LILLY ELI & CO
Form 10-Q
October 26, 2012

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, 2012
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 Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes ý No o

The number of shares of common stock outstanding as of October 20, 2012:

Class	Number of Shares Outstanding
Common	1,160,452,507

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,	
	2012	2011	2012	2011
	(Dollars in millions, except per-share data)			
Revenue	$5,443.3	$6,147.9	$16,646.0	$18,239.9
Cost of sales	1,203.6	1,338.1	3,548.2	3,746.2
Research and development	1,342.8	1,280.9	3,815.0	3,665.5
Marketing, selling, and administrative	1,757.4	1,917.8	5,536.0	5,746.5
Acquired in-process research and development (Note 4)	—	—	—	388.0
Asset impairments, restructuring, and other special charges (Note 5)	53.3	25.2	77.1	233.8
Other – net, (income) expense (Note 13)	(788.5)	83.4	(726.0)	152.2
	3,568.6	4,645.4	12,250.3	13,932.2
Income before income taxes	1,874.7	1,502.5	4,395.7	4,307.7
Income taxes (Note 10)	548.1	266.2	1,134.4	818.2
Net income	$1,326.6	$1,236.3	$3,261.3	$3,489.5
Earnings per share – basic and diluted (Note 9)	$1.18	$1.11	$2.92	$3.13
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,	
	2012	2011	2012	2011
	(Dollars in millions)			
Net income	$1,326.6	$1,236.3	$3,261.3	$3,489.5
Other comprehensive income (loss), net of tax	398.3	(496.0)	322.7	164.2
Comprehensive income	$1,724.9	$740.3	$3,584.0	$3,653.7

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Balance Sheets
ELI LILLY AND COMPANY AND SUBSIDIARIES

	September 30, 2012	December 31, 2011
	(Dollars in millions) (Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	$5,319.2	$5,922.5
Short-term investments (Note 6)	1,580.7	974.6
Accounts receivable, net of allowances of $111.0 (2012) and $110.1 (2011)	3,268.2	3,597.7
Other receivables	527.3	640.2
Inventories	2,553.4	2,299.8
Prepaid expenses and other	790.1	813.4
Total current assets	14,038.9	14,248.2
Other Assets		
Investments (Note 6)	5,224.3	4,029.8
Goodwill and other intangibles – net (Note 3)	5,031.1	5,128.1
Sundry	2,387.8	2,493.4
Total other assets	12,643.2	11,651.3
Property and Equipment		
Land, buildings, equipment, and construction-in-progress	14,944.4	14,594.0
Less accumulated depreciation	(7,305.5)	(6,833.7)
Property and equipment, net	7,638.9	7,760.3
Total assets	$34,321.0	$33,659.8
Liabilities and Shareholders' Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	$9.1	$1,522.3
Accounts payable	1,328.7	1,125.2
Employee compensation	772.7	804.7
Sales rebates and discounts	1,695.6	1,771.3
Dividends payable	—	542.3
Income taxes payable	338.2	261.6
Other current liabilities	2,816.4	2,903.5
Total current liabilities	6,960.7	8,930.9
Other Liabilities		
Long-term debt	5,510.9	5,464.7
Accrued retirement benefits (Note 11)	2,702.4	3,068.5
Long-term income taxes payable (Note 10)	1,275.1	1,086.3
Other noncurrent liabilities	1,815.0	1,573.8
Total other liabilities	11,303.4	11,193.3
Shareholders' Equity (Notes 7 and 8)		
Common stock	725.8	724.1
Additional paid-in capital	4,919.9	4,886.8
Retained earnings	17,062.2	14,897.8
Employee benefit trust	(3,013.2)	(3,013.1)

Accumulated other comprehensive loss	(3,535.9)	(3,858.6)
Noncontrolling interests	(7.6)	(6.1)
Cost of common stock in treasury	(94.3)	(95.3)
Total shareholders' equity	16,056.9	13,535.6
Total liabilities and shareholders' equity	$34,321.0	$33,659.8

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,	
	2012	2011
	(Dollars in millions)	
Cash Flows from Operating Activities		
Net income	$3,261.3	$3,489.5
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	1,117.6	1,054.7
Change in deferred income taxes	206.2	222.0
Stock-based compensation expense	100.3	110.7
Impairment charges, indefinite lived intangibles	16.0	151.0
Acquired in-process research and development, net of tax	—	252.2
Income related to prepayment of revenue-sharing obligation (Note 4)	(787.8)	—
Other changes in operating assets and liabilities	(271.5)	76.7
Other operating activities, net	60.7	(67.0)
Net Cash Provided by Operating Activities	3,702.8	5,289.8
Cash Flows from Investing Activities		
Net purchases of property and equipment	(492.2)	(416.1)
Net change in short-term investments	257.3	545.0
Proceeds from sales and maturities of noncurrent investments	3,557.4	1,082.6
Purchases of noncurrent investments	(5,506.8)	(2,659.3)
Purchase of product rights	(102.0)	(605.7)
Purchase of in-process research and development	—	(388.0)
Cash paid for acquisitions, net of cash acquired	(199.3)	(307.8)
Net change in loan to collaboration partner (Note 4)	165.0	(165.0)
Proceeds from prepayment of revenue-sharing obligation (Note 4)	1,212.1	—
Other investing activities, net	(61.8)	(33.3)
Net Cash Used for Investing Activities	(1,170.3)	(2,947.6)
Cash Flows from Financing Activities		
Dividends paid	(1,639.2)	(1,636.2)
Net change in short-term borrowings	(15.2)	(28.6)
Repayment of long-term debt	(1,500.0)	(54.6)
Other financing activities, net	—	0.4
Net Cash Used for Financing Activities	(3,154.4)	(1,719.0)
Effect of exchange rate changes on cash and cash equivalents	18.6	(18.7)
Net (decrease) increase in cash and cash equivalents	(603.3)	604.5

Cash and cash equivalents at January 1	5,922.5	5,993.2
Cash and Cash Equivalents at Sept 30	$5,319.2	$6,597.7

See Notes to Consolidated Condensed Financial Statements

Segment Information

We operate in one significant business segment—human pharmaceutical products. Operations of the animal health business segment are not material and share many of the same economic and operating characteristics as human pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. 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. Income before income taxes for the animal health business for the third quarters of 2012 and 2011 was $106.0 million and $93.0 million, respectively, and $370.0 million and $228.0 million for the nine months ended September 30, 2012 and 2011, respectively.

Revenue by Category

Worldwide revenue by category was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(Dollars in millions)			
Revenue — to unaffiliated customers:				
Pharmaceutical products				
Neuroscience	$1,815.8	$2,488.0	$5,544.0	$7,547.1
Endocrinology	1,646.1	1,692.9	5,041.2	4,965.4
Oncology	791.7	817.8	2,442.4	2,483.5
Cardiovascular	650.9	630.1	1,936.4	1,852.5
Other pharmaceuticals	59.4	68.1	199.6	181.0
Total pharmaceutical products	4,963.9	5,696.9	15,163.6	17,029.5
Animal health	479.4	451.0	1,482.4	1,210.4
Total revenue	$5,443.3	$6,147.9	$16,646.0	$18,239.9

Notes to Consolidated Condensed Financial Statements

Note 1: Basis of Presentation

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the 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, 2011. We issued our financial statements by filing with the Securities and Exchange Commission (SEC) and have evaluated subsequent events up to the time of the filing.

