

LILLY ELI & CO
Form 10-Q
July 29, 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 JUNE 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)
LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285

35-0470950
(I.R.S. Employer
Identification No.)

(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 July 20, 2011:

Class	Number of Shares Outstanding
Common	1,157,688,685

PART I. Financial Information*Item 1. Financial Statements*

Consolidated Condensed Statements of Operations

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
	(Dollars in millions, except per-share data)			
Revenue	\$ 6,252.8	\$ 5,748.7	\$ 12,092.0	\$ 11,234.2
Cost of sales	1,228.0	1,023.9	2,408.1	2,146.4
Research and development	1,260.6	1,187.2	2,384.6	2,226.3
Marketing, selling, and administrative	2,043.0	1,755.4	3,828.7	3,369.8
Acquired in-process research and development (Notes 3 and 4)			388.0	50.0
Asset impairments, restructuring, and other special charges (Note 5)	132.3	27.3	208.6	53.5
Other net, expense (income) (Note 13)	57.6	18.4	68.8	(56.1)
	4,721.5	4,012.2	9,286.8	7,789.9
Income before income taxes	1,531.3	1,736.5	2,805.2	3,444.3
Income taxes (Note 10)	334.0	387.6	552.0	847.3
Net income	\$ 1,197.3	\$ 1,348.9	\$ 2,253.2	\$ 2,597.0
Earnings per share basic and diluted (Note 9)	\$ 1.07	\$ 1.22	\$ 2.02	\$ 2.35
Dividends paid per share	\$.49	\$.49	\$.98	\$.98

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

	June 30, 2011	December 31, 2010
	(Dollars in millions)	
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	\$ 6,113.5	\$ 5,993.2
Short-term investments (Note 6)	216.3	733.8
Accounts receivable, net of allowances of \$116.0 (2011) and \$100.4 (2010)	3,833.6	3,493.8
Other receivables	612.9	664.3
Inventories	2,870.2	2,517.7
Prepaid taxes	436.5	828.3
Prepaid expenses and other	867.3	608.9
Total current assets	14,950.3	14,840.0
Other Assets		
Investments (Note 6)	2,943.0	1,779.5
Goodwill and other intangibles net (Notes 3 and 4)	4,955.4	4,818.8
Sundry	1,976.9	1,622.4
	9,875.3	8,220.7
Property and Equipment		
Land, buildings, equipment, and construction-in-progress	14,670.1	14,486.6
Less accumulated depreciation	(6,716.4)	(6,545.9)
	7,953.7	7,940.7
	\$ 32,779.3	\$ 31,001.4
Liabilities and Shareholders Equity		
Current Liabilities		
Short-term borrowings	\$ 1,528.5	\$ 156.0
Accounts payable	1,187.6	1,072.2
Employee compensation	584.7	851.8
Sales rebates and discounts	1,807.6	1,372.6
Dividends payable	542.3	540.0
Income taxes payable	183.1	457.5
Other current liabilities	2,786.7	2,651.3
Total current liabilities	8,620.5	7,101.4
Other Liabilities		
Long-term debt	5,200.1	6,770.5
Accrued retirement benefit (Note 11)	1,848.6	1,887.4
Long-term income taxes payable (Note 10)	1,283.0	1,234.8
Other noncurrent liabilities	1,550.1	1,594.5
	9,881.8	11,487.2

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

Shareholders Equity (Notes 7 and 8)		
Common stock	724.1	721.3
Additional paid-in capital	4,793.5	4,798.5
Retained earnings	13,888.2	12,732.6
Employee benefit trust	(3,013.1)	(3,013.2)
Deferred costs-ESOP	(10.7)	(52.4)
Accumulated other comprehensive loss	(2,009.9)	(2,670.1)
Noncontrolling interests	0.2	(7.5)
	14,372.3	12,509.2
Less cost of common stock in treasury	95.3	96.4
	14,277.0	12,412.8
	\$ 32,779.3	\$ 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

	Six Months Ended	
	2011	June 30, 2010
	(Dollars in millions)	
Cash Flows from Operating Activities		
Net income	\$ 2,253.2	\$ 2,597.0
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	696.5	645.0
Change in deferred income taxes	14.5	317.2
Stock-based compensation expense	74.2	128.2
Acquired in-process research and development, net of tax	252.2	32.5
Net marketing investigation charges paid		(80.5)
Other changes in operating assets and liabilities	(89.4)	(703.5)
Other operating activities, net	15.2	(66.3)
Net Cash Provided by Operating Activities	3,216.4	2,869.6
Cash Flows from Investing Activities		
Net purchases of property and equipment	(240.4)	(279.3)
Net change in short-term investments	519.0	(2.6)
Proceeds from sales and maturities of noncurrent investments	435.4	383.0
Purchases of noncurrent investments	(1,636.1)	(252.2)
Purchase of product rights	(432.8)	(400.0)
Cash paid for acquisition		(148.4)
Purchase of in-process research and development	(388.0)	(50.0)
Loan to collaboration partner	(165.0)	
Other investing activities, net	(31.4)	(57.3)
Net Cash Used for Investing Activities	(1,939.3)	(806.8)
Cash Flows from Financing Activities		
Dividends paid	(1,095.3)	(1,075.9)
Net change in short-term borrowings	(128.5)	(1.3)
Repayment of long-term debt	(54.6)	0.7
Other financing activities, net	0.3	(2.0)
Net Cash Used in Financing Activities	(1,278.1)	(1,078.5)
Effect of exchange rate changes on cash and cash equivalents	121.3	(283.7)
Net Increase in Cash and Cash Equivalents	120.3	700.6
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 June 30	\$ 6,113.5	\$ 5,163.5
--------------------------------------	------------	------------

