

LILLY ELI & CO  
Form 10-Q  
October 28, 2011

**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, 2011**

**COMMISSION FILE NUMBER 001-6351**

**ELI LILLY AND COMPANY**

(Exact name of Registrant as specified in its charter)

INDIANA  
(State or other jurisdiction of  
incorporation or organization)

35-0470950  
(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  No

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  Accelerated filer  Non-accelerated filer  Smaller reporting Company

(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  No

## Edgar Filing: LILLY ELI & CO - Form 10-Q

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  No

The number of shares of common stock outstanding as of October 20, 2011:

Class	Number of Shares Outstanding
Common	1,157,762,135

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,	
	2011	2010	2011	2010
	(Dollars in millions, except per-share data)			
Revenue	\$ 6,147.9	\$ 5,654.8	\$ 18,239.9	\$ 16,889.0
Cost of sales	1,338.1	987.6	3,746.2	3,134.0
Research and development	1,280.9	1,219.8	3,665.5	3,446.1
Marketing, selling, and administrative	1,917.8	1,694.9	5,746.5	5,064.7
Acquired in-process research and development (Notes 3 and 4)			388.0	50.0
Asset impairments, restructuring, and other special charges (Note 5)	25.2	59.5	233.8	113.0
Other net, expense (income) (Note 13)	83.4	21.7	152.2	(34.4)
	4,645.4	3,983.5	13,932.2	11,773.4
Income before income taxes	1,502.5	1,671.3	4,307.7	5,115.6
Income taxes (Note 10)	266.2	368.4	818.2	1,215.7
Net income	\$ 1,236.3	\$ 1,302.9	\$ 3,489.5	\$ 3,899.9
Earnings per share basic and diluted (Note 9)	\$ 1.11	\$ 1.18	\$ 3.13	\$ 3.53
Dividends paid per share	\$ .49	\$ .49	\$ 1.47	\$ 1.47

See Notes to Consolidated Condensed Financial Statements.

Edgar Filing: LILLY ELI & CO - Form 10-Q

Consolidated Condensed Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES

	September 30, 2011	December 31, 2010
	(Unaudited)	(Dollars in millions)
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents (Note 6)	\$ 6,597.7	\$ 5,993.2
Short-term investments (Note 6)	186.6	733.8
Accounts receivable, net of allowances of \$126.3 (2011) and \$100.4 (2010)	3,533.2	3,493.8
Other receivables	564.4	664.3
Inventories	2,513.3	2,517.7
Prepaid taxes	378.4	828.3
Prepaid expenses and other	799.1	608.9
<b>Total current assets</b>	<b>14,572.7</b>	<b>14,840.0</b>
<b>Other Assets</b>		
Investments (Note 6)	3,219.6	1,779.5
Goodwill and other intangibles net (Notes 3 and 4)	5,221.9	4,818.8
Sundry	2,215.8	1,622.4
<b>Total other assets</b>	<b>10,657.3</b>	<b>8,220.7</b>
<b>Property and Equipment</b>		
Land, buildings, equipment, and construction-in-progress	14,618.5	14,486.6
Less accumulated depreciation	(6,806.3)	(6,545.9)
<b>Property and equipment, net</b>	<b>7,812.2</b>	<b>7,940.7</b>
<b>Total assets</b>	<b>\$ 33,042.2</b>	<b>\$ 31,001.4</b>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current Liabilities</b>		
Short-term borrowings	\$ 1,628.7	\$ 156.0
Accounts payable	1,154.3	1,072.2
Employee compensation	689.3	851.8
Sales rebates and discounts	1,882.3	1,372.6
Dividends payable		540.0
Income taxes payable	144.4	457.5
Other current liabilities	2,720.3	2,651.3
<b>Total current liabilities</b>	<b>8,219.3</b>	<b>7,101.4</b>
<b>Other Liabilities</b>		
Long-term debt	5,451.3	6,770.5
Accrued retirement benefit (Note 11)	1,805.9	1,887.4
Long-term income taxes payable (Note 10)	1,058.8	1,234.8
Other noncurrent liabilities	1,449.0	1,594.5
<b>Total other liabilities</b>	<b>9,765.0</b>	<b>11,487.2</b>

Edgar Filing: LILLY ELI & CO - Form 10-Q

Shareholders' Equity (Notes 7 and 8)		
Common stock	724.1	721.3
Additional paid-in capital	4,838.8	4,798.5
Retained earnings	15,125.9	12,732.6
Employee benefit trust	(3,013.1)	(3,013.2)
Deferred costs-ESOP	(14.4)	(52.4)
Accumulated other comprehensive loss	(2,505.4)	(2,670.1)

Edgar Filing: LILLY ELI & CO - Form 10-Q

---

Noncontrolling interests	(2.7)	(7.5)
Shareholders' equity, including treasury shares	15,153.2	12,509.2
Less cost of common stock in treasury	95.3	96.4
Total shareholders' equity	15,057.9	12,412.8
Total liabilities and shareholders' equity	\$ 33,042.2	\$ 31,001.4

See Notes to Consolidated Condensed Financial Statements.

Edgar Filing: LILLY ELI & CO - Form 10-Q

Consolidated Condensed Statement of Cash Flows

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

Nine Months Ended  
September 30,  
2011                      2010

(Dollars in millions)

<b>Cash Flows from Operating Activities</b>		
Net income	\$ 3,489.5	\$ 3,899.9
<b>Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:</b>		
Depreciation and amortization	1,054.7	989.7
Impairment charges, indefinite lived intangibles	151.0	
Change in deferred income taxes	222.0	479.8
Stock-based compensation expense	110.7	175.2
Acquired in-process research and development, net of tax	252.2	32.5
Other changes in operating assets and liabilities	76.7	(820.3)
Other operating activities, net	(67.0)	(128.1)
<b>Net Cash Provided by Operating Activities</b>	<b>5,289.8</b>	<b>4,628.7</b>
<b>Cash Flows from Investing Activities</b>		
Net purchases of property and equipment	(416.1)	(443.4)
Net change in short-term investments	545.0	(200.6)
Proceeds from sales and maturities of noncurrent investments	1,082.6	444.4
Purchases of noncurrent investments	(2,659.3)	(518.2)
Purchase of product rights	(605.7)	(419.0)
Cash paid for acquisition, net of cash acquired	(307.8)	(328.7)
Purchase of in-process research and development	(388.0)	(50.0)
Loan to collaboration partner	(165.0)	
Other investing activities, net	(33.3)	(79.8)
<b>Net Cash Used for Investing Activities</b>	<b>(2,947.6)</b>	<b>(1,595.3)</b>
<b>Cash Flows from Financing Activities</b>		
Dividends paid	(1,636.2)	(1,621.2)
Net change in short-term borrowings	(28.6)	125.1
Proceeds from issuance of long-term debt		1.0
Repayment of long-term debt	(54.6)	(0.7)
Other financing activities, net	0.4	23.5
<b>Net Cash Used in Financing Activities</b>	<b>(1,719.0)</b>	<b>(1,472.3)</b>
Effect of exchange rate changes on cash and cash equivalents	(18.7)	(115.2)
<b>Net Increase in Cash and Cash Equivalents</b>	<b>604.5</b>	<b>1,445.9</b>
Cash and cash equivalents at January 1	5,993.2	4,462.9

Edgar Filing: LILLY ELI & CO - Form 10-Q

Cash and Cash Equivalents at September 30	\$ 6,597.7	\$ 5,908.8
---	------------	------------

See Notes to Consolidated Condensed Financial Statements.



Edgar Filing: LILLY ELI & CO - Form 10-Q

Consolidated Condensed Statements of Comprehensive Income

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Net income	\$ 1,236.3	\$ 1,302.9	\$ 3,489.5	\$ 3,899.9
Other comprehensive income (loss), net of tax <sup>1</sup>	(496.0)	777.9	164.2	(57.9)
Comprehensive income	\$ 740.3	\$ 2,080.8	\$ 3,653.7	\$ 3,842.0

<sup>1</sup> The significant components of other comprehensive income (loss) were losses from foreign currency translation adjustments of \$487.2 million for the three months ended September 30, 2011 and gains of \$135.8 million for the nine months ended September 30, 2011. The significant components of other comprehensive income (loss) were gains from foreign currency translation adjustments of \$727.0 million for the three months ended September 30, 2010 and losses of \$193.5 million for the nine months ended September 30, 2010. 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 2011 and 2010 was \$93.0 million and \$58.2 million, respectively, and \$228.0 million and \$161.4 million for the nine months ended September 30, 2011 and 2010, respectively.