Note 2: Implementation of New Financial Accounting Pronouncements

There are no new accounting pronouncements that have had or will have a material impact on our consolidated condensed financial statements.

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 preliminarily recorded $151.5 million of marketed product assets, with $55.4 million of other net assets. The final determination may result in asset and liability fair values that differ from the preliminary estimates, but it is not expected that these differences will be material to our consolidated financial statements.

On July 7, 2011, we acquired the animal health business of Janssen Pharmaceutica NV, a Johnson & Johnson company, for total purchase consideration of $307.8 million in cash. We obtained a portfolio of more than 50 animal health products. In connection with this acquisition, we recorded $234.4 million of marketed product assets and $29.6 million of acquired in-process research and development (IPR&D) assets, with $43.8 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 sold by us 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,	
	2012	2011	2012	2011
	(Dollars in millions)			
Net product sales	$5,301.2	$5,971.7	$16,170.5	$17,748.1
Collaboration and other revenue	142.1	176.2	475.5	491.8
Total revenue	$5,443.3	$6,147.9	$16,646.0	$18,239.9

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. Amylin issued a secured note in the amount of $1.20 billion to us under which any revenue-sharing payments made to us would reduce amounts outstanding under the note. Upon completion of the acquisition of Amylin by Bristol-Myers Squibb in August 2012, Amylin's obligation of $1.26 billion for the revenue-sharing payments and the secured note, 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 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 anticipate transferring responsibility for commercialization of exenatide to Amylin in substantially all markets during the first half 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 will be 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 as other-net, (income) expense. All income allocated to the business outside the U.S. will be recognized on a pro rata basis as a gain on the disposition of a business in other-net, (income) expense as control of the business transfers to Amylin market by market during 2013. We expect to recognize a net gain of approximately $490 million in 2013 contingent upon the transfer of the commercial rights outside the United States.

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 beyond December 31, 2013. We are 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 operations are 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 U.S. 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. will continue until those operations transfer to Amylin. Prior to its termination, 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,	
	2012	2011	2012	2011
	(Dollars in millions)			
Net product sales	$49.5	$46.4	$151.1	$131.9
Collaboration and other revenue	4.7	60.3	70.1	180.5
Total revenue	$54.2	$106.7	$221.2	$312.4
Income related to prepayment of Amylin's obligation [1]	$787.8	$—	$787.8	$—

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

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,	
	2012	2011	2012	2011
	(Dollars in millions)			
Net product sales	$6.2	$16.2	$69.0	$61.2
Collaboration and other revenue	80.4	81.1	241.0	240.1
Total revenue	$86.6	$97.3	$310.0	$301.3

Bristol-Myers Squibb Company

Pursuant to a commercial agreement 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. The companies have jointly agreed to expand the investment in the ongoing clinical development plan for Erbitux to further explore its use in additional tumor types. Under this arrangement, 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 agreement. 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.

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 territory, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. Sales of Erbitux to BMS for commercial use are reported in net product sales.

Merck KGaA

A development and license agreement with Merck with respect to Erbitux granted Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and co-exclusive rights with BMS and us in Japan. Merck also has rights to manufacture Erbitux for supply in its territory. 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 for development; and 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.

Necitumumab

The commercial agreement with BMS described above includes the co-development and co-commercialization of necitumumab, which is currently in Phase III clinical testing for squamous non-small cell lung cancer. We and BMS share the cost of developing and potentially commercializing necitumumab in the U.S., Canada, and Japan. We maintain exclusive rights to necitumumab in all other markets. We will fund 45 percent of the development costs for studies that will be used only in the U.S., and 72.5 percent for global studies. We will be responsible for the manufacturing of API, and BMS will be responsible for manufacturing the finished product. We could receive a payment of $250.0 million upon approval in the United States. In the U.S. and Canada, BMS will record sales and we will receive 45 percent of the profits for necitumumab, while we will provide 50 percent of the selling effort. In Japan, we and BMS will share costs and profits evenly.

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote Effient. We and D-S 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. D-S has exclusive marketing rights in Japan. 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 D-S a royalty specific to these territories. Profit-share payments made to D-S are recorded as marketing, selling, and administrative expenses. All royalties paid to D-S and the third-party manufacturer are recorded in cost of sales.

Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim (Boehringer) entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are Boehringer's two oral diabetes agents, linagliptin and empagliflozin. Subsequently in 2011, linagliptin was approved and launched in the U.S. (tradename Tradjenta™), Japan (tradename Trazenta®), Europe (tradename Trajenta®), and other countries. Empagliflozin is currently in Phase III clinical testing. Also included in the agreement are our new insulin glargine product and our novel basal insulin analog, both of which began Phase III clinical testing in the second half of 2011; and an option granted to Boehringer to co-develop and co-commercialize our anti-TGF-beta monoclonal antibody, which is currently in Phase II clinical testing. Under the terms of the agreement, we made an initial one-time payment to Boehringer of $388.0 million and recorded an acquired IPR&D charge, which was included as expense in the first quarter of 2011 and is deductible for tax purposes.

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 may pay up to €300.0 million in additional success-based regulatory milestones for empagliflozin. We will be eligible to receive up to a total of $650.0 million in success-based regulatory milestones on our two insulin products. Should Boehringer 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 not significant for the nine months ended September 30, 2012 and 2011, respectively.

Cymbalta®

Boehringer Ingelheim

We were in a collaborative arrangement with Boehringer to jointly develop, market, and promote Cymbalta (duloxetine) outside the U.S. and Japan. Pursuant to the terms of the agreement, we generally shared equally in development, marketing, and selling expenses, and paid Boehringer a commission on sales in the co-promotion territories. We manufactured the product for all territories. Reimbursements or payments for the cost sharing of

marketing, selling, and administrative expenses were recorded in the respective expense line items in the consolidated condensed statements of operations. The commission paid to Boehringer was recorded in marketing, selling, and administrative expenses. In March 2010, the parties agreed to terminate this agreement, and we reacquired the exclusive rights to develop and market duloxetine for all indications in countries outside the U.S. and

Japan. In connection with the termination, we paid Boehringer approximately $400 million and will also pay to Boehringer a percentage of our sales of duloxetine in these countries through the end of 2012 as consideration for the rights acquired. We record these costs as intangible assets that are amortized to marketing, selling, and administrative expenses using the straight-line method over the life of the original agreement, which is through the third quarter of 2015.

Quintiles

We were in a collaborative arrangement with Quintiles Transnational Corp. (Quintiles) to jointly market and promote Cymbalta in the U.S. Pursuant to the terms of the agreement, Quintiles shared in the costs to co-promote Cymbalta with us and received a commission based upon net product sales. Quintiles' obligation to promote Cymbalta expired during 2009, and we incurred a lower commission for three years after completion of their promotion efforts. The commissions paid to Quintiles are recorded in marketing, selling, and administrative expenses.