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		Six Months Ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
	(Dollars in millions)			
Net income	\$ 1,197.3	\$ 1,348.9	\$ 2,253.2	\$ 2,597.0
Other comprehensive income (loss), net of tax ¹	178.9	(530.7)	660.2	(835.7)
Comprehensive income	\$ 1,376.2	\$ 818.2	\$ 2,913.4	\$ 1,761.3

¹ The significant components of other comprehensive income (loss) were gains from foreign currency translation adjustments of \$178.5 million and \$623.0 million for the three months and six months ended June 30, 2011, respectively. The significant components of other comprehensive income (loss) for the three months and six months ended June 30, 2010 were losses from foreign currency translation adjustments of \$543.5 million and \$920.5 million, respectively.

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 second quarters of 2011 and 2010 was \$70.0 million and \$66.4 million, respectively, and \$135.3 million and \$103.1 million for the six months ended June 30, 2011 and 2010, respectively

Revenue by Category

Worldwide revenue by category was as follows:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Revenue to unaffiliated customers:				
Neuroscience	\$ 2,653.8	\$ 2,363.7	\$ 5,059.1	\$ 4,607.8
Endocrinology	1,683.6	1,518.7	3,272.5	2,996.5
Oncology	825.8	949.0	1,665.7	1,856.8
Cardiovascular	640.6	532.0	1,222.5	1,051.7
Animal health	389.5	324.2	759.3	613.8
Other pharmaceuticals	59.5	61.1	112.9	107.6
Total revenue	\$ 6,252.8	\$ 5,748.7	\$ 12,092.0	\$ 11,234.2

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 second quarter and first six months of 2011 we recorded \$45.8 million and \$89.5 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

In May 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		Six Months Ended	
	June 30, 2011	2010	June 30, 2011	2010
	(Dollars in millions)			
Net product sales	\$ 6,086.5	\$ 5,589.3	\$ 11,776.4	\$ 10,921.8
Collaboration and other revenue	166.3	159.4	315.6	312.4
Total revenue	\$ 6,252.8	\$ 5,748.7	\$ 12,092.0	\$ 11,234.2

Erbix[®]

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 all of the rights with respect to Erbitux outside the U.S. (excluding Japan) remain with Merck KGaA. The following table summarizes the revenue recognized with respect to Erbitux:

	Three Months Ended		Six Months Ended	
	2011	June 30, 2010	2011	June 30, 2010
	(Dollars in millions)			
Net product sales	\$ 18.0	\$ 21.5	\$ 45.0	\$ 38.4
Collaboration and other revenue	82.1	82.3	159.0	157.8
Total revenue	\$ 100.1	\$ 103.8	\$ 204.0	\$ 196.2

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[®] (exenatide injection) and other forms of exenatide such as exenatide once weekly (proposed trade name 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. The following table summarizes the revenue recognized with respect to Byetta:

	Three Months Ended		Six Months Ended	
	2011	June 30, 2010	2011	June 30, 2010
	(Dollars in millions)			
Net product sales	\$ 44.7	\$ 43.7	\$ 85.5	\$ 87.0
Collaboration and other revenue	59.2	63.2	120.2	135.7
Total revenue	\$ 103.9	\$ 106.9	\$ 205.7	\$ 222.7

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 U.S. Food and Drug Administration (FDA) for Bydureon. In October 2010, we received a complete response letter from the FDA that requested a safety study to measure the potential for heart rhythm disturbances when exenatide is used at higher than average doses. In this completed study, exenatide at concentrations higher than those typically achieved with the clinical dose did not cause clinically important (or adverse) effects on electrocardiogram (QT prolongation). In July 2011, we submitted a reply to the complete response letter. Based on the requirements for additional data, this will likely be considered a Class 2 resubmission requiring a six-month review.

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. We expect to launch Bydureon in Europe starting in the third quarter of 2011.

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 will amortize to cost of sales over the estimated life of the supply agreement beginning with product launch. 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, which must be repaid in three years. 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 June 30, 2011, we have contributed approximately \$100 million.

Cymbalta®

Beginning in 2002, we were in a collaborative arrangement with Boehringer Ingelheim (BI) 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 BI a commission on sales in the co-promotion territories. We manufacture 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 BI 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 BI approximately \$400 million and will also pay to BI 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 \$71.7 million and \$22.9 million in the quarters ended June 30, 2011 and 2010, respectively, and \$128.0 million and \$31.6 million in the six months ended June 30, 2011 and 2010, respectively.

Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim (BI) entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are BI's two oral diabetes agents, linagliptin and empagliflozin (BI 10773). In the second quarter of 2011, linagliptin was approved (tradename Tradjenta[®]) and launched in the U.S., approved in Japan (tradename Trazenta[®]) where we expect to launch in the third quarter of 2011, and recommended for approval by the European Medicines Agency's Committee for Medicinal

Products for Human Use (tradename Tradjenta®). Empagliflozin is currently in Phase III clinical testing. Also included in the agreement are our two basal insulin analogues, LY2605541 and LY2963016, both expected to begin Phase III clinical testing in the second half of 2011; and an option granted to BI 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 BI 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.

We paid a \$361.6 million success-based regulatory milestone in connection with the FDA approval of Tradjenta, which was capitalized as an intangible asset and is being amortized to cost of sales. We may pay up to an additional 380 million in success-based regulatory milestones for linagliptin and empagliflozin, approximately 80 million of which potentially will be payable in the third quarter of 2011. 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 BI 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.

TPG-Axon Capital

In 2008, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) whereby both we and TPG were obligated to fund the Phase III development of semagacestat and solanezumab. In the third quarter of 2010, we halted the development of semagacestat based on preliminary results of Phase III clinical trials, which resulted in a charge to research and development of approximately \$80 million. In February 2011, we amended this agreement. Under the amended agreement, TPG's remaining obligation to fund solanezumab costs will not be material and will not extend beyond the first half of 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately \$70.0 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 has not been 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 \$51.5 million and \$31.6 million in the quarters ended June 30, 2011 and 2010, respectively, and \$96.9 million and \$96.7 million in the six months ended June 30, 2011 and 2010, respectively.

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

We recognized restructuring charges of \$132.3 million and \$208.6 million in the second quarter and first six months of 2011, respectively, and \$27.3 million and \$53.5 million in the second quarter and first six 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. 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 June 30, 2011, we had outstanding foreign currency forward commitments to purchase 1.48 billion U.S. dollars and sell 1.03 billion euro, commitments to buy 567.4 million euro and sell 814.8 million U.S. dollars, commitments to purchase 301.2 million British pounds and sell 340.0 million euro, and commitments to purchase 278.1 million U.S. dollars and sell 22.39 billion Japanese yen, which will settle within 30 days.

In the normal course of business, our operations are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt and investment positions and may enter into interest

rate swaps or collars to help maintain that balance. Interest rate swaps or collars that convert our fixed-rate debt or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. At June 30, 2011, approximately 95 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		Six Months Ended	
	2011	June 30, 2010	2011	June 30, 2010
	(Dollars in millions)			
Fair value hedges				
Effect from hedged fixed-rate debt	\$ 63.5	\$ 205.1	\$ 10.2	\$ 236.7
Effect from interest rate contracts	(63.5)	(205.1)	(10.2)	(236.7)
Cash flow hedges				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.3	2.3	4.5	4.5
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	20.7	(49.4)	50.7	(46.4)

The effective portion of net gains on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was \$35.8 million and \$25.8 million for the three and six months ended June 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 six months ended June 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.

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

Fair Value of Financial Instruments

The following tables summarize certain fair value information at June 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)	
June 30, 2011						
Cash and cash equivalents	\$ 6,113.5	\$ 6,113.5	\$ 3,156.5	\$ 2,957.0	\$	\$ 6,113.5
Short-term investments						
U.S. government and agencies	\$ 88.2	\$ 88.1	\$ 88.2	\$	\$	\$ 88.2
Corporate debt securities	114.0	113.7		114.0		114.0
Other debt securities	14.1	14.1		14.1		14.1
Short-term investments	\$ 216.3	\$ 215.9				
Noncurrent investments						
U.S. government and agencies	\$ 335.0	\$ 333.8	\$ 335.0	\$	\$	\$ 335.0
Corporate debt securities	1,422.4	1,423.1		1,422.4		1,422.4
Mortgage-backed	418.5	450.8		418.5		418.5
Asset-backed	239.8	247.8		239.8		239.8
Other debt securities	40.0	41.4		35.7	4.3	40.0
Marketable equity	327.7	158.1	327.7			327.7
Equity method and other investments ⁽¹⁾	159.6	159.6				
Investments	\$ 2,943.0	\$ 2,814.6				
December 31, 2010						
Cash and cash equivalents	\$ 5,993.2	\$ 5,993.2	\$ 2,138.6	\$ 3,854.6	\$	\$ 5,993.2
Short-term investments						
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				
Noncurrent investments						

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

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 methods and other investments ⁽¹⁾	164.4	164.4				
Investments	\$ 1,779.5	\$ 1,577.5				

⁽¹⁾ 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)	
Long-term debt, including current portion					
June 30, 2011	\$ (6,728.6)	\$	\$ (7,021.0)	\$	\$ (7,021.0)
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) (Dollars in millions)	Significant Unobservable Inputs (Level 3)	
June 30, 2011					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Other receivables	\$ 22.0	\$	\$ 22.0	\$	\$ 22.0
Sundry	266.5		266.5		266.5
Foreign exchange contracts not designated as hedging instruments					
Other receivables	7.0		7.0		7.0
Other current liabilities	(12.9)		(12.9)		(12.9)
Equity contracts designed as hedging instruments					
Other current liabilities	(9.8)		(9.8)		(9.8)
December 31, 2010					
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 \$145.1 million and \$163.5 million as of June 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 \$2.05 billion of our investments in debt securities, measured at fair value, will mature within five years.