Revenue by Category

Worldwide revenue by category was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Revenue to unaffiliated customers:				
Neuroscience	\$ 2,488.0	\$ 2,246.4	\$ 7,547.1	\$ 6,854.2
Endocrinology	1,692.9	1,510.4	4,965.4	4,506.9
Oncology	817.8	980.3	2,483.5	2,837.1
Cardiovascular	630.1	517.6	1,852.5	1,569.3
Animal health	451.0	353.3	1,210.4	967.1
Other pharmaceuticals	68.1	46.8	181.0	154.4
Total revenue	\$ 6,147.9	\$ 5,654.8	\$ 18,239.9	\$ 16,889.0

---

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, 2010. 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

In 2010, the Financial Accounting Standards Board (FASB) issued an Accounting Standard Update (ASU) that applies to the annual fee imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs as part of U.S. health care reform. This fee is allocated to companies based on their prior-calendar-year market share for branded prescription drug sales into these government programs. This guidance clarifies how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by U.S. health care reform. This fee is recorded as selling, general, and administrative expense in our consolidated results of operations and will be amortized on a straight-line basis for the year. This guidance was effective for us January 1, 2011. In accordance with this guidance, in the third quarter and first nine months of 2011 we recorded \$44.8 million and \$134.3 million, respectively, related to this fee, which is not deductible for tax purposes.

In 2010, the FASB issued an ASU related to Revenue Recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This guidance was effective for us January 1, 2011, and did not have a material impact on our consolidated financial position or results of operations.

In 2009, the FASB issued an ASU related to Revenue Recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration should be allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. This guidance was effective for us January 1, 2011, and did not have a material impact on our consolidated financial position or results of operations.

Note 3: Acquisitions

Acquisitions of Businesses

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 marketed animal health products. We have not yet finalized our acquisition accounting but we anticipate the majority of the value of the assets recorded will be marketed product intangibles. This transaction was not material to our consolidated financial statements.

On July 20, 2010, we acquired all of the outstanding stock of Alnara Pharmaceuticals, Inc. (Alnara), a privately-held company developing protein therapeutics for the treatment of metabolic diseases, for total purchase consideration of \$291.7 million, which included an upfront payment of \$188.7 million and up to \$200.0 million in additional payments contingent upon potential future regulatory and commercial milestones. The fair value of the contingent consideration at the acquisition date was \$103.0 million. Alnara's lead product in development is liprotamase, a non-porcine pancreatic enzyme replacement therapy. Liprotamase is under review by the U.S. Food and Drug Administration (FDA) for the treatment of exocrine pancreatic insufficiency. In connection with this acquisition, we recorded \$264.0 million of acquired in-process research and development (IPR&D) assets, \$100.5 million of goodwill, and \$92.4 million of deferred tax liability.

On May 28, 2010, we acquired the European marketing rights to several animal health product lines divested by Pfizer Inc. as part of its acquisition of Wyeth, Inc., for total purchase consideration of \$148.4 million in cash. These products, including vaccines, parasiticides, and feed additives, serve both the production animal and companion animal markets. We also acquired a manufacturing facility in Sligo, Ireland, currently used in the production of animal vaccines. This acquisition has been accounted for as business combination and we recorded \$76.2 million of developed product technology. This acquisition was not material to our consolidated financial statements.

#### Product Acquisition

In March 2010, we entered into a license agreement with Acrux Limited to acquire the exclusive rights to commercialize its proprietary testosterone solution Axiron®. At the time of the licensing, the product had not been approved and had no alternative future use. The charge of \$50.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2010 and is deductible for tax purposes. In the fourth quarter of 2010, Axiron was approved by the FDA for the treatment of testosterone deficiency in men. In the first quarter of 2011, the product was available in pharmacies in the U.S. In connection with this arrangement, our partner is entitled to future milestones and royalties based on sales.

#### 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,	
	2011	2010	2011	2010
	(Dollars in millions)			
Net product sales	\$ 5,971.7	\$ 5,486.8	\$ 17,748.1	\$ 16,408.6
Collaboration and other revenue	176.2	168.0	491.8	480.4
<b>Total revenue</b>	<b>\$ 6,147.9</b>	<b>\$ 5,654.8</b>	<b>\$ 18,239.9</b>	<b>\$ 16,889.0</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Net product sales	\$ 16.2	\$ 18.5	\$ 61.2	\$ 56.9
Collaboration and other revenue	81.1	76.9	240.1	234.7
<b>Total revenue</b>	<b>\$ 97.3</b>	<b>\$ 95.4</b>	<b>\$ 301.3</b>	<b>\$ 291.6</b>

## Edgar Filing: LILLY ELI & CO - Form 10-Q

### *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 and co-promoting Erbitux in the U.S. and Canada with BMS, exclusively, and in Japan with BMS and Merck KGaA. 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 KGaA (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 also 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 supply of product; for research and development; and for marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. Royalty expense paid to third parties, net of any royalty reimbursements received, is recorded as a reduction of collaboration and other revenue.

#### 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 U.S. 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.

#### Exenatide

We are in a collaborative arrangement with Amylin Pharmaceuticals (Amylin) for the joint development, marketing, and selling of Byetta<sup>®</sup> (exenatide injection) and other forms of exenatide such as exenatide once weekly (tradename Bydureon ). We and Amylin are co-promoting Byetta in the U.S. Amylin is responsible for manufacturing and primarily utilizes third-party contract manufacturers to supply Byetta. However, we are manufacturing Byetta pen delivery devices for Amylin. We are responsible for development and commercialization costs outside the U.S.

Under the terms of our arrangement, we report as collaboration and other revenue our 50 percent share of gross margin on Amylin's net product sales in the U.S. We report as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. We pay Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs are recorded in cost of sales. 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 record 50 percent of U.S. research and development costs and marketing and selling costs in the respective line items on the consolidated condensed statements of operations.

A New Drug Application (NDA) has been submitted to the FDA for Bydureon. In October 2010, we received a complete response letter from the FDA and in July 2011 we submitted a reply. The FDA has assigned a new Prescription Drug User Fee Act (PDUFA) action date of January 28, 2012.

In June 2011, the European Commission granted marketing authorization to Bydureon for the once-weekly treatment of type 2 diabetes in combination with certain oral therapies. European launches have begun, starting with the United Kingdom and Germany. Launches in other European countries are expected over the course of 2011 and 2012. Net product sales of Bydureon have not been significant to date.

Edgar Filing: LILLY ELI & CO - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Net product sales	\$ 46.4	\$ 39.1	\$ 131.9	\$ 126.0
Collaboration and other revenue	60.3	63.6	180.5	199.3
<b>Total revenue</b>	<b>\$ 106.7</b>	<b>\$ 102.7</b>	<b>\$ 312.4</b>	<b>\$ 325.3</b>

Amylin is constructing and will operate a manufacturing facility for Bydureon, and we have entered into a supply agreement in which Amylin will supply Bydureon product to us for sales outside the U.S. The estimated total cost of the facility is approximately \$550 million. In 2008, we paid \$125.0 million to Amylin, which we are amortizing to cost of sales over the estimated life of the supply agreement. We would be required to reimburse Amylin for a portion of any future impairment of this facility, recognized in accordance with GAAP. A portion of the \$125.0 million payment we made to Amylin would be creditable against any amount we would owe as a result of impairment. In accordance with the arrangement and pursuant to Amylin's request, in the second quarter of 2011 we loaned Amylin \$165.0 million. Interest on this loan is to be received quarterly and all outstanding principal and interest is due three years from the date of the advance. We have also agreed to cooperate with Amylin in the development, manufacturing, and marketing of Bydureon in a dual-chamber cartridge pen configuration. We will contribute 60 percent of the total initial capital costs of the project, our portion of which will be approximately \$130 million. As of September 30, 2011, we have contributed approximately \$105 million.

