.4	142.1	29	%
Total revenue	$3,311.9	$2,460.7	$5,772.6	$5,443.3	6	%

Product	Nine Months Ended September 30, 2013 U.S.[1]	Outside U.S.	Total	Nine Months Ended September 30, 2012 Total	Percent Change from 2012	
	(Dollars in millions)					
Cymbalta	$3,383.5	$817.7	$4,201.2	$3,573.7	18	%
Alimta	877.1	1,099.7	1,976.8	1,909.9	4	%
Humalog	1,087.9	789.5	1,877.4	1,779.5	6	%
Cialis	663.0	908.1	1,571.1	1,413.4	11	%
Humulin	482.9	463.4	946.3	896.1	6	%
Forteo	355.2	530.0	885.2	836.4	6	%
Zyprexa	84.4	762.3	846.7	1,316.6	(36	)%
Evista	562.7	211.9	774.6	769.2	1	%
Strattera	319.3	188.8	508.1	457.5	11	%
Effient	280.2	97.9	378.1	336.6	12	%
Other pharmaceutical products	475.5	783.5	1,259.0	1,399.2	(10	)%
Animal health products	921.2	651.9	1,573.1	1,482.4	6	%
Total net product sales	9,492.9	7,304.7	16,797.6	16,170.5	4	%
Collaboration and other revenue[2]	353.2	153.5	506.7	475.5	7	%
Total revenue	$9,846.1	$7,458.2	$17,304.3	$16,646.0	4	%

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

[2] Collaboration and other revenue in 2013 consists primarily of royalties for Erbitux and revenue associated with Trajenta. Collaboration and other revenue in 2012 also includes revenue associated with exenatide in the United States.

U.S. 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, increased 15 percent and 22 percent during the third quarter and first nine months of 2013, respectively, driven by higher prices, partially offset by lower volume in the third quarter resulting from a reduction in inventory levels in both wholesale and retail channels. Sales outside the U.S. decreased 2 percent during the third quarter of 2013, driven by lower prices and, to a lesser extent, the unfavorable impact of foreign exchange rates, partially offset by increased volume. Sales outside the U.S. increased 3 percent during the first nine months of 2013, driven primarily by increased volume, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

We will lose effective exclusivity for Cymbalta in the U.S. on December 11, 2013. Several manufacturers have received tentative approvals to market generic duloxetine, and we expect generic duloxetine to be introduced in the market immediately following the loss of exclusivity. While it is difficult to predict the precise impact on Cymbalta sales, we expect the introduction of generics to result in a rapid and severe decline in our Cymbalta sales, which will have a material adverse effect on results of operations and cash flows. See "Financial Expectations for 2013" below for further detail regarding the anticipated impact of the loss of patent exclusivity for Cymbalta in the U.S. during the fourth quarter of 2013.

U.S. sales of Alimta, a treatment for various cancers, increased 7 percent during the third quarter of 2013, driven by the favorable impact of buying patterns and, to a lesser extent, higher prices. For the first nine months of 2013, U.S. sales increased 6 percent, due to the favorable impact of buying patterns and, to a lesser extent, higher prices and increased demand. Sales outside the U.S. increased 7 percent and 1 percent in the third quarter and first nine months of 2013, respectively, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, for the first nine months, lower prices.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 6 percent during the third quarter, driven by increased demand, partially offset by lower net effective selling prices. For the first nine months of 2013, U.S. sales increased 5 percent, driven by increased demand and wholesaler buying patterns, partially offset by lower net effective selling prices. Sales outside the U.S. increased 8 percent and 7 percent in the third quarter and first nine months of 2013, respectively, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia (BPH), increased 14 percent and 16 percent in the third quarter and first nine months of 2013, respectively, driven by higher prices. Sales outside the U.S. increased 6 percent and 8 percent in the third quarter and first nine months of 2013, respectively, driven by increased volume and, to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 22 percent in the third quarter of 2013, driven by higher prices and, to a lesser extent, increased volume. For the first nine months of 2013, U.S. sales increased 13 percent, driven by higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 5 percent in the third quarter of 2013, driven by decreased volume and the unfavorable impact of foreign exchange rates, partially offset by higher prices. For the first nine months of 2013, sales outside the U.S. decreased 1 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by higher prices.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men, remained flat in the third quarter of 2013 as higher prices were offset by decreased volume. For the first nine months of 2013, U.S. sales decreased 3 percent, driven by decreased volume, partially offset by higher prices. Sales outside the U.S. increased 11 percent and 13 percent in the third quarter and first nine months of 2013, respectively, due to increased volume, primarily in Japan, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, decreased 51 percent and 72 percent in the third quarter and first nine months of 2013, respectively. Sales outside the U.S. decreased 20 percent and 25 percent in the third quarter and first nine months of 2013, respectively. The decreases were due to the loss of patent exclusivity in 2011 in the U.S. and most major international markets outside of Japan. Zyprexa sales in Japan were approximately $120 million and $365 million for