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

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:

	June 30, 2011	December 31, 2010
	(Dollars in millions)	
Unrealized gross gains	\$ 184.5	\$ 262.6
Unrealized gross losses	55.7	61.1
Fair value of securities in an unrealized gain position	1,600.9	1,031.8
Fair value of securities in an unrealized loss position	1,338.4	758.1

Other-than-temporary impairment losses on fixed income securities of \$6.6 million and \$7.1 million were recognized in the statement of operations for the three and six months ended June 30, 2011, respectively, compared with \$5.7 million and \$6.7 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 June 30, 2011.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
	(Dollars in millions)			
Proceeds from sales	\$ 237.6	\$ 189.0	\$ 498.5	\$ 367.7
Realized gross gains on sales	48.6	11.4	88.0	74.6
Realized gross losses on sales	1.6	0.5	5.1	2.3

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 \$36.3 million and \$54.4 million in the second quarter of 2011 and 2010, respectively. In the first six months of 2011 and 2010, we recognized pretax stock-based compensation expense of \$74.2 million and \$128.2 million, respectively.

PAAs 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 June 30, 2011, the total remaining unrecognized compensation cost related to nonvested PAAs amounted to \$42.4 million, which will be amortized over the weighted-average remaining requisite service period of approximately 13 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of June 30, 2011, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$70.2 million, which will be amortized over the weighted-average remaining requisite service period of approximately 24 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 June 30, 2011, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to \$70.8 million, which will be amortized over the weighted-average remaining requisite service period of 26 months.

Note 8: Shareholders' Equity

As of June 30, 2011, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first six 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 quarter, we made a cash payment of approximately \$140 million for tax years 2005-2006. We anticipate an additional cash payment of approximately \$40 million in the third quarter related to the settlement.

While it is reasonably possible that the IRS examination of 2007 and certain matters related to tax years 2008-2009 could conclude within the next 12 months, resolution of these matters is still dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the range of the reasonably possible changes in unrecognized tax benefits that could occur within the next 12 months related to these years, nor is it possible to estimate the total future cash flows related to these unrecognized tax benefits.

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		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
(Dollars in millions)				
Components of net periodic benefit cost				
Service cost	\$ 58.1	\$ 53.0	\$ 117.0	\$ 110.8
Interest cost	112.2	107.7	224.0	215.8
Expected return on plan assets	(171.7)	(160.0)	(343.3)	(317.6)
Amortization of prior service cost	2.4	1.6	4.6	3.4
Recognized actuarial loss	49.3	41.6	98.8	82.3
Net periodic benefit cost	\$ 50.3	\$ 43.9	\$ 101.1	\$ 94.7

	Retiree Health Benefit Plans			
	Three Months		Six Months Ended	
	Ended June 30,		June 30,	
	2011	2010	2011	2010
(Dollars in millions)				
Components of net periodic benefit cost				
Service cost	\$ 14.0	\$ 12.3	\$ 28.8	\$ 28.0
Interest cost	29.5	30.2	59.0	59.9
Expected return on plan assets	(31.8)	(30.6)	(63.8)	(61.3)
Amortization of prior service cost	(10.7)	(9.3)	(21.5)	(18.6)
Recognized actuarial loss	22.1	20.9	44.3	42.5
Net periodic benefit cost	\$ 23.1	\$ 23.5	\$ 46.8	\$ 50.5

On a global basis, we have contributed approximately \$50 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2011. In addition, we have contributed approximately \$250 million of discretionary funding to our global post-retirement benefit plans in 2011. During the remainder of 2011, we expect to make contributions to our defined benefit pension plans of approximately \$30 million to satisfy minimum funding requirements. We do not anticipate making any additional discretionary contributions in 2011.

Note 12: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. Except as specifically noted 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, 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):

Gemzar®: Teva Parenteral Medicines, Inc. (Teva); Sun Pharmaceutical Industries Inc. (Sun); and several other generic companies sought permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013). We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006) and several other generic companies, seeking rulings that our patents are valid and are being infringed. In November 2007, Sun filed a declaratory judgment action in the U.S. District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent, and the opinion was affirmed by a panel of the Court of Appeals for the Federal Circuit in July 2010. The Supreme Court has declined to review this decision. In March 2010, the district court in Indiana upheld the validity of our compound patent in the Teva case, but applied collateral estoppel with regard to our method-of-use patent, given the ruling in the Sun case. Generic gemcitabine was introduced to the U.S. market in mid-November 2010.

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. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is 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 the patent's validity. The generic manufacturers may appeal this decision.

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 (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 generic manufacturers may request a review of this decision. 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 to result in a rapid and severe decline in future revenues in the relevant market. We are already experiencing this with Gemzar.