Cymbalta®

We were in a collaborative arrangement with Boehringer Ingelheim (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 condensed consolidated 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 2012 as consideration for the rights acquired. We record these costs as intangible assets, which will be amortized to marketing, selling, and administrative expenses using the straight-line method over the life of the original agreement, which is through 2015.

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote Effient. Within this arrangement, 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. Worldwide Effient sales were \$83.5 million and \$36.3 million in the quarters ended September 30, 2011 and 2010, respectively, and \$211.5 million and \$67.9 million in the nine months ended September 30, 2011 and 2010, respectively.

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 (BI 10773). 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 two basal insulin analogues, LY2963016





(began Phase III clinical testing in the third quarter of 2011) and LY2605541 (expected to begin Phase III clinical testing in the fourth quarter 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 approximately 300 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 basal insulin analogues. 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 equally 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. Revenues related to this collaboration have not been significant to date.

#### TPG-Axon Capital

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby both we and TPG were obligated to fund the Phase III development of solanezumab. Under the agreement, TPG's obligation to fund solanezumab costs was not material and did not extend beyond the first half of 2011. In exchange for its 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. Reimbursements received from TPG for its portion of research and development costs incurred were recorded as a reduction to the research and development expense line item on the consolidated condensed statements of operations. The reimbursement from TPG was not material in any period.

#### 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 \$58.6 million and \$35.6 million in the quarters ended September 30, 2011 and 2010, respectively, and \$155.5 million and \$132.2 million in the nine months ended September 30, 2011 and 2010, respectively.

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

We recognized restructuring charges of \$25.2 million and \$233.8 million in the third quarter and first nine months of 2011, respectively, and \$59.5 million and \$113.0 million in the third quarter and first nine months of 2010, respectively, as a result of the 2009 initiative to reorganize global operations, streamline various functions of the business, and reduce the number of total employees as well as other previously announced strategic actions to reduce our cost structure and global workforce. These charges primarily related to severance costs, which have either been paid or are expected to be paid in 2011 or 2012. We anticipate additional charges during the remainder of 2011 relating to these previously announced initiatives and strategic decisions.

#### 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 put in place using the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other net, expense (income). 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, 2011, we had outstanding foreign currency forward commitments to purchase 1.13 billion U.S. dollars and sell 822.5 million euro, commitments to purchase 854.7 million euro and sell 1.17 billion U.S. dollars, and commitments to purchase 293.2 million British pounds and sell 336.7 million euro, which will settle within 35 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, 2011, approximately 90 percent of our total debt is at a fixed rate. We have converted approximately 70 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 Statement of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
<b>Fair value hedges</b>				
Effect from hedged fixed-rate debt	\$ 245.4	\$ 122.5	\$ 255.7	\$ 359.2
Effect from interest rate contracts	(245.4)	(122.5)	(255.7)	(359.2)
<b>Cash flow hedges</b>				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.3	2.2	6.7	6.7
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	(51.7)	20.3	(1.0)	(26.1)



## Edgar Filing: LILLY ELI & CO - Form 10-Q

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.

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

During the three months and nine months ended September 30, 2011 and 2010, net losses related to ineffectiveness and net losses related to the portion of our risk-management hedging instruments, fair value and cash flow hedges 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, 2011 and December 31, 2010 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			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>September 30, 2011</b>						
Cash and cash equivalents	\$ 6,597.7	\$ 6,597.7	\$ 4,378.7	\$ 2,219.0	\$	\$ 6,597.7
<b>Short-term investments</b>						
U.S. government and agencies	\$ 55.6	\$ 55.5	\$ 55.6	\$	\$	\$ 55.6
Corporate debt securities	118.8	118.9		118.8		118.8
Other debt securities	12.2	12.2		12.2		12.2
<b>Short-term investments</b>	<b>\$ 186.6</b>	<b>\$ 186.6</b>				
<b>Noncurrent investments</b>						
U.S. government and agencies	\$ 420.5	\$ 413.0	\$ 420.5	\$	\$	\$ 420.5
Corporate debt securities	1,602.7	1,621.4		1,602.7		1,602.7
Mortgage-backed	556.9	587.1		556.9		556.9
Asset-backed	254.7	262.1		254.7		254.7
Other debt securities	27.5	30.4		26.0	1.5	27.5
Marketable equity	184.1	131.5	184.1			184.1
Equity method and other investments <sup>(1)</sup>	173.2	173.2				
<b>Investments</b>	<b>\$ 3,219.6</b>	<b>\$ 3,218.7</b>				
<b>December 31, 2010</b>						
Cash and cash equivalents	\$ 5,993.2	\$ 5,993.2	\$ 2,138.6	\$ 3,854.6	\$	\$ 5,993.2

Edgar Filing: LILLY ELI & CO - Form 10-Q

<b>Short-term investments</b>					
Commercial paper	\$ 540.8	\$ 540.8	\$	\$ 540.8	\$ 540.8
U.S. government and agencies	128.9	128.9	128.9		128.9
Corporate debt securities	63.4	63.9		63.4	63.4
Other securities	0.7	0.7		0.7	0.7
Short-term investments	\$ 733.8	\$ 734.3			
<b>Noncurrent investments</b>					
U.S. government and agencies	\$ 359.2	\$ 361.8	\$ 359.2	\$	\$ 359.2
Corporate debt securities	367.9	368.9		367.9	367.9
Mortgage-backed	315.5	350.7		315.5	315.5
Asset-backed	132.4	140.8		132.4	132.4
Other debt securities	6.4	8.3		3.3	3.1
Marketable equity	433.7	182.6	433.7		433.7
Equity method and other investments <sup>(1)</sup>	164.4	164.4			
Investments	\$ 1,779.5	\$ 1,577.5			

<sup>(1)</sup> Fair value not applicable

Description	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2) (Dollars in millions)	Significant Unobservable Inputs (Level 3)	
<b>Long-term debt, including current portion</b>					
September 30, 2011	\$ (7,080.0)	\$	\$ (7,418.3)	\$	\$ (7,418.3)
December 31, 2010	\$ (6,788.7)	\$	\$ (7,030.0)	\$	\$ (7,030.0)

Edgar Filing: LILLY ELI & CO - Form 10-Q

Description	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>September 30, 2011</b>					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Other receivables	\$ 14.2	\$	\$ 14.2	\$	\$ 14.2
Sundry	519.7		519.7		519.7
Foreign exchange contracts not designated as hedging instruments					
Other receivables	10.3		10.3		10.3
Other current liabilities	(6.6)		(6.6)		(6.6)
Equity contracts designed as hedging instruments					
Other receivables	5.7		5.7		5.7
<b>December 31, 2010</b>					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Sundry	\$ 278.3		\$ 278.3		278.3
Foreign exchange contracts not designated as hedging instruments					
Other receivables	13.7		13.7		13.7
Other current liabilities	(31.6)		(31.6)		(31.6)
Equity contracts designed as hedging instruments					
Other current liabilities	(35.6)		(35.6)		(35.6)

The fair value of the contingent consideration liability related to prior acquisitions, a Level 3 measurement in the fair value hierarchy, was \$140.6 million and \$163.5 million as of September 30, 2011 and December 31, 2010, respectively.

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 \$2.3 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, 2011	December 31, 2010
	(Dollars in millions)	
Unrealized gross gains	\$ 78.1	\$ 262.6
Unrealized gross losses	77.2	61.1
Fair value of securities in an unrealized gain position	1,540.3	1,031.8
Fair value of securities in an unrealized loss position	1,646.8	758.1

## Edgar Filing: LILLY ELI & CO - Form 10-Q

Other-than-temporary impairment losses on fixed income securities of \$10.9 million and \$17.9 million were recognized in the statement of operations for the three and nine months ended September 30, 2011, respectively, compared with \$4.7 million and \$11.4 million for the same periods in 2010. 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 are composed of 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, 2011.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Proceeds from sales	\$ 775.7	\$ 59.9	\$ 1,274.2	\$ 427.6
Realized gross gains on sales	25.6	7.8	113.6	82.4
Realized gross losses on sales	2.5	1.6	7.6	3.9

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.

In April 2011, we entered into a \$1.20 billion revolving credit facility agreement to replace our facility that was to expire in May 2011. The new agreement expires in April 2015.