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 eight 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. We made development milestone payments of $49.0 million in 2010 related to Phase II trials of baricitinib and would pay an additional $50.0 million upon initiation of Phase III trials for rheumatoid arthritis.

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 $65.2 million and $58.6 million in the quarters ended September 30, 2012 and 2011, respectively, and $211.0 million and $155.5 million in the nine months ended September 30, 2012 and 2011, respectively.

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

We recognized asset impairments, restructuring, and other special charges of $53.3 million and $77.1 million in the third quarter and first nine months of 2012, respectively, and $25.2 million and $233.8 million in the third quarter and first nine months of 2011, respectively. The 2012 charges primarily relate to the recognition of an asset impairment related to 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. The 2011 charges primarily related to severance costs.

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. 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 entered into with 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, 2012, we had outstanding foreign currency forward commitments to purchase 863.9 million U.S. dollars and sell 669.9 million euro, commitments to purchase 892.2 million euro and sell 1.16 billion U.S. dollars, and commitments to purchase 202.0 million British pounds and sell 252.4 million euro, 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 or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt or investments 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, 2012, approximately 100 percent 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.

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,	
	2012	2011	2012	2011
	(Dollars in millions)			
Fair value hedges				
Effect from hedged fixed-rate debt	$12.1	$245.4	$43.8	$255.7
Effect from interest rate contracts	(12.1)	(245.4)	(43.8)	(255.7)
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 on foreign currency exchange contracts not designated as hedging instruments	(23.7)	(51.7)	(38.5)	(1.0)

The effective portion of net gains on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $15.5 million and $41.2 million for the three and nine months ended September 30, 2011, respectively. There have been 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 $9.0 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.
During the three and nine months ended September 30, 2012 and 2011, 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, 2012 and December 31, 2011 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
	(Dollars in millions)					
September 30, 2012						
Cash and cash equivalents	$5,319.2	$5,319.2	$5,235.3	$83.9	$	$5,319.2
Short-term investments						
U.S. government and agencies	$61.0	$61.0	$61.0	$	$	$61.0
Corporate debt securities	1,509.1	1,507.1		1,509.1		1,509.1
Other securities	10.6	10.6		10.6		10.6
Short-term investments	$1,580.7	$1,578.7				
Noncurrent investments						
U.S. government and agencies	$1,124.1	$1,121.1	$885.7	$238.4	$	$1,124.1
Corporate debt securities	2,623.8	2,593.2		2,623.8		2,623.8
Mortgage-backed	401.6	405.3		401.6		401.6
Asset-backed	676.1	692.5		676.1		676.1
Other securities	3.3	3.3		3.3		3.3
Marketable equity	183.4	83.0	183.4			183.4
Equity method and other investments[1]	212.0	212.0				
Noncurrent investments	$5,224.3	$5,110.4				
December 31, 2011						
Cash and cash equivalents	$5,922.5	$5,922.5	$5,264.6	$657.9	$	$5,922.5
Short-term investments						
U.S. government and agencies	$362.3	$362.3	$351.3	$11.0	$	$362.3
Corporate debt securities	600.7	601.1		600.7		600.7
Other securities	11.6	11.6		11.6		11.6
Short-term investments	$974.6	$975.0				
Noncurrent investments						
U.S. government and agencies	$908.8	$901.3	$673.5	$235.3	$	$908.8
Corporate debt securities	2,081.3	2,093.3		2,081.3		2,081.3
Mortgage-backed	443.8	479.1		443.8		443.8
Asset-backed	245.0	253.2		245.0		245.0
Other securities	10.0	11.9		8.7	1.3	10.0
Marketable equity	180.8	107.5	180.8			180.8

Equity method and other investments[1]	160.1	160.1
Noncurrent investments	$4,029.8	$4,006.4

[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
	(Dollars in millions)				
Long-term debt, including current portion					
September 30, 2012	$(5,520.0)	$	$(6,072.2)	$	$(6,072.2)
December 31, 2011	$(6,981.5)	$	$(7,451.5)	$	$(7,451.5)

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
	(Dollars in millions)				
September 30, 2012					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Sundry	$581.7	$	$581.7	$	$581.7
Foreign exchange contracts not designated as hedging instruments					
Other receivables	7.0		7.0		7.0
Other current liabilities	(18.4)		(18.4)		(18.4)
December 31, 2011					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Other receivables	$6.1	$	$6.1	$	$6.1
Sundry	531.7		531.7		531.7
Foreign exchange contracts not designated as hedging instruments					
Other receivables	16.2		16.2		16.2
Other current liabilities	(25.9)		(25.9)		(25.9)

The fair value of the contingent consideration liability related to prior acquisitions, a Level 3 measurement in the fair value hierarchy, was $66.9 million and $121.6 million as of September 30, 2012 and December 31, 2011, respectively. The decrease in the fair value of the contingent consideration was primarily due to a $50.0 million approval milestone paid for Amyvid™ in the second quarter of 2012.

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.

Approximately $5.44 billion of our investments in debt securities, measured at fair value, will mature within five years.

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, 2012	December 31, 2011
	(Dollars in millions)	
Unrealized gross gains	$150.6	$103.0
Unrealized gross losses	34.7	80.0
Fair value of securities in an unrealized gain position	5,050.6	2,498.9
Fair value of securities in an unrealized loss position	942.3	2,164.4

Other-than-temporary impairment losses on fixed income securities of $0.8 million and $8.2 million were recognized in the statement of operations for the three and nine months ended September 30, 2012, respectively, compared with $10.9 million and $17.9 million for the same periods in 2011. The amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position include fixed-rate debt securities of varying maturities. The value of fixed income securities is sensitive to changes in the yield curve and other market conditions. Approximately 85 percent of the securities in a loss position are investment-grade debt securities. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not 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, 2012.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(Dollars in millions)			
Proceeds from sales	$1,698.8	$775.7	$5,334.1	$1,274.2
Realized gross gains on sales	43.1	25.6	70.0	113.6
Realized gross losses on sales	2.2	2.5	7.4	7.6

Realized gains and losses on sales of available-for-sale securities 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 cost of $34.4 million and $36.5 million in the third quarter of 2012 and 2011, respectively. In the first nine months of 2012 and 2011, we recognized pretax stock-based compensation expense of $100.3 million and $110.7 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 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, 2012, the total remaining unrecognized compensation cost related to nonvested PAs amounted to $29.9 million, which will be amortized over the weighted-average remaining requisite service period of approximately 12 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, 2012, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to $60.1 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, 2012, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to $66.5 million, which will be amortized over the weighted-average remaining requisite service period of 23 months.

Note 8: Shareholders' Equity

As of September 30, 2012, we have $419.2 million remaining to purchase of our previously announced $3.00 billion share repurchase program. We did not acquire any shares pursuant to this program during the first nine months of 2012. During the second quarter, the board of directors authorized the resumption of this share repurchase program. We expect to complete this program during the remainder of 2012.