Zyprexa® Litigation

We are a defendant in approximately 50 Zyprexa product liability lawsuits in the U.S. covering approximately 130 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 40 of the lawsuits, covering about 40 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). We have trials scheduled in Texas and California state courts in September 2011. 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 have 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 RICO statute, 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. Plaintiffs sought review of this decision by the U.S. Supreme Court, which has denied plaintiffs' request for review. 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 120 lawsuits involving approximately 400 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 340 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court, and we have a trial with a group of these claimants scheduled in that court in October 2011.

Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES). 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		Six Months Ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
	(Dollars in millions)			
Interest expense	\$ 45.1	\$ 47.5	\$ 90.9	\$ 95.1
Interest income	(17.8)	(11.0)	(33.3)	(21.6)
Other	30.3	(18.1)	11.2	(129.6)
Other-net, expense (income)	\$ 57.6	\$ 18.4	\$ 68.8	\$ (56.1)

Other expense for the second quarter 2011 is primarily related to the partial impairment of 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 six 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 \$6.25 billion and \$12.09 billion for the second quarter and first six months of 2011, respectively, driven primarily by the increase in revenue related to the collective growth of Cymbalta, Zyprexa, animal health products, Alimta, Humalog®, and Cialis®, offset by a decline in Gemzar revenue. This revenue growth, as well as a lower effective tax rate, was more than offset by increased selling, general and administrative costs, lower gross margin percentage, and the items noted below. As a result, net income for the second quarter and the first six months of 2011 decreased 11 percent and 13 percent, to \$1.20 billion and \$2.25 billion, respectively, compared with the same periods of 2010. Earnings per share for the second quarter and the first six months of 2011 decreased 12 percent and 14 percent to \$1.07 per share and \$2.02 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 \$111.3 million (pretax), or \$.08 per share, in the second quarter and \$200.3 million (pretax), or \$.14 per share, in the first six months of 2011. Marketing, selling, and administrative charges increased by \$45.8 million (pretax), or \$.04 per share, in the second quarter and \$89.5 million (pretax), or \$.08 per share, in the first six months of 2011, as a result of the mandatory pharmaceutical manufacturers' fee.

We incurred acquired in-process research and development (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 \$132.3 million (pretax), or \$.11 per share in the second quarter, and \$208.6 million (pretax), or \$.17 per share, for the first six months of 2011, respectively, primarily related to severance costs from previously announced strategic actions.

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 \$71.2 million (pretax), or \$.05 per share, in the second quarter and \$133.7 million (pretax), or \$.09 per share, for the first six 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 \$27.3 million (pretax), or \$.02 per share, in the second quarter, and \$53.5 million (pretax), or \$.04 per share, for the first six months of 2011, respectively, 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.

Late-Stage Pipeline

Our long-term success depends to a great extent on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies. We currently have approximately 70 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. There is a high rate of failure 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 are 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. As a consequence, 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 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

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

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

mGlu2/3 (Q1 2011) a prodrug receptor agonist for the treatment of schizophrenia

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

NERI (Q4 2010) a potent and highly selective norepinephrine reuptake inhibitor for the treatment of major depression

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 β) 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.

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. We launched in the United Kingdom in July 2011, and expect to launch in certain European countries in the second half of 2011 and the first half of 2012. In July 2011, we submitted a reply to the complete response letter issued in October 2010 by the FDA. The FDA will likely require up to six months to review our reply.

Empagliflozin and linagliptin. In January, we announced a global agreement with Boehringer Ingelheim (BI) to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development. Included are BI's two oral diabetes agents, linagliptin and empagliflozin, as well as our two basal insulin analogues, LY2605541 and LY2963016, along with an option to co-develop and co-commercialize our anti-TGF-beta monoclonal antibody. In May, the FDA approved Tradjenta (linagliptin), a prescription medication used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. Tradjenta was launched in the U.S. in May in collaboration with BI. In addition, during the second quarter linagliptin was approved in Japan, Mexico, and Brazil and received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use. Tradjenta is protected by a compound patent in the U.S. that expires in 2023. BI 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 are working to address the FDA's questions and plan to submit our response to the complete response letter in the second half of 2011.

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.

mGlu2/3. In February, we began the first Phase III clinical trial for our mGlu2/3 prodrug to investigate potential use in the treatment of schizophrenia.

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 (DMC) 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.

Acquisition

In July 2011, we acquired from Johnson & Johnson Company the animal health business of its Janssen Pharmaceutica NV subsidiary. Our animal health division, Elanco, obtained a portfolio of about 50 marketed animal health products. The transaction is not material to our consolidated financial statements.

Legal, Regulatory, and Other Matters

The U.S. District Court for the District of New Jersey ruled that our method-of-use patent for Strattera, which expires in 2017, was invalid. In July 2011, the U.S. Court of Appeals for the Federal Circuit overturned this decision, upholding the patent. The generic manufacturers may request a review of this decision.

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 referred to 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. 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.

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. Under the statute, this fee is to be allocated to companies based on their prior-calendar-year market share for branded prescription drug sales into these government programs. A guidance project is currently under way within the IRS and U.S. Treasury concerning the implementation of this fee. 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.