#### 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 \$36.5 million and \$46.8 million in the third quarter of 2011 and 2010, respectively. In the first nine months of 2011 and 2010, we recognized pretax stock-based compensation expense of \$110.7 million and \$175.2 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 periods. As of September 30, 2011, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$29.5 million, which will be amortized over the weighted-average remaining requisite service period of approximately 11 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, 2011, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$59.0 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, 2011, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to \$61.4 million, which will be amortized over the weighted-average remaining requisite service period of 23 months.

#### Note 8: Shareholders' Equity

As of September 30, 2011, we have purchased \$2.58 billion of our previously announced \$3.00 billion share repurchase program. During the first nine months of 2011, we did not acquire any shares pursuant to this program, nor do we expect any share repurchases under this program for the remainder of 2011.



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 IRS began its examination of tax years 2005-2007 during the third quarter of 2008. In the first quarter of 2010, we began the process of advancing the examination procedures to tax years 2008-2009 for certain matters under examination in the 2005-2007 audit cycle.

In the first quarter of 2011, we effectively settled the examinations of tax years 2005-2006. Additionally, in the first quarter of 2011, we advanced the audit of 2007 and certain matters related to tax years 2008-2009. Considering the current status of the 2007 audit and those matters related to 2008-2009, as well as the effective settlement of the audit of tax years 2005-2006, our gross unrecognized tax benefits were reduced by approximately \$200 million in the first quarter of 2011, and our consolidated results of operations benefited from an immaterial reduction in income tax expense. During the second and third quarters of 2011, we made cash payments of approximately \$180 million for tax years 2005-2006.

In the third quarter of 2011, we effectively settled the IRS examination of 2007 and certain matters related to tax years 2008-2009. The examination of the remainder of 2008-2009 will commence in the fourth quarter of 2011. Considering this next examination cycle, as well as the effective settlement of 2007 and certain matters related to 2008-2009, we reduced our gross unrecognized tax benefits by approximately \$260 million in the third quarter of 2011. Our consolidated results of operations benefited from a reduction in tax expense of approximately \$45 million in the third quarter, and we made a cash payment of approximately \$120 million related to this settlement.

The U.S. health care legislation (both the primary Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act) eliminated the tax-free nature of the subsidy we receive for sponsoring retiree drug coverage that is actuarially equivalent to Medicare Part D. This provision is effective January 1, 2013. While this change has a future impact on our net tax deductions related to retiree health benefits, we were required to record a one-time charge to adjust our deferred tax asset for this change in the law in the quarter of enactment. Accordingly, we recorded a non-cash charge of \$85.1 million in the first quarter of 2010.

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,	
	2011	2010	2011	2010
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 57.7	\$ 54.7	\$ 174.7	\$ 165.5
Interest cost	111.8	107.9	335.8	323.7
Expected return on plan assets	(171.9)	(158.8)	(515.2)	(476.4)
Amortization of prior service cost	2.2	1.7	6.9	5.0
Recognized actuarial loss	50.4	41.2	149.2	123.5
Net periodic benefit cost	\$ 50.2	\$ 46.7	\$ 151.4	\$ 141.3

	Retiree Health Benefit Plans	
	Three Months Ended September 30,	Nine Months Ended September 30,

Edgar Filing: LILLY ELI & CO - Form 10-Q

	2011	2010	2011	2010
	(Dollars in millions)			
<b>Components of net periodic benefit cost</b>				
Service cost	\$ 14.4	\$ 14.1	\$ 43.1	\$ 42.2
Interest cost	29.5	30.3	88.6	90.2
Expected return on plan assets	(31.9)	(30.6)	(95.7)	(92.0)
Amortization of prior service cost	(10.7)	(9.3)	(32.2)	(27.9)
Recognized actuarial loss	22.2	21.3	66.5	63.8
<b>Net periodic benefit cost</b>	<b>\$ 23.5</b>	<b>\$ 25.8</b>	<b>\$ 70.3</b>	<b>\$ 76.3</b>

On a global basis, we have contributed to our defined benefit pension plans in 2011 substantially all of the \$80 million required to satisfy minimum funding requirements. In addition, we have contributed approximately \$250 million of discretionary funding in the aggregate to several of our global post-retirement benefit plans in 2011. We do not anticipate making any substantial contributions during the remainder of the year.

#### 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 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 the following U.S. patent litigation matters brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

**Alimta<sup>®</sup>:** 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. The generic manufacturers have appealed this decision.

**Strattera<sup>®</sup>:** Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun Ltd.), and Teva USA each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent and data-based pediatric exclusivity period (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun Ltd., and Teva USA in the U.S. District Court for the District of New Jersey. In August 2010, the court ruled that our patent was invalid; however, in July 2011, the Court of Appeals for the Federal Circuit overturned this decision, upholding the patent. The Federal Circuit Court of Appeals denied the generic manufacturers' petition for rehearing en banc in October 2011. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals in the Actavis case.

We believe the Hatch-Waxman challenges to Alimta and Strattera 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 in either of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect a loss of exclusivity in the cases described above would result in a rapid and severe decline in future revenues in the relevant market.

#### Zyprexa<sup>®</sup> Litigation

We are a defendant in approximately 40 Zyprexa product liability lawsuits in the U.S. covering approximately 110 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. Approximately 25 of the lawsuits, covering about 15 plaintiffs, are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596). A jury trial began in October 2011 in a California state court. We are waiting for a decision. We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

## Edgar Filing: LILLY ELI & CO - Form 10-Q

We were served with lawsuits filed by 13 states alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. We settled the Zyprexa-related claims of all of these states, incurring pretax charges of \$230.0 million in 2009 and \$15.0 million in 2008.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which made or will make payments for their members or insured patients being prescribed Zyprexa. These actions were consolidated into a single lawsuit, brought under certain state consumer-protection statutes, the federal civil Racketeer Influenced and Corrupt Organizations Act, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers, and denied our motion for summary judgment. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs' overpricing claim. The U.S. Supreme Court denied plaintiffs' request for review of the Second Circuit decision. The case has now been remanded back to Judge Weinstein for further proceedings on potential individual third-party payor claims.

### Byetta Litigation

We have been named as a defendant in approximately 115 lawsuits involving approximately 430 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 480 additional claimants who have not yet filed suit. Approximately 90 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court, and we expect a trial with a group of these claimants to be scheduled in that court in January 2012.

### Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol. These claims are covered by insurance, subject to deductibles and coverage limits.

### 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 for other products 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. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

### Note 13: Other - Net, Expense (Income)

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Interest expense	\$ 45.0	\$ 47.2	\$ 135.9	\$ 142.3
Interest income	(22.2)	(16.3)	(55.5)	(37.9)
Other	60.6	(9.2)	71.8	(138.8)
Other-net, expense (income)	\$ 83.4	\$ 21.7	\$ 152.2	\$ (34.4)

Other expense for third quarter of 2011 is primarily 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.

## Edgar Filing: LILLY ELI & CO - Form 10-Q

Other expense for 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 April 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.

Other income for the first nine months of 2010 is primarily related to damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany and gains related to the disposition of investment securities.

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

### Operating Results

#### Executive Overview

#### Financial Results

Our worldwide revenue increased 9 percent and 8 percent to \$6.15 billion and \$18.24 billion for the third quarter and first nine months of 2011, respectively, driven primarily by the increase in revenue related to the collective growth of Cymbalta, animal health products, Humalog<sup>®</sup>, Alimta, Cialis<sup>®</sup>, and, for the first nine months of 2011, Zyprexa, offset by a decline in Gemzar<sup>®</sup> revenue. This revenue growth, as well as a lower effective tax rate, was more than offset by lower gross margin percentage; increased marketing, selling, and administrative costs; higher other expense, and the 2011 items noted below. As a result, net income for the third quarter and the first nine months of 2011 decreased 5 percent and 11 percent, to \$1.24 billion and \$3.49 billion, respectively, compared with the same periods of 2010. Earnings per share for the third quarter and the first nine months of 2011 decreased 6 percent and 11 percent to \$1.11 per share and \$3.13 per share, respectively, compared with the same periods of 2010.

#### 2011

As a result of higher rebates and subsidies included in the enactment of health care reform in the U.S. during 2010, total revenue was reduced by \$128.5 million (pretax), or \$.09 per share, in the third quarter and \$328.8 million (pretax), or \$.23 per share, in the first nine months of 2011. Marketing, selling, and administrative charges increased by \$44.8 million (pretax), or \$.04 per share, in the third quarter and \$134.3 million (pretax), or \$.12 per share, in the first nine months of 2011, as a result of the mandatory pharmaceutical manufacturers' fee.