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 major taxing jurisdictions for years before 2007.

The U.S. examination of certain matters related to tax years 2008-2009 that were not settled as part of previous examinations remains in progress. Because this examination still largely remains in the informational stage, the resolution of all issues in this audit period will likely extend beyond the next 12 months.

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,	
	2012	2011	2012	2011
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$66.7	$57.7	$193.8	$174.7
Interest cost	113.0	111.8	338.7	335.8
Expected return on plan assets	(171.2)	(171.9)	(512.6)	(515.2)
Amortization of prior service cost	0.8	2.2	2.5	6.9
Recognized actuarial loss	71.4	50.4	213.3	149.2
Net periodic benefit cost	$80.7	$50.2	$235.7	$151.4

	Retiree Health Benefit Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$16.1	$14.4	$48.4	$43.1
Interest cost	28.6	29.5	85.6	88.6
Expected return on plan assets	(31.8)	(31.9)	(95.4)	(95.7)
Amortization of prior service cost	(8.8)	(10.7)	(26.3)	(32.2)
Recognized actuarial loss	24.6	22.2	72.9	66.5
Net periodic benefit cost	$28.7	$23.5	$85.2	$70.3

On a global basis, we have contributed approximately $60 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2012. In addition, we have contributed approximately $340 million of discretionary funding to our global post-retirement benefit plans in 2012. During the remainder of 2012, we expect to make contributions to our defined benefit pension plans of approximately $10 million to satisfy minimum funding requirements. We do not anticipate making any additional discretionary contributions in 2012.

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 specifically noted below with respect to the Alimta® Hatch-Waxman Act 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.

Patent Litigation

We are engaged in U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984). Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patents and data-based pediatric exclusivity period (compound patent licensed from the Trustees of Princeton University and expiring in 2017, concomitant nutritional supplement use patent expiring in 2022) and alleging the patents are invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. In July 2011, the district court entered judgment in our favor, upholding that patent’s validity. In August 2012, the U.S. Court of Appeals for the Federal Circuit (CAFC) affirmed the district court's judgment in our favor. Teva and APP have filed a petition for en banc review of the CAFC's panel decision. The CAFC has not yet ruled on the defendants' petition.

In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP, Pliva Hrvatska D.O.O., and Barr seeking rulings that our concomitant nutritional supplement use patent is valid and infringed. Trial in this case is scheduled to begin in August 2013. In January 2012 and April 2012, we filed similar lawsuits against Accord Healthcare Inc. and Apotex Inc., respectively.

We believe the Hatch-Waxman challenges to the Alimta patents are without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, 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 a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

Zyprexa® Litigation

We are a defendant in approximately 10 Zyprexa product liability lawsuits in the U.S. covering approximately 75 plaintiffs. The lawsuits allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and

punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa.

Many of the claims also allege that we improperly promoted the drug. We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

Byetta Litigation

We have been named as a defendant in approximately 115 lawsuits involving approximately 500 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 500 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits, covering about 485 plaintiffs, are filed in California and coordinated in a Los Angeles Superior Court. We and Amylin are currently scheduled for trial in two separate single-plaintiff cases in the first half of 2013, the first of which is currently scheduled to begin in February. We believe these claims are without merit and are prepared to defend against them vigorously.

Diethylstilbestrol Litigation

In approximately 90 U.S. lawsuits against us involving approximately 90 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed diethylstilbestrol (DES) during pregnancy in the 1950s and 1960s. Approximately 80 of these claimants allege that they were indirectly exposed in utero to the medicine and later developed breast cancer as a consequence. Five cases involving five plaintiffs who developed breast cancer are scheduled for trial in the U.S. District Court of Massachusetts in January 2013. We believe these claims 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 future 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 - Net, (Income) Expense

Other–net, (income) expense comprised the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(Dollars in millions)			
Income related to prepayment of Amylin's obligation (Note 4)	$(787.8)	$—	$(787.8)	$—
Interest expense	47.0	45.0	135.3	135.9
Interest income	(25.7)	(22.2)	(79.0)	(55.5)
Other	(22.0)	60.6	5.5	71.8
Other-net, (income) expense	$(788.5)	$83.4	$(726.0)	$152.2

Other-net, income of $788.5 million and $726.0 million for the third quarter and the first nine months of 2012, respectively, is primarily related to the income recognized from the early payment of the exenatide revenue-sharing obligation by Amylin. See Note 4 for additional information.

Other-net, expense of $152.2 million for the first nine months of 2011 is primarily related to the partial impairment of Amyvid and liprotamase, partially offset by gains on the disposition of investment securities. In the third quarter of 2011, we recognized an expense related to the partial impairment of Amyvid (florbetapir), an acquired IPR&D asset, due to a delay in the expected product launch and lower sales projections during the early part of the product's expected life cycle, resulting in a reduction to the fair value of Amyvid. In the second quarter of 2011, we received a complete response letter from the FDA for the NDA for liprotamase, an acquired IPR&D asset, which communicated the need for us to conduct an additional clinical trial prior to a resubmission, resulting in a reduction to the fair value of liprotamase.

19

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

Operating Results

Executive Overview

Financial Results

Worldwide total revenue decreased 11 percent and 9 percent to $5.44 billion and $16.65 billion for the third quarter and first nine months of 2012, respectively, primarily driven by steep sales declines for Zyprexa due to the loss of patent exclusivity in most major markets outside of Japan, partially offset by growth in Cymbalta, Forteo®, Effient, Alimta, and our animal health portfolio. Net income for the third quarter increased 7 percent to $1.33 billion, but decreased 7 percent to $3.26 billion for the first nine months of 2012. Earnings per share (EPS) increased 6 percent for the third quarter and decreased 7 percent for the first nine months of 2012 to $1.18 per share and $2.92 per share, respectively, compared with the same periods of 2011. The increase in net income and EPS for the third quarter was driven by the income recognized from the early payment of the Amylin revenue-sharing obligation (described below), partially offset by lower gross margin. The decrease in net income and EPS for the first nine months of 2012 was a result of lower gross margin attributable to the Zyprexa sales declines and the increase in the effective tax rate. Net income and EPS comparisons for the first nine months of 2012 also benefited from the impact of the asset impairments, restructuring, and other special charges incurred in 2011, and from the acquired in-process research and development (IPR&D) charge incurred in 2011, all described below.

2012

Collaborations (Note 4)

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

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

- We recognized asset impairments, restructuring, and other special charges of $23.8 million (pretax), or $0.01 per share in the first quarter, primarily related to changes in returns reserve estimates for the withdrawal of Xigris. We recognized asset impairments, restructuring, and other special charges of $53.3 million (pretax), or $0.04 per share in the third quarter, primarily related to asset impairments associated with the decision to stop development of a delivery device platform.

2011

Collaborations (Note 4)

- We incurred an acquired IPR&D charge in the first quarter associated with the diabetes collaboration with Boehringer Ingelheim (Boehringer) of $388.0 million (pretax), which decreased earnings per share by $0.23.