In addition, the federal government created an expedited regulatory approval pathway in the U.S. for biosimilars or follow-on biologics (copies of biological compounds). Biologics will have at least 12 years of data-package protection following launch. Congress is expected to take up patent law reform in 2011. Patent reform legislation that would strengthen pharmaceutical patents by adopting a system that is more transparent, objective, predictable, and simple, is awaiting final action in Congress. Highly similar patent reform bills have already passed the Senate and the House and must be reconciled.

The Obama Administration continues to include suggested changes to the manner in which the U.S. would tax the international income of U.S.-based companies. Some provisions changing taxation of international income were enacted in August 2010. These provisions did not have a material effect on our consolidated results of operations. 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.

Certain other federal and state health care proposals may continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These proposals include legalizing the importation of prescription drugs and other 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.

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 second quarter and the first six months of 2011 increased 9 percent and 8 percent to \$6.25 billion and \$12.09 billion, respectively, driven primarily by the increase in revenue related to the collective growth of Cymbalta, Zyprexa, animal health products, Alimta, Humalog, and Cialis, offset by a decline in Gemzar revenue. For the second quarter, worldwide sales volume increased 5 percent and the favorable impact of foreign exchange

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

rates contributed 4 percent of revenue growth. For the first six months of 2011, worldwide sales volume increased 5 percent and the favorable impact of foreign exchange rates contributed 2 percent of revenue growth (numbers do not add due to rounding). Reflecting the loss of U.S. patent exclusivity for Gemzar in November 2010, price had a negligible impact on revenue growth for both the second quarter and first six months of 2011. Revenue in the U.S. increased by \$84.6 million, or 3 percent, and \$127.1 million, or 2 percent, for the second quarter and first six months of 2011, respectively, compared with the same periods of 2010 due to higher prices offset in part by \$111.3 million and \$200.3 million in the second quarter and first six 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 \$419.5 million, or 17 percent, and \$730.7 million, or 15 percent, for the second quarter and first six 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 six-month period.

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

Product	Three Months Ended June 30, 2011			Three Months Ended June 30, 2010	Percent Change from 2010
	U.S. ¹	Outside U.S.	Total ² (Dollars in millions)	Total	
Zyprexa	\$ 711.2	\$ 697.1	\$ 1,408.3	\$ 1,262.9	12
Cymbalta	758.4	245.0	1,003.4	867.7	16
Alimta	251.9	361.5	613.4	551.8	11
Humalog	341.6	245.3	586.9	504.6	16
Cialis	180.3	297.0	477.2	418.7	14
Animal health products	218.3	171.2	389.5	324.2	20
Humulin [®]	146.0	165.8	311.8	265.2	18
Evista [®]	174.5	89.0	263.5	259.5	2
Forteo [®]	110.2	120.8	231.0	209.6	10
Strattera	98.0	59.6	157.7	147.1	7
Gemzar	17.2	95.3	112.4	293.4	(62)
Other pharmaceutical products	214.0	317.3	531.4	484.6	10
Total net product sales	3,221.6	2,864.9	6,086.5	5,589.3	9
Collaboration and other revenue ³	124.8	41.6	166.3	159.4	4
Total revenue	\$ 3,346.4	\$ 2,906.5	\$ 6,252.8	\$ 5,748.7	9

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

Product	Six Months Ended June 30, 2011			Six Months Ended June 30, 2010	Percent Change from 2010
	U.S. ¹	Outside U.S.	Total ²	Total	
	(Dollars in millions)				
Zyprexa	\$ 1,308.2	\$ 1,381.9	\$ 2,690.1	\$ 2,477.9	9
Cymbalta	1,449.6	462.6	1,912.1	1,670.9	14
Alimta	484.9	708.4	1,193.3	1,079.2	11
Humalog	645.4	466.9	1,112.3	1,011.0	10
Cialis	338.1	573.5	911.6	827.0	10
Animal health products	420.7	338.6	759.3	613.8	24
Humulin	275.5	326.2	601.7	523.0	15
Evista	348.6	181.0	529.6	501.1	6
Forteo	221.9	225.1	447.0	404.1	11
Strattera	184.6	111.8	296.4	293.5	1
Gemzar	76.5	192.0	268.5	581.2	(54)
Other pharmaceutical products	427.4	627.0	1,054.5	939.1	12
Total net product sales	6,181.4	5,595.0	11,776.4	10,921.8	8
Collaboration and other revenue ³	241.2	74.4	315.6	312.4	1
Total revenue	\$ 6,422.6	\$ 5,669.4	\$ 12,092.0	\$ 11,234.2	8

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

² Numbers may not add due to rounding.