We incurred acquired IPR&D charges in the first quarter associated with the diabetes collaboration with Boehringer Ingelheim of \$388.0 million (pretax), which decreased earnings per share by \$.23.

We recognized restructuring charges of \$25.2 million (pretax), or \$.02 per share in the third quarter, and \$233.8 million (pretax), or \$.18 per share, for the first nine months of 2011, respectively, primarily related to severance costs from previously announced strategic actions that we are taking to reduce our cost structure and global workforce.

#### 2010

As a result of higher rebates included in the enactment of health care reform in the U.S. during 2010, total revenue was reduced by \$23.8 million (pretax), or \$.02 per share, in the third quarter and \$157.5 million (pretax), or \$.11 per share, for the first nine months of 2010. We also recorded a one-time non-cash charge in the first quarter of \$85.1 million, or \$.08 per share, associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan.

We incurred acquired IPR&D charges associated with the Axiron in-licensing arrangement of \$50.0 million (pretax), which decreased earnings per share by \$.03 in the first quarter.

We recognized restructuring charges of \$59.5 million (pretax), or \$.03 per share, in the third quarter, and \$113.0 million (pretax), or \$.07 per share, for the first nine months of 2010, respectively, primarily related to severance and other related costs from previously announced strategic actions.

#### Late-Stage Pipeline



## Edgar Filing: LILLY ELI & CO - Form 10-Q

Our long-term success depends to a great extent on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies. We currently have approximately 65 potential new drugs in human testing and a larger number of projects in preclinical development.

There are many difficulties and uncertainties inherent in pharmaceutical research and development 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 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 research and development spending across our portfolio of molecules, and a delay in, or termination of, one project will not by itself necessarily cause a significant change in our total research and development spending. Due to the risks and uncertainties involved in the research and development process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our research and development projects, nor can we reliably estimate the future potential revenue that will be generated from a successful research and development project. Each project represents only a portion of the overall pipeline and none is individually material to our consolidated research and development expense. While we do accumulate certain research and development 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 research and development 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:

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

**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-BI10773 (Q3 2010)** an 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

**LY2963016\* (Q3 2011)** a new insulin glargine product for the treatment of type 1 and type 2 diabetes

**Necitumumab\* (Q4 2009)** a fully human monoclonal antibody for the treatment of squamous non-small cell lung cancer (NSCLC)

**Pomaglumetad Methionil (Q1 2011)** an agonist metabotropic glutamate 2/3 (mGlu 2/3) receptor for the treatment of schizophrenia

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

**Solanezumab\* (Q2 2009)** an amyloid beta (A $\beta$ ) antibody for the treatment of Alzheimer's disease.

The following NMEs have been submitted for regulatory review for potential use in the disease described. The quarter the NME initially was submitted for any indication is shown in parentheses:

**Arxxant (Q1 2006)** a treatment for diabetic retinopathy

**Florbetapir (Q3 2010)** a molecular imaging tool for the detection of beta-amyloid plaque in the brain

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

\* Biological product

The following late-stage pipeline developments have occurred since January 1, 2011:

**Bydureon.** In June, the European Commission granted marketing authorization for Bydureon, the first once-weekly treatment for type 2 diabetes in combination with certain oral therapies. European launches have begun, starting with the United Kingdom and Germany. Launches in other European countries are expected over the course of 2011 and 2012. In July 2011, we submitted a reply to the FDA complete response letter and the FDA assigned a new PDUFA action date of January 28, 2012.

## Edgar Filing: LILLY ELI & CO - Form 10-Q

**Linagliptin and empagliflozin.** In January, we announced a global agreement with Boehringer Ingelheim (Boehringer) to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development, including Boehringer's two investigational oral diabetes agents, linagliptin and empagliflozin. In 2011, linagliptin was approved and launched in the U.S. (tradename Tradjenta), Japan (tradename Trazenta), Europe (tradename Trajenta), and other countries. Tradjenta is protected by a compound patent in the U.S. that expires in 2023. Boehringer has applied for a patent term extension to 2025.

**Florbetapir.** In March, we received a complete response letter from the FDA for the NDA for Amyvid (florbetapir) that was primarily focused on the need to establish a reader training program for market implementation that helps to ensure reader accuracy and consistency of interpretations of existing Amyvid scans. We submitted our response to the FDA's complete response letter.

**LY2963016.** In September, we began the first Phase III clinical trial for LY2963016.

**Liprotamase.** In April, we received a complete response letter from the FDA for the NDA for liprotamase that communicated the need for us to conduct an additional clinical trial prior to a re-submission. We are working diligently to address the agency's questions.

**Pomaglumetad Methionil.** In February, we began the first Phase III clinical trial for pomaglumetad methionil.

**Necitumumab.** In February, we and Bristol-Myers Squibb Company stopped enrollment in one of the two global Phase III studies. The decision to stop enrollment in the Phase III non-squamous NSCLC INSPIRE trial (combination treatment with Alimta) followed an independent Data Monitoring Committee recommendation that no new or recently enrolled patients continue treatment in the trial because of safety concerns related to thromboembolism (blood clots) in the experimental arm of the study. The second Phase III study in squamous NSCLC looking at the combination use of necitumumab with Gemzar is continuing.

#### Legal, Regulatory, and Other Matters

In October 2011, we announced the withdrawal of our Xigris® [drotrecogin alfa (activated)] product in all markets following results of the PROWESS-SHOCK study, which showed the study did not meet the primary endpoint of a statistically significant reduction in 28-day all-cause mortality in patients with septic shock. We are working with regulatory agencies on this withdrawal, and we are in the process of notifying health care professionals and clinical trial investigators. We expect to incur a charge in the fourth quarter of 2011 for asset impairments and contractual commitments related to Xigris. The exact amount of the charge has not yet been determined, but is estimated to be in the range of \$75.0 million to \$95.0 million (pre-tax), or approximately \$.05 per share (after tax). Revenue related to Xigris has not been material to our consolidated condensed financial statements.

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. Challenges to the constitutionality of the PPACA are working their way through the courts and are expected ultimately to be decided by the U.S. Supreme Court.

Changes to the rebates for prescription drugs sold to Medicaid beneficiaries, which increase the minimum statutory rebate for branded drugs from 15.1 percent to 23.1 percent, became effective in the first quarter of 2010. This rebate has been expanded to managed Medicaid, a program that provides for the delivery of Medicaid benefits via managed care organizations, under arrangements between those organizations and state Medicaid agencies. Additionally, a prescription drug discount program for outpatient drugs in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities) has been expanded.

Beginning in 2011, drug manufacturers are providing a discount of 50 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the doughnut hole (the coverage gap in Medicare prescription drug coverage). The doughnut hole will be phased out by the federal government between 2011 and 2020. Additionally, beginning in 2011, a non-tax-deductible annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. This fee is allocated to companies based on their prior-calendar-year market share for branded prescription drug sales into these government programs. These costs are included in marketing, selling, and administrative expense in our consolidated condensed statement of operations.

Also, there are changes to the tax treatment of subsidies paid by the government to employers, such as us, who provide their retirees with a drug benefit at least equivalent to the Medicare Part D drug benefit. Beginning in 2013, the federal government will tax the subsidy it provides to such employers. While this tax will not take effect for two more years, accounting rules dictated that we adjust our deferred tax asset through a one-time non-cash charge upon enactment of the tax law change, which we recorded in the first quarter of 2010.

Recent efforts to address the U.S. budget deficits increase the risk that rebates or other measures that would reduce pharmaceutical companies' revenue may be enacted. The Budget Control Act created a Super Committee comprised of members of the Congress tasked with identifying budget cuts totaling \$1.2 trillion. Certain other federal and state health care proposals continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These proposals include various cost-control strategies. We expect pricing pressures at state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.



Edgar Filing: LILLY ELI & CO - Form 10-Q

The Obama Administration continues to suggest changes to the manner in which the U.S. would tax the international income of U.S.-based companies. 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, continues 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. On October 25, 2010, Puerto Rico enacted income and excise tax legislation affecting our operations. This tax is included in costs of sales in our consolidated condensed statement of operations. We believe this tax should be creditable against our U.S. income taxes. International operations also are generally subject to extensive price and market regulations, and several European countries have recently required either price decreases or rebate increases in response to economic pressures. There are proposals for cost-containment measures pending in a number of additional 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 effect of the downturn in the global economy on local governments.