the three and nine months ended September 30, 2013, respectively, and were negatively impacted by the continued weakness of the Japanese yen.

U.S. 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, increased 14 percent and 8 percent in the third quarter and first nine

months of 2013, respectively, driven by higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 19 percent and 14 percent in the third quarter and first nine months of 2013, respectively, driven by the unfavorable impact of foreign exchange rates and lower prices, partially offset by higher volume in Japan.

We will lose effective patent exclusivity for Evista in the U.S. in March 2014. We are aware of manufacturers that have received tentative approvals to market generic raloxifene hydrochloride, the active ingredient in Evista, and we expect generic raloxifene hydrochloride to be introduced in the market immediately following the loss of exclusivity. While it is difficult to predict the precise impact on Evista sales, we expect the introduction of generics to result in a rapid and severe decline in our Evista sales, which will have a material adverse effect on results of operations and cash flows.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. in adults, increased 23 percent and 11 percent in the third quarter and first nine months of 2013, respectively, driven primarily by higher prices. Sales outside the U.S. increased 12 percent in both the third quarter and first nine months of 2013, driven by increased volume in Japan, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

U.S. 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 (PCI), including patients undergoing angioplasty, atherectomy, or stent placement, increased 15 percent and 12 percent in the third quarter and first nine months of 2013, respectively, driven by higher prices. Sales outside the U.S. increased 10 percent and 15 percent in the third quarter and first nine months of 2013, respectively, driven by increased volume and the favorable impact of foreign exchange rates.

U.S. sales of animal health products increased 11 percent in the third quarter of 2013, due primarily to increased demand. The increase in U.S. demand reflects the favorable impact from the withdrawal of a competitor's food animal product from the U.S. market. For the first nine months of 2013, U.S. sales increased 8 percent due primarily to increased demand for Trifexis®. Sales outside the U.S. increased 11 percent in the third quarter, driven primarily by increased volume in both food and companion animal products and, to a lesser extent, higher prices for food animal products, partially offset by the unfavorable impact of foreign exchange rates. For the first nine months of 2013, sales outside the U.S. increased 3 percent as increased volume in companion animal products and, to a lesser extent, higher prices for food animal products were partially offset by the unfavorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue increased 1.3 percentage points to 79.2 percent and increased 0.9 percentage points to 79.6 percent for the third quarter and first nine months of 2013, respectively, compared with the same periods in 2012. The increase in gross margin percent for the third quarter was due to higher prices and lower manufacturing costs, partially offset by the unfavorable impact of foreign exchange rates on international inventories sold. For the first nine months of 2013, the increase in gross margin percent was due to higher prices and production volumes, partially offset by the unfavorable impact of foreign exchange rates on international inventories sold.

Marketing, selling, and administrative expenses decreased 6 percent to $1.65 billion and decreased 7 percent to $5.17 billion for the third quarter and first nine months of 2013, respectively, due primarily to ongoing cost-containment efforts, including the previously-announced reduction in U.S. sales and marketing activities related to the upcoming loss of patent exclusivity for Cymbalta and Evista, and, for the first nine months, the favorable impact of foreign exchange rates.