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

- We recognized asset impairments, restructuring, and other special charges of $25.2 million (pretax), or $0.02 per share in the third quarter, and $233.8 million (pretax), or $0.18 per share, for the first nine months, respectively, primarily related to severance costs from previously announced strategic actions.

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 more than 60 potential new drugs in human testing or under regulatory review, and a larger number of projects in preclinical research.

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

because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual-property rights of others. Delays and uncertainties in the U.S. Food and Drug Administration (FDA) approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. 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.

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

Dulaglutide* (Q3 2008) – a glucagon-like peptide 1 analog for the treatment of type 2 diabetes

Edivoxetine (Q4 2010) – a norepinephrine reuptake inhibitor for the treatment of major depression

Empagliflozin (Q3 2010) – a sodium glucose co-transporter (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim)

Enzastaurin (Q1 2006) – a small molecule for the treatment of diffuse large B-cell lymphoma

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

Ixekizumab* (Q4 2011) – a monoclonal antibody for the treatment of psoriasis

Necitumumab* (Q4 2009) – a fully human monoclonal antibody for the treatment of squamous non-small cell lung cancer (NSCLC) (in collaboration with Bristol-Myers Squibb)

New insulin glargine product (Q3 2011) – a new insulin glargine product for the treatment of type 1 and type 2 diabetes (in collaboration with Boehringer Ingelheim)

Novel basal insulin analog* (Q4 2011) – a novel basal insulin for the treatment of type 1 and type 2 diabetes (in collaboration with Boehringer Ingelheim)

Ramucirumab* (Q4 2009) – a monoclonal antibody for the treatment of metastatic breast, gastric, liver, NSCLC, and colorectal cancers

Solanezumab* (Q2 2009) – an amyloid beta (Aß) antibody for the treatment of Alzheimer’s disease

Tabalumab* (Q4 2010) – an anti-BAFF monoclonal antibody for the treatment of lupus and rheumatoid arthritis.

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

The following NME has 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:

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

The following are late-stage pipeline updates since January 1, 2012:

Dulaglutide – In October 2012, we announced positive top-line results of three completed Phase III AWARD trials (AWARD-1, AWARD-3 and AWARD-5) studying dulaglutide as a once-weekly treatment for type 2 diabetes. The primary efficacy endpoints, as measured by reduction in hemoglobin A1c (HbA1c) at the 1.5mg dose, were met in all three studies. Having met the primary endpoints, superiority for HbA1c lowering was examined, and both doses of dulaglutide (0.75 mg and 1.5 mg) demonstrated statistically

superior reduction in HbA1c from baseline compared to: exenatide twice-daily injection at 26 weeks (AWARD-1); metformin at 26 weeks (AWARD-3); and sitagliptin at 52 weeks (AWARD-5).

Evacetrapib – In October 2012, we initiated Phase III clinical trial testing.

Florbetapir – On April 6, 2012, the FDA approved Amyvid™ (florbetapir), a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. In June 2012, Amyvid became available to a limited number of imaging centers. In October 2012, the European Medicines Agency's (EMA) medicinal committee issued a positive opinion, recommending approval of Amyvid. The positive opinion is now referred for final action to the European Commission, which has the authority to approve medicines for the European Union (EU).

Linagliptin – In January 2012, the FDA approved Jentadueto™, a combination of linagliptin and metformin for the treatment of adults with type 2 diabetes (in collaboration with Boehringer Ingelheim). In July 2012, it was also approved by the European Commission. In August 2012, the FDA approved a supplemental new drug application for Tradjenta® as an add-on therapy to insulin in adults with type 2 diabetes. In September 2012, the EMA medicinal committee recommended a similar expansion of the therapeutic indication for Trajenta®, which is currently under review by the European Commission.

Pomaglumetad Methionil - In August 2012, we announced the decision to stop ongoing Phase III clinical studies investigating pomaglumetad methionil for the treatment of patients suffering from schizophrenia. The decision was based on a lack of efficacy in two registration trials. The decision was not based on any safety signals.

Ramucirumab – In October 2012, we announced that the REGARD trial, a Phase III study of ramucirumab as a second-line treatment in patients with metastatic gastric cancer, met its primary endpoint of improved overall survival and its secondary endpoint of increased progression-free survival.

Solanezumab – In August 2012, we announced that the primary endpoints, both cognitive and functional, were not met in either of the two Phase III, double-blind, placebo-controlled EXPEDITION trials in patients with mild-to-moderate Alzheimer's disease. However, a pre-specified secondary analysis of pooled data across both trials showed a 34 percent reduction of cognitive decline in patients with mild Alzheimer's disease. The next steps for solanezumab will be determined after discussions with regulators.

Legal and Regulatory Matters

The enactment of the "Patient Protection and Affordable Care Act" (PPACA) and "The Health Care and Education Reconciliation Act of 2010" in March 2010 brought significant changes to U.S. health care. These changes began to affect our financial results in the first quarter of 2010 and will continue to have significant impact on our results in the future. In June 2012, the U.S. Supreme Court upheld most aspects of PPACA. The individual mandate was found to be constitutional; however, the Court prohibited the Department of Health and Human Services from enforcing the Medicaid expansion in PPACA. Effectively, this makes the Medicaid expansion voluntary; we do not expect this to have a material impact on our consolidated results of operations.

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 other 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.

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.

International operations also are generally subject to extensive price and market regulations. There are proposals for cost-containment measures 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 austerity measures being pursued in a number of countries.

Revenue

Revenue decreased 11 percent and 9 percent, to $5.44 billion and $16.65 billion, for the third quarter and first nine months of 2012, respectively. The 11 percent revenue decline comprised a decrease of 9 percent due to lower volume and 3 percent due to the unfavorable effect of foreign exchange rates, partially offset by an increase of 1 percent due to price. For the first nine months of 2012, the 9 percent revenue decline comprised a decrease of 9 percent due to lower volume and 2 percent due to the unfavorable effect of foreign exchange rates, partially offset by an increase of 2 percent due to price. The decrease in volume was driven by the loss of patent exclusivity for Zyprexa in most major markets, partially offset by volume gains for certain other products. Total revenue in the U.S. decreased 9 percent and 6 percent, to $2.99 billion and $9.08 billion, for the third quarter and first nine months of 2012, respectively, due to the loss of patent exclusivity for Zyprexa, partially offset by higher prices and, to a lesser extent, increased volume in other products. Revenue outside the U.S. decreased 15 percent and 11 percent, to $2.46 billion and $7.56 billion, for the third quarter and first nine months of 2012, respectively, driven by the loss of patent exclusivity for Zyprexa in markets outside of Japan, the unfavorable effect of foreign exchange rates, and lower prices, partially offset by increased volume in other products.