Revenue

Revenue for the third quarter and the first nine months of 2011 increased 9 percent and 8 percent to \$6.15 billion and \$18.24 billion, respectively, driven primarily by the collective growth of Cymbalta, animal health products, Humalog, Alimta, Cialis, and, for the first nine months of 2011, Zyprexa, offset by a decline in Gemzar revenue. For the third quarter, worldwide sales volume increased 4 percent and the favorable impact of foreign exchange rates contributed 4 percent of revenue growth (numbers do not add due to rounding). For the first nine months of 2011, worldwide sales volume increased 5 percent and the favorable impact of foreign exchange rates contributed 3 percent of revenue growth. Reflecting the loss of U.S. patent exclusivity for Gemzar in November 2010, price had a negligible impact on revenue growth for both the third quarter and first nine months of 2011. Revenue in the U.S. increased by \$123.0 million, or 4 percent, and \$250.1 million, or 3 percent, for the third quarter and first nine months of 2011, respectively, compared with the same periods of 2010 due to higher prices offset in part by \$128.5 million and \$328.8 million in the third quarter and first nine months of 2011, respectively, in higher rebates and subsidies resulting from U.S. health care reform. Revenue growth in the U.S. also benefitted from increased volume. Revenue outside the U.S. increased \$370.1 million, or 15 percent, and \$1.10 billion, or 15 percent, for the third quarter and first nine months of 2011, respectively, compared with the same periods of 2010 due to increased demand and the positive impact of foreign exchange rates, partially offset by lower prices. The positive impact of foreign exchange rates was not as great for the nine-month period.

The following table summarizes our revenue activity for the three- and nine-month periods ended September 30, 2011 and 2010:

Product	Three Months Ended September 30, 2011			Three Months Ended September 30, 2010	Percent Change from 2010
	U.S. <sup>1</sup>	Outside U.S.	Total <sup>2</sup>	Total	
	(Dollars in millions)				
Zyprexa	\$ 563.2	\$ 619.1	\$ 1,182.3	\$ 1,212.7	(3)
Cymbalta	809.5	259.1	1,068.6	806.1	33
Alimta	258.9	370.8	629.7	560.3	12
Humalog	345.5	247.7	593.2	494.0	20
Cialis	168.2	301.6	469.8	406.5	16
Animal health products	237.9	213.2	451.0	353.3	28
Humulin®	142.6	158.9	301.5	278.0	8
Evista®	176.8	93.3	270.1	256.8	5
Forteo®	110.4	129.9	240.3	199.7	20
Strattera	96.3	56.8	153.2	127.9	20
Gemzar	(4.2)	95.1	91.0	324.6	(72)
Other pharmaceutical products	219.9	301.2	521.0	466.9	12
<b>Total net product sales</b>	<b>3,125.0</b>	<b>2,846.7</b>	<b>5,971.7</b>	<b>5,486.8</b>	<b>9</b>
Collaboration and other revenue <sup>3</sup>	148.5	27.7	176.2	168.0	5
<b>Total revenue</b>	<b>\$ 3,273.5</b>	<b>\$ 2,874.4</b>	<b>\$ 6,147.9</b>	<b>\$ 5,654.8</b>	<b>9</b>



Edgar Filing: LILLY ELI & CO - Form 10-Q

Product	Nine Months Ended September 30, 2011			Nine Months Ended September 30, 2010	Percent Change from 2010
	U.S. <sup>1</sup>	Outside U.S.	Total <sup>2</sup> (Dollars in millions)	Total	
Zyprexa	\$ 1,871.4	\$ 2,001.0	\$ 3,872.4	\$ 3,690.6	5
Cymbalta	2,259.1	721.7	2,980.8	2,477.0	20
Alimta	743.9	1,079.1	1,823.0	1,639.5	11
Humalog	990.9	714.6	1,705.5	1,505.1	13
Cialis	506.3	875.1	1,381.4	1,233.5	12
Animal health products	658.6	551.7	1,210.4	967.1	25
Humulin	418.0	485.1	903.2	801.0	13
Evista	525.5	274.3	799.7	757.9	6
Forteo	332.3	355.0	687.3	603.8	14
Strattera	280.9	168.6	449.5	421.3	7
Gemzar	72.3	287.2	359.5	905.8	(60)
Other pharmaceutical products	647.2	928.3	1,575.4	1,406.0	12
<b>Total net product sales</b>	<b>9,306.4</b>	<b>8,441.7</b>	<b>17,748.1</b>	<b>16,408.6</b>	<b>8</b>
Collaboration and other revenue <sup>3</sup>	389.6	102.2	491.8	480.4	2
<b>Total revenue</b>	<b>\$ 9,696.0</b>	<b>\$ 8,543.9</b>	<b>\$ 18,239.9</b>	<b>\$ 16,889.0</b>	<b>8</b>

<sup>1</sup> U.S. revenue includes revenue in Puerto Rico.

<sup>2</sup> Numbers may not add due to rounding.

<sup>3</sup> Collaboration and other revenue is primarily composed of Erbitux royalties and 50 percent of Byetta's gross margin in the U.S.

Product Highlights

Zyprexa is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. Zyprexa sales in the U.S. decreased 7 percent and increased 2 percent in the third quarter and first nine months of 2011, respectively, with the third quarter decrease driven by lower volume, partially offset by higher net effective selling prices. The increase during the first nine months of 2011 was driven by higher prices, partially offset by lower volume. Sales outside the U.S. increased 2 percent and 7 percent, respectively, compared with the same periods of 2010 driven primarily by the favorable impact of foreign exchange rates, and, for the third quarter, partially offset by lower prices and lower volume. We lost effective exclusivity for Zyprexa in the U.S. on October 23, 2011. In the five major European countries, which in the aggregate had approximately \$240 million and \$810 million in sales in the third quarter and first nine months of 2011, respectively, we lost effective exclusivity in Spain in April 2011 and in France, Germany, Italy, and the United Kingdom in September 2011. Several manufacturers have launched generic olanzapine in these markets, including in the U.S. While it is difficult to predict the precise magnitude of the impact on Zyprexa sales, we expect the introduction of generics to result in a rapid and severe decline in our Zyprexa sales, which will have a material adverse effect on future results of operations and cash flows. In Japan, our second-largest market for Zyprexa, with approximately \$135 million and \$390 million of sales in the third quarter and first nine months of 2011, respectively, our patent expires in December 2015.

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 26 percent and 13 percent during the third quarter and first nine months of 2011, respectively. The increases were driven by increased prices and higher demand. Sales outside the U.S. increased 59 percent and 52 percent during the third quarter and first nine months of 2011, respectively, compared with the same periods in 2010, driven primarily by increased demand in international markets and, to a lesser extent, the favorable impact of foreign exchange rates.