³ 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, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. Zyprexa sales in the U.S. increased 11 percent and 7 percent in the second quarter and first six months of 2011, respectively, driven by higher prices, and, for the first six months of 2011, partially offset by lower volume. Sales outside the U.S. increased 12 percent and 10 percent, respectively, compared with the same periods of 2010 driven by the favorable impact of foreign exchange rates, and, to a lesser extent for the first six months of 2011, higher volume. We will lose effective exclusivity for Zyprexa in the U.S. in October 2011. We will also lose effective exclusivity in most of Europe in 2011. In the five major European countries, which in the aggregate had approximately \$300 million and \$570 million in sales in the second quarter and first six months of 2011, respectively, we lost effective exclusivity in Spain in April 2011 and we will lose effective exclusivity in France, Germany, Italy, and the United Kingdom in September 2011. Several manufacturers have received tentative approvals to market generic olanzapine, and we expect generic olanzapine to be introduced in these markets immediately following the expiration of the patents. While it is difficult to predict the precise timing and the 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 results of operations and cash flows. In Japan, our second-largest market for Zyprexa, with approximately \$130 million and \$250 million of sales in the second quarter and first six 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 7 percent during the second quarter and first six months of 2011. The increase was due to increased demand, and to a lesser extent, higher net effective selling prices. Sales outside the U.S. increased 53 percent and 48 percent during the second quarter and first six months of 2011, respectively, compared with the same period in 2010, driven primarily by increased demand in international markets and the 2010 launch in Japan, and, to a lesser extent, the favorable impact of foreign exchange rates.

U.S. sales of Alimta, a treatment for various cancers, decreased 1 percent during the second quarter and increased 2 percent during the first six months of 2011, with the decrease in the second quarter driven by decreased volume. The increase in the first six months of 2011 was due to higher prices partially offset by lower volume. Sales outside the U.S. increased 21 percent and 17 percent in the second quarter and first six months of 2011, respectively, due to increased demand, as well as the favorable impact of foreign exchange rates.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 14 percent and 6 percent for the second quarter and first six months of 2011, respectively, due to increased demand and, for the second quarter, higher prices. Sales outside the U.S. increased 20 percent and 16 percent for the second quarter and first six months of 2011, respectively, driven by increased demand and the favorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 9 percent and 7 percent for the second quarter and first six months of 2011, respectively, with changes in the second quarter driven by increased demand and higher prices, partially offset by wholesaler buying patterns. The increase for the first six months of 2011 is due to higher prices. Sales outside the U.S. increased 17 percent and 12 percent during the second quarter and first six months of 2011, respectively, driven by increased demand and the favorable impact of foreign exchange rates, and to a lesser extent for the first six months of 2011, higher prices.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 27 percent and 20 percent during the second quarter and first six months of 2011, respectively, driven by increased demand for Humulin[®] ReliOn[®], as well as higher prices for Humulin in the second quarter. Sales outside the U.S. increased 11 percent during the second quarter and first six months of 2011, driven by the favorable impact of foreign exchange rates and increased demand.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 1 percent during the second quarter and increased 4 percent during the first six months of 2011, respectively, with the second quarter decrease due to decreased demand, partially offset by higher prices. The increase in the first six months was due to higher prices, partially offset by decreased demand. Sales outside the U.S. increased 6 percent and 8 percent for the second quarter and first six months of 2011, respectively, with the second quarter increase driven by the favorable impact of foreign exchange rates. The increase in the first six months of 2011 was due to the favorable impact of foreign exchange rates, and, to a lesser extent, increased demand 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 16 percent and 11 percent during the second quarter and first six months

of 2011, respectively, driven by decreased demand, partially offset by higher prices in the first six months of 2011. Sales outside the U.S. increased 55 percent and 45 percent for the second quarter and the first six 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, as well as higher prices during the first six months of 2011.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. adults, decreased 2 percent and 9 percent during the second quarter and first six months of 2011, respectively, due to decreased demand, and, for the first six months of 2011, lower net effective selling prices. Sales outside the U.S. increased 28 percent and 24 percent for the second quarter and first six months of 2011, respectively, driven primarily by strong demand in international markets including Japan and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower prices. The U.S. District Court for the District of New Jersey ruled that the U.S. method-of-use patent for Strattera, which expires in 2017, was invalid. In July 2011, the U.S. Court of Appeals for the Federal Circuit overturned this decision, upholding the patent. The generic manufacturers may request a review of this decision.

U.S. sales of Gemzar, a product approved to treat various cancers, decreased 91 percent and 79 percent during the second quarter and first six 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 8 percent and 12 percent for the second quarter and first six months of 2011, respectively, due primarily to generic competition in most major markets. We expect sales to continue to decline in 2011, with severe declines in the U.S.

We report as revenue for Erbitux, a product approved to treat various cancers, the net royalties received from our collaboration partners and our product sales. Our revenues decreased 4 percent to \$100.1 million and increased

4 percent to \$204.0 million during the second quarter and first six months of 2011, respectively.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, decreased 4 percent to \$171.2 million and 8 percent to \$336.6 million during the second quarter and first six months of 2011, respectively, due to competitive pressures in the U.S. and European markets. We report as revenue our 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues decreased 3 percent to \$103.9 million and 8 percent to \$205.7 million during the second quarter and first six months of 2011, respectively.