The following table summarizes our revenue activity for the three- and nine-month periods ended September 30, 2012 and 2011:

	Three Months Ended September 30, 2012			Three Months Ended September 30, 2011	Percent Change from
Product	U.S.[1]	Outside U.S.	Total[2]	Total	2011
	(Dollars in millions)				
Cymbalta	$964.6	$271.2	$1,235.8	$1,068.6	16 %
Alimta	288.8	354.8	643.6	629.7	2 %
Humalog®	337.3	238.5	575.8	593.2	(3)%
Cialis®	205.7	276.4	482.1	469.8	3 %
Animal health products	275.3	204.1	479.4	451.0	6 %
Zyprexa	67.8	306.7	374.5	1,182.3	(68)%
Forteo	127.3	161.4	288.7	240.3	20 %
Humulin®	131.9	153.5	285.4	301.5	(5)%
Evista®	168.3	78.7	247.0	270.1	(9)%
Strattera®	90.0	55.6	145.6	153.2	(5)%
Effient	80.4	29.3	109.7	83.5	31 %
Other pharmaceutical products	141.6	292.0	433.6	528.5	(18)%
Total net product sales	2,879.0	2,422.2	5,301.2	5,971.7	(11)%
Collaboration and other revenue[3]	107.2	34.9	142.1	176.2	(19)%
Total revenue	$2,986.2	$2,457.1	$5,443.3	$6,147.9	(11)%

	Nine Months Ended September 30, 2012			Nine Months Ended September 30, 2011	Percent Change from
Product	U.S.[1]	Outside U.S.	Total[2]	Total	2011
	(Dollars in millions)				
Cymbalta	$2,777.1	$796.6	$3,573.7	$2,980.8	20 %
Alimta	824.8	1,085.1	1,909.9	1,823.0	5 %
Humalog	1,039.3	740.2	1,779.5	1,705.5	4 %
Animal health products	849.7	632.7	1,482.4	1,210.4	22 %
Cialis	571.1	842.3	1,413.4	1,381.4	2 %
Zyprexa	300.3	1,016.3	1,316.6	3,872.4	(66)%
Humulin	429.1	467.0	896.1	903.2	(1)%
Forteo	367.4	469.0	836.4	687.3	22 %
Evista	522.5	246.7	769.2	799.7	(4)%
Strattera	288.3	169.2	457.5	449.5	2 %
Effient	251.2	85.4	336.6	211.5	59 %
Other pharmaceutical products	476.1	923.1	1,399.2	1,723.4	(19)%
Total net product sales	8,696.9	7,473.6	16,170.5	17,748.1	(9)%
Collaboration and other revenue[3]	386.4	89.1	475.5	491.8	(3)%
Total revenue	$9,083.3	$7,562.7	$16,646.0	$18,239.9	(9)%

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

2 Numbers may not add due to rounding.

3 Collaboration and other revenue consists primarily of royalties for Erbitux and revenue associated with exenatide in the U.S.

24

Product Highlights

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 19 percent and 23 percent during the third quarter and the first nine months of 2012, respectively. The increases were due to higher prices and increased demand. Sales outside the U.S. increased 5 percent and 10 percent during the third quarter and the first nine months of 2012, respectively, driven primarily by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Alimta, a treatment for various cancers, increased 12 percent and 11 percent during the third quarter and the first nine months of 2012, respectively, driven by increased demand, and to a lesser extent, higher prices. Sales outside the U.S. decreased 4 percent in the third quarter due to lower prices in Japan and the unfavorable impact of foreign exchange rates, partially offset by increased demand. Sales outside the U.S. increased 1 percent in the first nine months of 2012, due to increased demand, partially offset by lower prices in Japan and the unfavorable impact of foreign exchange rates.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 2 percent in the third quarter, driven by decreased volume, and increased 5 percent in the first nine months of 2012, driven by higher prices, partially offset by decreased volume. U.S. sales of Humalog have been negatively impacted by the product's removal from a large formulary in 2012. Sales outside the U.S. decreased 4 percent in the third quarter, due primarily to the unfavorable impact of foreign exchange rates, partially offset by increased volume. For the first nine months of 2012, sales outside the U.S. increased 4 percent due to increased volume, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 22 percent and 13 percent in the third quarter and the first nine months of 2012, respectively, driven by higher prices and increased demand. Sales outside the U.S. decreased 8 percent in the third quarter of 2012, driven by the unfavorable impact of foreign exchange rates. Sales outside the U.S. decreased 4 percent in the first nine months of 2012, driven by the unfavorable impact of foreign exchange rates, partially offset by increased demand.

U.S. sales of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, decreased 88 percent and 84 percent in the third quarter and the first nine months of 2012, respectively. Sales outside the U.S. decreased 50 percent and 49 percent in the third quarter and the first nine months of 2012, respectively. The decreases were due to the loss of patent exclusivity in the U.S. and most major international markets outside of Japan.

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, increased 15 percent and 11 percent in the third quarter and the first nine months of 2012, respectively, due to higher prices, and partially offset in the first nine months by decreased demand. Sales outside the U.S. increased 24 percent and 32 percent in the third quarter and the first nine months of 2012, respectively, primarily due to increased demand in Japan, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, decreased 7 percent in the third quarter, driven primarily by decreased demand, partially offset by higher prices, and increased 3 percent in the first nine months of 2012 driven by higher prices, partially offset by decreased demand. U.S. sales of Humulin have been negatively impacted by the product's removal from a large formulary in 2012, as well as the continued decline in the market for human insulin and the termination of the Humulin ReliOn agreement. Sales outside the U.S. decreased 3 percent and 4 percent in the third quarter and the first nine months of 2012, respectively, driven primarily by the unfavorable impact of foreign exchange rates, partially offset by increased demand.

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, decreased 5 percent and 1 percent in the third quarter and the first nine months of 2012, respectively, driven by decreased demand, partially offset by higher prices. Sales outside the U.S. decreased 16 percent and 10 percent in the third quarter and the first nine months of 2012, respectively, driven by decreased volume and, to a lesser extent, the unfavorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. in adults, decreased 7 percent in the third quarter due to decreased demand, and increased 3 percent in the first nine months of 2012 due to higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 2 percent and remained relatively flat during the third quarter and for the first nine months of 2012,

respectively, driven by the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased volume.

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 31 percent and 62 percent in the third quarter and the first nine months of 2012, respectively, driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 32 percent and 52 percent in the third quarter and the first nine months of 2012, respectively, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates.

We report as revenue for Erbitux, a product approved to treat various cancers, the net royalties received from our collaboration partners and our product sales. Our revenues decreased 11 percent to $86.6 million in the third quarter due to the timing of product shipments to collaboration partners. Our revenues increased 3 percent to $310.0 million in the first nine months of 2012.

Animal health product sales in the U.S. increased 16 percent in the third quarter due primarily to increased demand for companion animal products. Sales in the U.S. increased 29 percent in the first nine months of 2012 due to increased demand for companion animal products and, to a lesser extent, customer buying patterns for companion animal products and higher prices. Sales outside the U.S. decreased 4 percent in the third quarter driven primarily by the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased volume. The growth of animal health products outside the U.S. was negatively impacted in the third quarter by economic conditions in certain markets. Sales outside the U.S. increased 15 percent in the first nine months of 2012, driven primarily by the impact of the acquisition of certain Janssen animal health assets in Europe (see Note 3), as well as growth of other products.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue decreased by 0.3 percentage points, to 77.9 percent, for the third quarter and 0.8 percentage points, to 78.7 percent, for the first nine months of 2012. The decreases in gross margin percent were primarily due to lower sales of Zyprexa, largely offset by the impact of foreign exchange rates on international inventories sold, which decreased cost of sales in the third quarter and first nine months of 2012 and increased cost of sales in the third quarter and first nine months of 2011.