U.S. sales of Alimta, a treatment for various cancers, increased 5 percent and 3 percent during the third quarter and first nine months of 2011, driven by increased demand, and, to a lesser extent for the first nine months of 2011, higher prices. Sales outside the U.S. increased 18 percent



## Edgar Filing: LILLY ELI & CO - Form 10-Q

for both the third quarter and first nine months of 2011, respectively, due to the favorable impact of foreign exchange rates as well as increased demand, and, to a lesser extent for the first nine months of 2011, higher prices.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 20 percent and 10 percent for the third quarter and first nine months of 2011, respectively, driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 21 percent and 18 percent for the third quarter and first nine

months of 2011, respectively, with the third quarter increase due to the favorable impact of foreign exchange rates, as well as increased demand. The increase in the first nine months of 2011 is due to increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction (also approved in October 2011 for benign prostatic hyperplasia in the U.S.), increased 10 percent and 8 percent for the third quarter and first nine months of 2011, respectively, with changes driven by higher prices. Sales outside the U.S. increased 19 percent and 14 percent during the third quarter and first nine months of 2011, respectively, driven by the favorable impact of foreign exchange rates and, to a lesser extent, higher prices and increased demand.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 18 percent and 19 percent during the third quarter and first nine months of 2011, respectively, driven primarily by higher prices for Humulin, as well as increased demand for Humulin® ReliOn. Sales outside the U.S. increased 1 percent and 8 percent during the third quarter and first nine months of 2011, respectively, with the third quarter increase driven by the favorable impact of foreign exchange rates, offset by lower prices. The increase during the first nine months is due to increased volume and the favorable impact of foreign exchange rates, partially offset by lower prices.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, increased 6 percent and 5 percent during the third quarter and first nine months of 2011, respectively, driven by higher prices, partially offset by lower volume. Sales outside the U.S. increased 3 percent and 6 percent for the third quarter and first nine months of 2011, respectively, driven by the favorable impact of foreign exchange rates, partially offset by lower prices.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men, decreased 7 percent and 9 percent during the third quarter and first nine months of 2011, respectively, due to decreased demand, partially offset by higher prices in the first nine months of 2011. Sales outside the U.S. increased 60 percent and 50 percent for the third quarter and the first nine months of 2011, respectively, due primarily to increased demand resulting from the recent launch in Japan, and, to a lesser extent, the favorable 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. adults, increased 13 percent and decreased 3 percent during the third quarter and first nine months of 2011, respectively, with the third quarter increase due to higher prices and increased volume. The decrease during the first nine months of 2011 was due to decreased demand and lower net effective selling prices. Sales outside the U.S. increased 33 percent and 27 percent for the third quarter and first nine months of 2011, respectively, driven primarily by higher demand in international markets including Japan and, to a lesser extent the favorable impact of foreign exchange rates.

U.S. sales of Gemzar, a product approved to treat various cancers, decreased 102 percent and 88 percent during the third quarter and first nine months of 2011, respectively, due to a rapid and severe decline in sales as a result of generic competition, which began in November 2010, following the expiration of the compound patent. Sales outside the U.S. decreased 9 percent and 11 percent for the third quarter and first nine months of 2011, respectively, due primarily to generic competition in most major markets. We expect sales to continue to decline in 2011.

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 increased 2 percent, to \$97.2 million, and 3 percent, to \$301.3 million, during the third quarter and first nine months of 2011, respectively.

We are in a collaborative arrangement with Amylin for the joint development, marketing, and selling of Byetta (exenatide injection) and other forms of exenatide such as exenatide once weekly (tradenname Bydureon), for the treatment of type 2 diabetes. Worldwide sales of exenatide increased 1 percent, to \$171.0 million, and decreased 5 percent, to \$507.6 million, during the third quarter and first nine months of 2011, respectively, with the decrease in the first nine months of 2011 due to competitive pressures in the U.S. We report as revenue our 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta and Bydureon sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues increased 4 percent, to \$106.7 million, and decreased 4 percent, to \$312.4 million, during the third quarter and first nine months of 2011, respectively.

Animal health product sales in the U.S. increased 20 percent and 22 percent during the third quarter and first nine months of 2011, respectively, due to increased demand for food animal products and the recent U.S. launch of Trifexis, a monthly oral parasiticide for dogs. Sales outside the U.S. increased 37 percent and 29 percent during the third quarter and first nine months of 2011, respectively, driven by the impact of the acquisition of certain Janssen and Pfizer animal health assets in Europe, and to a lesser extent the favorable impact of foreign exchange rates and increased demand.

---

Gross Margin, Costs, and Expenses

For the third quarter and first nine months of 2011, respectively, gross margins as a percentage of total revenue decreased by 4.3 percentage points, to 78.2 percent, and 1.9 percentage points, to 79.5 percent. These decreases were primarily due to the impact of foreign exchange rates on inventories sold during the third quarter and first nine months of 2011, which increased cost of sales in those periods of 2011, but decreased cost of sales in the same periods of 2010.

Marketing, selling, and administrative expenses increased 13 percent, to \$1.92 billion and \$5.75 billion for the third quarter and first nine months of 2011, respectively. These increases were driven by the recently announced diabetes collaboration with Boehringer Ingelheim, as well as the effect of foreign exchange rates and marketing efforts to support launches of new products and new indications. In addition, higher administrative expenses in the U.S. included \$44.8 million and \$134.3 million for the third quarter and first nine months of 2011, respectively, related to the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform. Research and development expenses were \$1.28 billion and \$3.67 billion for the third quarter and first nine months of 2011, respectively. Compared with the same periods of 2010, research and development expenses grew 5 percent and 6 percent the third quarter and first nine months of 2011, respectively, due primarily to increased late-stage clinical trial costs, including costs relating to the diabetes collaboration with Boehringer Ingelheim.

Acquired IPR&D charges were \$388.0 million for first nine months of 2011, all of which were associated with the diabetes collaboration with Boehringer Ingelheim, compared with \$50.0 million for the same period in 2010. We incurred \$25.2 million and \$233.8 million of asset impairments, restructuring, and other special charges in the third quarter and first nine months of 2011, respectively, compared with \$59.5 million and \$113.0 million for the same periods in 2010. See Notes 3, 4, and 5 to the consolidated condensed financial statements for additional information.

Other net, expense (income) was a net expense of \$83.4 million and \$152.2 million for the third quarter and first nine months of 2011, respectively, compared to a net expense of \$21.7 million and other income of \$34.4 million for the same respective periods of 2010. The increase in the third quarter 2011 expense was driven primarily by the partial impairment of the acquired in-process research and development asset related to Amyvid. The increase in the first nine months of 2011 expense was driven by the partial impairment of the acquired in-process research and development assets related to liprotamase and Amyvid, partially offset by gains on the disposition of investment securities. Other income for the first nine months of 2010 was primarily related to damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany and gains related to the disposition of investment securities.

The effective tax rate was 17.7 percent and 19.0 percent in the third quarter and first nine months of 2011, respectively, compared with an effective tax rate of 22.0 percent and 23.8 percent in the third quarter and first nine months of 2010, respectively. The largest driver of the decrease in the third quarter was the recognition of an approximately \$45 million discrete benefit primarily as a result of the resolution of the federal income tax examination of 2007 and certain matters related to 2008-2009. In addition, the tax rate for the first nine months of 2010 was negatively affected by a one-time charge of \$85.1 million associated with the imposition of tax on the prescription drug subsidy of our retiree health plan as part of U.S. health care reform.

Financial Condition

As of September 30, 2011, cash, cash equivalents, and short-term investments totaled \$6.78 billion compared with \$6.73 billion at December 31, 2010. Cash, cash equivalents, and short-term investments increased slightly as cash flow from operations of \$5.29 billion was essentially offset by dividends paid of \$1.64 billion, net noncurrent investment activity of \$1.58 billion, acquisitions of \$1.30 billion, and net purchases of property and equipment of \$416.1 million.

Total debt as of September 30, 2011 increased by \$153.5 million compared with December 31, 2010, to \$7.08 billion, primarily due to the adjustment required to reflect the change in the fair value of hedged debt. Our current debt ratings from Standard & Poor's and Moody's remain AA- and A2, respectively.

As of the third quarter of 2011, the U.S. and global economies face strengthening headwinds and substantial volatility. U.S. economic data in the third quarter continued to disappoint, with Gross Domestic Product and payroll figures lower than expected. Given the increasing worries regarding the fragility of the economic recovery and the potential deterioration of the European sovereign debt situation, the Federal Reserve in the third quarter announced additional accommodative policy steps. Both domestically and abroad, high sovereign debt levels, sluggish growth, ratings downgrades, and ongoing fiscal deficits have spurred efforts at fiscal austerity. The threat of contagion from peripheral countries to larger core European countries has generated significant uncertainty and prompted officials to consider broader, more holistic solutions to stabilize the region. Given this backdrop, both private and public health care payers are facing heightened fiscal challenges and are taking steps to reduce the costs of care, including pressures for increased pharmaceutical discounts and rebates in the U.S., price cuts in government systems outside the U.S., and efforts to drive greater use of generic drugs globally. We continue to monitor the potential impacts of the economic environment on prescription trends, the creditworthiness of our wholesalers and other customers, including foreign government backed agencies, and suppliers, the uncertain impact of recent health care legislation, the federal government's involvement in the U.S. economy, and various international

government funding levels.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including debt service, capital expenditures, and dividends in 2011. We believe that amounts accessible through existing commercial paper markets will be adequate to fund short-term borrowings. Because of the high credit quality of our short- and long-term debt, our access to credit markets remains strong. 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 2011 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 effective exclusivity for the following key products:

Cymbalta June 2013 (U.S.)