Research and development expenses increased 3 percent to $1.38 billion and increased 6 percent to $4.06 billion for the third quarter and first nine months of 2013, respectively, driven by increased investment in early stage discovery and development and, for the first nine months of 2013, expenses related to late-stage clinical trials. During the first quarter of 2013, we made milestone payments of $92.2 million to Boehringer Ingelheim following the regulatory submissions for empagliflozin and also incurred approximately $60 million in costs related to the discontinuation of the rheumatoid arthritis program for tabalumab.

There were no asset impairments, restructuring, and other special charges recognized in the third quarter of 2013 compared to $53.3 million during the same period in 2012. For the first nine months of 2013, we recognized $85.2 million of asset impairments, restructuring, and other special charges compared to $77.1 million in 2012. See

Note 5 for additional information.

Other–net, (income) expense was an expense of $31.3 million and income of $509.8 million for the third quarter and first nine months of 2013, respectively, compared with income of $788.5 million and $726.0 million for the same respective periods in 2012. Comparisons between these periods in 2013 and 2012 are largely affected by income recognized related to the termination of the exenatide collaboration with Amylin. See Notes 4 and 14 for additional information.

The effective tax rate was 20.5 percent for both the third quarter and first nine months of 2013, compared with an effective tax rate of 29.2 percent and 25.8 percent for the same respective periods in 2012. The decrease in the effective tax rate for both periods reflects both the tax impact of the payment received from Amylin in the third quarter of 2012 and, to a lesser extent, the reinstatement of the R&D tax credit in the U.S. effective January 1, 2013. In addition, the decrease in the effective tax rate for the first nine months of 2013 reflects the one-time impact of the R&D tax credit for 2012 that was recorded in the first quarter of 2013, partially offset by the tax impact of the transfer to Amylin of exenatide commercial rights outside the U.S. in the first quarter of 2013.

Financial Condition

Cash and cash equivalents increased to $4.37 billion as of September 30, 2013, compared with $4.02 billion as of December 31, 2012, as cash flow from operations of $4.01 billion was partially offset by dividends paid of $1.59 billion, share repurchases of $1.20 billion, and net purchases of property and equipment of $548.1 million. Total debt decreased to $5.28 billion as of September 30, 2013, compared with $5.53 billion as of December 31, 2012 due to the decrease in fair value of our hedged debt. Our current debt ratings from Standard & Poor’s and Moody’s are AA- and A2, respectively. Our ratings outlook from both Moody's and Standard & Poor's is stable.

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. We continue to focus specifically on the economic health of the European economy, as heightened economic concerns persist. Currently, we believe economic conditions in Europe will not have a material impact on our liquidity.

In October 2013, we commenced repurchasing shares under a newly-announced $5.00 billion share repurchase program which will be completed over time. 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, capital expenditures, and potential business development activity. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. We currently have $1.36 billion of unused committed bank credit facilities, $1.20 billion of which backs our commercial paper program. Various risks and uncertainties, including those discussed in "Forward-Looking Statements", may affect our operating results and cash generated from operations.

We will lose U.S. patent protection for Cymbalta in December 2013 and for Evista in March 2014. See "Executive Overview—Legal, Regulatory, and Other Matters" for additional information.

Legal and Regulatory Matters

Information relating to certain legal proceedings can be found in Note 12 and is incorporated here by reference.

Financial Expectations for 2013

We have narrowed our 2013 EPS guidance and revised our capital expenditure estimate for 2013. All other elements of our 2013 financial guidance remain unchanged. For the full year of 2013, we now expect EPS to be in the range of $4.33 to $4.38. We still anticipate that total revenue will be between $22.6 billion and $23.4 billion. We expect overall revenue growth in 2013, driven by a portfolio of products including Humalog, Humulin, Cialis, Strattera, Forteo, Alimta, Cymbalta outside the U.S., Effient, Trajenta, and Axiron®, as well as animal health products. In addition, significant revenue growth is expected in the emerging markets, particularly China, while a weaker Japanese yen will dampen revenue growth in Japan. For the fourth quarter of 2013, we estimate that U.S. sales of Cymbalta will be approximately $500 million, reflecting the loss of U.S. patent exclusivity on December 11, 2013. In addition, this estimate includes substantial reserves for expected future returns of product. This estimate is subject to variability based upon a variety of factors, including product demand prior to the loss of patent exclusivity, as well as the speed and magnitude of revenue erosion after the loss of patent exclusivity.