Marketing, selling, and administrative expenses decreased 8 percent and 4 percent, to $1.76 billion and $5.54 billion, for the third quarter and first nine months of 2012, respectively, driven primarily by lower marketing expense.

Research and development expenses increased 5 percent and 4 percent, to $1.34 billion and $3.82 billion, for the third quarter and first nine months of 2012, respectively, driven by expenses related to late-stage clinical trials.

No acquired IPR&D charges were incurred in the first nine months of 2012, compared with $388.0 million for the same period in 2011, all of which was associated with the diabetes collaboration with Boehringer. We incurred asset impairments, restructuring, and other special charges of $53.3 million and $77.1 million for the third quarter and first nine months of 2012, respectively, compared with $25.2 million and $233.8 million for the third quarter and first nine months of 2011, respectively. See Notes 4 and 5 for additional information.

Other—net, (income) expense was a net income of $788.5 million and $726.0 million for the third quarter and first nine months of 2012, respectively, compared with net expense of $83.4 million and $152.2 million for the same respective periods in 2011. The increases were driven by the income recognized from the early payment of the exenatide revenue-sharing obligation by Amylin. The third quarter of 2011 included expense from the partial impairment of an acquired in-process research and development asset related to Amyvid. See Notes 4 and 13 for additional information.

The effective tax rates were 29.2 percent and 25.8 percent for the third quarter and first nine months of 2012, respectively, compared with effective tax rates of 17.7 percent and 19.0 percent for the same respective periods in 2011. The increase in the effective tax rate for the third quarter of 2012 reflects the tax impact of the payment received from Amylin and the expiration of the R&D tax credit in the U.S. at the end of 2011, while the third-quarter 2011 tax rate was lower primarily due to the recognition of a $45.4 million discrete benefit primarily as a result of the resolution of the IRS audit of our 2007 federal income tax return. For the first nine months of 2012, the increase in the effective tax rate was also affected by the tax benefit of the 2011 IPR&D charge associated with the Boehringer diabetes collaboration.

26

Financial Condition

Cash, cash equivalents, and short-term investments remained flat at a total of $6.90 billion as of September 30, 2012 compared to December 31, 2011. Cash flow from operations of $3.70 billion and the $1.38 billion in proceeds from the early payment of Amylin's revenue-sharing obligations and loan were offset by net increases in investment securities with maturities extending beyond one year of $1.95 billion, dividends paid of $1.64 billion, and the maturity and repayment of long-term debt of $1.50 billion.

Total debt as of September 30, 2012 decreased by $1.47 billion compared with December 31, 2011, to $5.52 billion, due primarily to the previously mentioned long-term debt maturity and payment of $1.50 billion. Our current debt ratings from Standard & Poor’s and Moody’s are AA- and A2, respectively.

Both the U.S. and global economy continued to show mixed signals in the third quarter. In the U.S., the Federal Reserve announced another round of quantitative easing aimed at keeping interest rates near historic lows. While the most recent unemployment rate was better than expected, broader labor market concerns and debate regarding the fiscal cliff in the nation's capital serve to reinforce the Fed's accommodative approach. In Europe, the European Central Bank clarified its position on providing stimulus to struggling countries, requiring that they apply for stimulus and adhere to austerity measures as part of accessing funds from the European Stability Mechanism. Monetary easing in Europe provided some clarity, but current economic fundamentals reinforce uncertainty in a recovery. Although this uncertainty persists, we have not experienced an overall deterioration of accounts receivable collection in Europe. Our largest exposure to loss remains with the public sector in certain Southern European countries; however, we consider this exposure to be immaterial. 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. Currently, we believe economic conditions in Europe will not have a material impact on our liquidity.

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, debt service, capital expenditures, and share repurchases in 2012. We believe that amounts accessible through existing commercial paper markets will be adequate to fund short-term borrowings. We currently have $1.24 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 the Financial Expectations for 2012 section, may affect our operating results and cash generated from operations.

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).

Zyprexa has already lost exclusivity in the U.S. and most major markets outside of Japan. In the U.S., Zyprexa lost exclusivity in October 2011. In addition, we face U.S. patent litigation over Alimta, and it is possible we could lose our exclusivity prior to the expiration of the relevant patents. See the Hatch-Waxman patent litigation discussion in Note 12. The loss of exclusivity for Alimta, Cymbalta, and Evista will likely result in generic competition, generally causing a rapid and severe decline in revenue from the affected product, which would have a material adverse effect on our results of operations. The U.S. patent for Humalog expires in May 2013. Humalog is currently protected in Europe only by formulation patents. We do not currently expect the loss of 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, it is difficult to predict the likelihood 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 in these markets.

Legal, Regulatory and Other Matters

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

Financial Expectations for 2012

As a result of the income from the early repayment of the Amylin revenue-sharing obligation, we now expect 2012 earnings per share to be in the range of $3.68 to $3.78. Certain other elements of our 2012 financial guidance have

also been revised. We still anticipate that total revenue will be between $21.8 billion and $22.8 billion. This includes an expected decline of more than $3 billion in Zyprexa sales due to patent expirations in most markets outside of Japan. The reduction in revenue due to Zyprexa patent expirations is expected to be partially offset by growth in

key franchises including Cymbalta, Cialis, Alimta, Humalog, and Forteo, as well as continued growth of newer products such as Effient and Axiron®. We also anticipate strong, double-digit revenue growth from our Elanco Animal Health business. Both Japan and emerging markets are expected to post continued strong underlying volume growth; however, overall revenue growth in these markets in 2012 will be adversely affected by pricing actions in Japan and by the expected impact of patent expirations, including Zyprexa, in some emerging market countries.

We still anticipate that gross margin as a percent of revenue will be approximately 78 percent in 2012. Marketing, selling, and administrative expenses are still expected to decline and be in the range of $7.3 billion to $7.7 billion. Research and development expense is still expected to be flat to increasing and in the range of $5.0 billion to $5.3 billion. Other—net, (income) expense is now expected to be in a range between $640 million and $715 million of net income in 2012, a change from the prior range of net expense of $75 million and net income of $50 million. Operating cash flows are still expected to be more than sufficient to fund capital expenditures of approximately $800 million, as well as anticipated business development activity, our current dividend, and share repurchases.

We caution investors that any forward-looking statements or projections made by us, including those above, are based on management's belief at the time they are made. However, they are subject to risks and uncertainties. Actual results may differ materially from these and other forward-looking statements due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. Pharmaceutical products can develop unexpected safety or efficacy concerns. Our results may also be affected by such factors as competitive developments affecting current products; market uptake of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; issues with product supply; regulatory changes or other developments; regulatory compliance problems or government investigations; patent disputes; changes in patent law or regulations related to data-package exclusivity; other litigation involving current or future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates and global macroeconomic conditions. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2011 Form 10-K, "Risk Factors." Investors should not place undue reliance on forward-looking statements, which speak only as of the date of 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.