Humalog May 2013 (U.S.)

Evista March 2014 (U.S.).

Cymbalta could receive an additional six months of exclusivity, based on completion of pediatric studies.

Zyprexa and Gemzar have already lost effective exclusivity in the U.S. and Europe. In the U.S. Gemzar lost effective exclusivity in November 2010 and Zyprexa lost effective exclusivity on October 23, 2011. Humalog is currently protected in Europe only by formulation patents, and to this point no company has received approval to market a biosimilar version of this compound. In addition, we face U.S. patent litigation over Alimta and Strattera, and it is possible we could lose our effective exclusivity for one or both of these products prior to the expiration of the relevant patents. See the Hatch-Waxman patent litigation discussion in Note 12 and in the Legal and Regulatory Matters section below. Revenue from Alimta, Cymbalta, and Humalog contributes materially to our results of operations, liquidity, and financial position. The loss of exclusivity for Alimta and Cymbalta would 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. We do not currently expect the loss of exclusivity for Humalog to result in a rapid and severe decline in revenue; however, it is difficult to predict the likelihood and impact of biosimilars entering the market. However, our goal is to partially mitigate the effect on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, in 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 new products in these markets.

#### Legal and Regulatory Matters

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 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 the following U.S. patent litigation matters brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

Alimta: 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. The generic manufacturers have appealed this decision.

## Edgar Filing: LILLY ELI & CO - Form 10-Q

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun Ltd.), and Teva USA each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent and data-based pediatric exclusivity period (expiring in 2017), and alleging that this patent is invalid. In 2007, we

brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun Ltd., and Teva USA in the U.S. District Court for the District of New Jersey. In August 2010, the court ruled that our patent was invalid; however, in July 2011, the Court of Appeals for the Federal Circuit overturned this decision, upholding the patent. The Federal Circuit Court of Appeals denied the generic manufacturers' petition for rehearing en banc in October 2011. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals in the Actavis case.

We believe the Hatch-Waxman challenges to Alimta and Strattera 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 in either of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect a loss of exclusivity in the cases described above would result in a rapid and severe decline in future revenues in the relevant market.

#### Zyprexa Litigation

We are a defendant in approximately 40 Zyprexa product liability lawsuits in the U.S. covering approximately 110 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. Approximately 25 of the lawsuits, covering about 15 plaintiffs, are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596). A jury trial began in October 2011 in a California state court. We are waiting for a decision. We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

We were served with lawsuits filed by 13 states alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. We settled the Zyprexa-related claims of all of these states, incurring pretax charges of \$230.0 million in 2009 and \$15.0 million in 2008.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which made or will make payments for their members or insured patients being prescribed Zyprexa. These actions were consolidated into a single lawsuit, brought under certain state consumer-protection statutes, the federal civil Racketeer Influenced and Corrupt Organizations Act, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers, and denied our motion for summary judgment. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs' overpricing claim. The U.S. Supreme Court denied plaintiffs' request for review of the Second Circuit decision. The case has now been remanded back to Judge Weinstein for further proceedings on potential individual third-party payor claims.

#### Byetta Litigation

We have been named as a defendant in approximately 115 lawsuits involving approximately 430 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 480 additional claimants who have not yet filed suit. Approximately 90 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court, and we expect a trial with a group of these claimants to be scheduled in that court in January 2012.

#### Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol. These claims are covered by insurance, subject to deductibles and coverage limits.

#### 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 for other products 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. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.





---

Financial Expectations for 2011

We have narrowed and lowered our 2011 earnings per share guidance to be in a range of \$3.84 to \$3.89, which includes the estimated Xigris asset impairment and contract termination charges. This guidance excludes potential future restructuring charges primarily related to severance and other related costs from previously announced strategic actions that we are taking to reduce our cost structure and global workforce. We still expect total revenue to grow in the mid-single digits, which assumes rapid and severe erosion of global Zyprexa sales after patent expirations in major markets, including the U.S. starting in October 2011, and the continued erosion of U.S. Gemzar sales. We expect these reductions in revenue to be offset by sales growth of Alimta, Cialis, Cymbalta, Effient, Humalog, and animal health products. We still anticipate that the impact of U.S. health care reform will lower 2011 revenue by \$400 million to \$500 million.

We still anticipate that gross margin as a percent of revenue will decline between two and three percentage points. Marketing, selling, and administrative expenses are still projected to grow in the high-single digits and include an estimated \$150 million to \$200 million in non-tax deductible expense for the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform, while research and development expense growth is still expected to be in the low single digits. Other net, expense is now expected to be a net expense of between \$175 million and \$225 million. Cash flows are expected to be sufficient to fund capital expenditures of approximately \$700 million, as well as anticipated business development activity and our dividend.

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 could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the implementation of U.S. health care reform; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired IPR&D charges; foreign exchange rates and global macroeconomic conditions; changes in effective tax rates; wholesaler inventory changes; other regulatory developments, litigation, patent disputes, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2010 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

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, 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, 2011, and concluded that they are effective.

- (b) *Changes in Internal Controls* . During the third quarter of 2011, 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 Part I, Item 2, Management's Discussion and Analysis, Legal and Regulatory Matters, for information on various legal proceedings, including but not limited to:

The U.S. patent litigation involving Alimta and Strattera

The Zyprexa product liability and related litigation, including claims brought on behalf of state Medicaid agencies and private healthcare payers

The Byetta product liability litigation.  
That information is incorporated into this Item by reference.

*Other Patent Litigation*

We have received challenges to Zyprexa patents in a number of countries outside the U.S. In June 2007, the Canadian Federal Court held that Novopharm Ltd.'s (Novopharm) challenge to the validity of our Zyprexa patent (expiring in 2011) was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novopharm suit, finding our patent invalid. However, in July 2010 the appeals court set aside the decision and remitted the limited issues of utility and sufficiency of disclosure to the trial court. These issues were heard by the trial court in January 2011, and we are waiting for a decision. In Australia, Apotex Pty. Ltd. has challenged the validity of our Zyprexa patent (expiring in March 2012). A trial was held in October 2011, and we are waiting for a ruling. We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation.

*Other Matters*

In May, Amylin filed a lawsuit against us in the U.S. District Court for the Southern District of California alleging various antitrust and unfair competition law violations as well as breach of contract. The lawsuit alleges that we are not using commercially reasonable efforts to support the success of Byetta and, ultimately, Bydureon. In the lawsuit, Amylin is seeking preliminary and permanent injunctive relief to impose restrictions on our diabetes sales force as well as damages and attorneys' fees. The district court declined to grant a preliminary injunction, and Amylin has appealed that decision to the Ninth Circuit Court of Appeals. The Ninth Circuit declined to enter an injunction pending the appeal and oral arguments in the appeal were heard in October 2011. We are waiting for a decision. The lawsuit will continue in the district court during pendency of the appeal. We believe the lawsuit has no merit and are prepared to defend against it vigorously.

*Employment Litigation*

We have also 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 collective 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 collective action at this time. Plaintiffs' appeal of the summary judgment ruling was heard in October 2011, and we are waiting for a ruling. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

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.

Edgar Filing: LILLY ELI & CO - Form 10-Q

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2011:

Period	Total		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)
	Number of Shares Purchased (a) (in thousands)	Average Price Paid per Share (b)	(in thousands)	(in millions)
July 2011		\$		\$ 419.2
August 2011				419.2
September 2011				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, 2011, we have purchased \$2.58 billion related to this program. During the first nine months of 2011, no shares were repurchased pursuant to this program, and we do not expect to purchase any shares under this program during the remainder of 2011.

#### Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 11.	Statement re: Computation of Earnings per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, 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 28, 2011

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

Date: October 28, 2011

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

Index to Exhibits

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

Exhibit

- |              |   |
|--------------|---|
| EXHIBIT 11.  | Statement re: Computation of Earnings per Share   |
| EXHIBIT 12.  | Statement re: Computation of Ratio of Earnings to Fixed Charges   |
| EXHIBIT 31.1 | Rule 13a-14(a) Certification of John C. Lechleiter, 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   |