We still anticipate that gross margin as a percent of revenue will be approximately 79 percent. Marketing, selling, and administrative expenses are still expected to be in the range of $7.0 billion to $7.2 billion. Research and

development expenses are still expected to be in the range of $5.3 billion to $5.5 billion. Other–net, (income) expense is still expected to be in a range between $440 million and $590 million of income. Capital expenditures are now anticipated to be approximately $1.0 billion.

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/financials.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, 2013, and concluded that they are effective.

(b) Changes in Internal Controls. During the third quarter of 2013, 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 12: Contingencies to the Consolidated Condensed Financial Statements for information on various legal proceedings, including but not limited to:

- The patent litigation involving Alimta.
- The product liability litigation involving Byetta, DES and Prozac.
- 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, 2012 (Part I, Item 3) and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2013 and June 30, 2013 (Part II, Item 1).

Other Product Liability Litigation

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

Along with several other manufacturers, we are named as a defendant in approximately 65 active cases in the U.S. involving approximately 1,700 active claimants related to claims that the analgesics Darvon and related formulations of propoxyphene contributed to various cardiac injuries. Additionally, approximately 80 cases involving approximately 225 claimants were recently dismissed and are on appeal to the Sixth Circuit. 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. A putative class action was filed in the U.S. District Court for the Eastern District of Louisiana (Ballard, et al. v. Eli Lilly and Company et al.) against Lilly and other manufacturers seeking to assert product liability claims on behalf of U.S. residents who ingested propoxyphene pain products and allegedly sustained personal injuries. Lilly and the remaining defendants were dismissed with prejudice on a dispositive motion, and a final appealable order was entered. 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.

Shareholder Derivative Litigation

In 2011, the company received a letter sent on behalf of shareholder Kim Barovic demanding that the board of directors cause the company to take (1) legal action against certain of its current and former officers and board members for allegedly causing damage to the company by failing to exercise proper oversight over the company's compliance with the U.S. Foreign Corrupt Practices Act (FCPA), and (2) all necessary actions to reform and improve certain corporate governance and internal procedures. In accordance with procedures established under the Indiana Business Corporation Law (Ind. Code § 23-1-32-4), the board established a committee of disinterested directors to consider the demands and determine what action, if any, the company should take in response. In February 2013, following its investigation, the committee determined, among other things, that it would not be in the best interests of the company to take any of the actions demanded by Ms. Barovic.

On August 9, 2013, Ms. Barovic brought a shareholder derivative suit (Barovic v. Lechleiter, et al.), filed in Marion County (Indiana) Superior Court. The suit seeks to maintain the action purportedly on behalf of the company against certain current and former directors and officers of the company and alleges breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The company is named in the suit as a nominal defendant. The suit does not seek damages from the company, but instead requests damages in an unspecified amount and certain equitable relief on the company's behalf. The company believes the suit is without merit and all of the individual defendants intend to defend themselves vigorously against the allegations in the complaint.

Employee Litigation

Reference is made to the discussion in Item 3 of our 2012 Annual Report on Form 10-K regarding Schaefer-LaRose v. Eli Lilly and Company, the U.S. Fair Labor Standards Act litigation brought by certain current and former sales representatives. In October 2013, the district court dismissed all plaintiffs' claims with prejudice, concluding this matter.

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 normal 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, 2012. 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

In December 2012, we announced a $1.50 billion share repurchase program. As of December 31, 2012, there were $1.10 billion of shares remaining to be purchased. During the first quarter of 2013, we completed this program by purchasing the remaining $1.10 billion of shares. There was no repurchase activity during the third quarter ended September 30, 2013. In October 2013, we announced a new $5.00 billion share repurchase program.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 11.	Statement re: Computation of Earnings per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings (Loss) 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 30, 2013

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

Date: October 30, 2013

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

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