Available Information on our Website

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The website link to our SEC filings is 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, 2012, and concluded that they are effective.

(b) Changes in Internal Controls. During the third quarter of 2012, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We are pursuing a multi-year initiative to outsource some accounting transaction-processing

activities, migrating to a consistent enterprise financial system across the

organization, and moving certain activities to newly-established captive shared services centers. In addition, we are in the process of reducing financial human resources at various locations around the world. None of these initiatives is in response to any identified deficiency or weakness in our internal control over financial reporting. These initiatives are expected to continue to enhance our internal control over financial reporting, but in the short term may increase our risk.

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 U.S. patent litigation involving Alimta

•The product liability litigation involving Zyprexa, Byetta, and diethylstilbestrol.

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, 2011 (Part I, Item 3) and our Quarterly Reports on Form 10-Q for the quarters ended March 31 and June 30, 2012 (Part II, Item 1).

Employment Litigation

We have been named as a defendant in a lawsuit filed in the U.S. District Court for the Northern District of New York (Schaefer-LaRose, et al. v. Eli Lilly and Company, filed November 14, 2006) claiming that our pharmaceutical sales representatives should have been categorized as “non-exempt” rather than “exempt” employees, and claiming that the company owes them back wages for overtime worked, as well as penalties, interest, and attorneys' fees. Other pharmaceutical industry participants face similar lawsuits. The case was transferred to the U.S. District Court for the Southern District of Indiana and involves approximately 400 plaintiffs. In September 2009, the district court granted our motion for summary judgment with regard to Ms. Schaefer-LaRose's claims and ordered the plaintiffs to demonstrate why the entire class action should not be decertified within 30 days. Plaintiffs filed a motion for reconsideration of the summary judgment decision and also opposed decertification, and in October 2010, the court denied plaintiffs' motion for reconsideration but decided not to decertify the class action at that time. In May 2012, the Seventh Circuit Court of Appeals affirmed the District Court's summary judgment ruling. In June 2012, the United States Supreme Court ruled, in a case against another pharmaceutical company, that sales representatives employed by that company were exempt from the overtime requirements of the Fair Labor Standards Act. We are waiting for the district court to rule on the status of the remaining plaintiffs in the Schaefer-LaRose case. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

Other Product Liability Litigation

We are currently a defendant in a variety of other product liability lawsuits involving primarily Darvon®, Prozac®, and Actos®.

Along with several other manufacturers, we have been named as a defendant in litigation in the U.S. related to the analgesic Darvon and related formulations of propoxyphene. These cases generally allege various cardiac injuries. There are approximately 70 cases pending involving approximately 210 claimants. Most of these cases have been consolidated in a multi-district litigation in the Eastern District of Kentucky. Two lawsuits have been filed as putative class actions in federal courts in Louisiana seeking to assert product liability claims on behalf of U.S. residents who ingested propoxyphene and allegedly sustained personal injuries (Ballard, et al. v. Eli Lilly and Company et al. and Lewis v. Eli Lilly and Company and Xanodyne). We transferred the U.S. regulatory approvals and all marketing rights to our propoxyphene products in 2002 to 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.

We have been named as a defendant in four lawsuits - one in the U.S. District Court for the Western District of Louisiana, one in the U.S. District Court for the Northern District of Texas, and two in state courts (Tennessee and Indiana), involving allegations that the antidepressant Prozac caused or contributed to birth defects in children born to women who ingested the drug during pregnancy. We are aware of approximately 325 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.

We have been named along with Takeda Pharmaceutical Company Limited, and Takeda affiliates (together "Takeda") as a defendant in product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until September 2006. Under our agreement with Takeda, we will be indemnified by Takeda for our losses and expenses in connection with the U.S. litigation in accordance with the terms of the agreement. In addition, we have been named along with Takeda as a defendant in two purported product liability class actions in Ontario, Canada (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al. and Brewer et al. v. Takeda Canada et al.), and one in Quebec, Canada (Jimmy Whyte et al. v. Eli Lilly et al.). We have also been named along with Takeda in an individual action for damages in Ontario, Canada (Antonacci v. Takeda Pharmaceutical Company Ltd, et al.). All are related to Actos, which we promoted in Canada until 2009. We believe these claims are without merit and are prepared to defend against them vigorously.

Other Matters

In 2004 we, along with several other pharmaceutical companies, were named in a lawsuit in California state court brought by approximately 20 California pharmacies alleging that pharmaceutical companies prevented commercial importation of prescription drugs from outside the U.S. and used Canadian pharmaceutical prices as an agreed floor for prices in the U.S. in violation of antitrust laws. The case sought restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative conduct. Summary judgment was granted to us and the other defendants in December 2006; however in July 2010, the California Supreme Court overturned the lower court decision and remanded the case to the state court. In March 2011, the state court again granted summary judgment for us and the other defendants. Plantiffs' appeal of this decision was heard by the California Court of Appeal in June 2012, and in August 2012, the Court of Appeal affirmed the trial court's order of summary judgment in our favor. Plaintiffs filed a petition for certification before the California Supreme Court in October 2012. We believe the petition has no merit and are prepared to defend against it vigorously.

In Canada, several generic companies challenged the validity of our Zyprexa (olanzapine) patent. In September 2012, the Canadian Court of Appeals affirmed the lower court's decision that the olanzapine patent was invalid for lack of utility. We plan to file a petition for review of the Court of Appeal's decision before the Supreme Court of Canada. Absent a reversal by the Supreme Court of Canada, we will be exposed to damages to the defendant generic companies arising from our market exclusivity for Zyprexa. The total amount of damages cannot be determined until after a separate damages trial, which has not yet been scheduled.

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, 2011 and our Quarterly Reports on Form 10-Q for the quarters ended March 31 and June 30, 2012. There have been no material changes from the risk factors previously disclosed in those reports.

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

The following table summarizes the activity related to repurchases of our equity securities during the third quarter ended September 30, 2012:

Period	Total Number of Shares Purchased (a)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d)
	(in thousands)		(in thousands)	(in millions)
July 2012	—	$—	—	$419.2
August 2012	—	—	—	419.2

September 2012	—	—	—	419.2
Total	—		—	

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our $3.00 billion share repurchase program announced in March 2000. As of September 30, 2012, we

have $419.2 million remaining to purchase related to this program. We did not acquire any shares pursuant to this program during the first nine months of 2012. During the second quarter, the board of directors authorized the resumption of this share repurchase program. We expect to complete this program during the remainder of 2012.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 10.	2002 Lilly Stock Plan as amended through August 28, 2012
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 26, 2012

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

Date: October 26, 2012

/s/Arnold C. Hanish
Arnold C. Hanish
Vice President, Finance and Chief Accounting Officer

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