Animal health product sales in the U.S. increased 18 percent and 23 percent during the second quarter and first six 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 23 percent and 25 percent during the second quarter and first six months of 2011, respectively, driven by the impact of the acquisition of certain Pfizer animal health assets in Europe in the second quarter of 2010, increased demand, and the favorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

For the second quarter and first six months of 2011, respectively, gross margins as a percentage of total revenue decreased by 1.8 percentage points to 80.4 percent and 0.8 percentage points to 80.1 percent. These decreases in gross margin percent were primarily due to the impact of changes in foreign currencies compared to the U.S. dollar on international inventories sold during the quarter, which increased cost of sales in the second quarter of 2011, but decreased cost of sales in the second quarter of 2010.

Marketing, selling, and administrative expenses increased 16 percent and 14 percent to \$2.04 billion and \$3.83 billion for the second quarter and first six 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, as well as higher litigation expenses for the first six months of 2011. In addition, higher administrative expenses in the U.S. included \$45.8 million and \$89.5 million for the second quarter and first six months of 2011, respectively, related to the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform. Research and development expenses were \$1.26 billion and \$2.38 billion for the second quarter and first six months of 2011, respectively. Compared with the same periods of 2010, research and development expenses grew 6 percent and 7 percent the second quarter and first six 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 six 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 \$132.3 million and \$208.6 million of asset impairments, restructuring, and other special charges in the second quarter and first six months of 2011, respectively, compared with \$27.3 million and \$53.5 million for the same respective 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 \$57.6 million and \$68.8 million for the second quarter and first six months of 2011, compared to a net expense of \$18.4 million and other income of \$56.1 million for the same respective periods of 2010. The increase in the second quarter 2011 expense was driven by the partial impairment of the acquired in-process research and development asset related to lipotamase, partially offset by gains on the disposition of investment securities. Other income for the first six 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.

The effective tax rate was 21.8 percent and 19.7 percent in the second quarter and first six months of 2011, respectively, compared with an effective tax rate of 22.3 percent and 24.6 percent in the second quarter and first six months of 2010, respectively. The 2011 second quarter effective tax rate was lower primarily due to reinstatement of the U.S. research and development tax credit during the fourth quarter of 2010, effective for 2010 and 2011. The effective tax rate for the first six months of 2011 also benefited from the reinstatement of the U.S. research and development tax credit as well as the tax benefit of the IPR&D charge associated with the Boehringer Ingelheim diabetes collaboration. In addition, the tax rate for the first six months of 2010 was negatively impacted 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 June 30, 2011, cash, cash equivalents, and short-term investments totaled \$6.33 billion compared with \$6.73 billion at December 31, 2010. Cash, cash equivalents, and short-term investments decreased as cash flow from operations of \$3.22 billion, was more than offset by dividends paid of \$1.01 billion, acquisitions of \$820.8 million, net noncurrent investment activity of \$1.20 billion, and net purchases of property and equipment of \$240.4 million.

Total debt as of June 30, 2011 decreased by \$197.9 million compared with December 31, 2010, to \$6.73 billion, which was due to the repayment of \$125.0 million in short-term floating rate debt and approximately \$80 million in other debt. Our current debt ratings from Standard & Poor's and Moody's remain AA- and A2, respectively.

As of the second quarter of 2011, the U.S. and global economies face continued headwinds and ongoing volatility. U.S. economic data in the second quarter largely disappointed, as the manufacturing sector felt the supply chain impacts of the Japanese earthquake and as the labor market recovery slowed. Given the disappointing economic data and a moderation in the increase of commodity prices, the Federal Reserve continues to maintain its accommodative monetary policy. Both domestically and abroad, high sovereign debt levels and ongoing efforts at fiscal austerity in the U.S. and other developed countries continue to be a concern for many economists and are predicted to challenge the economic recovery. These concerns are particularly salient in those European countries whose fiscal troubles have driven them to receive rescue financing from the financial authorities. The threat of contagion from these 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 near-term impact 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:

Zyprexa October 2011 (U.S.), various dates in 2011 (major Europe)

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.

Gemzar has already lost effective exclusivity in the U.S. and major European countries (France, Germany, Italy, Spain, and the United Kingdom), and Humalog has lost exclusivity in major European countries. 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, Humalog, and Zyprexa contributes materially to our results of operations, liquidity, and financial position. The loss of exclusivity 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. 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 patent-protected products in these markets.

Legal and Regulatory Matters (Copy from Footnote)

We are a party to various legal actions and government investigations. The most significant of these are described below. Except as specifically noted 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, 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):

Gemzar: Teva Parenteral Medicines, Inc. (Teva); Sun Pharmaceutical Industries Inc. (Sun); and several other generic companies sought permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013). We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006) and several other generic companies, seeking rulings that our patents are valid and are being infringed. In November 2007, Sun filed a declaratory judgment action in the U.S. District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent, and the opinion was affirmed by a panel of the Court of Appeals for the Federal Circuit in July 2010. The Supreme Court has declined to review this decision. In March 2010, the district court in Indiana upheld the validity of our compound patent in the Teva case, but applied collateral estoppel with regard to our method-of-use patent, given the ruling in the Sun case. Generic gemcitabine was introduced to the U.S. market in mid-November 2010.

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. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is 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 the patent's validity. The generic manufacturers may appeal this decision.

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 (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 generic manufacturers may request a review of this decision.

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.

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 to result in a rapid and severe decline in future revenues in the relevant market. We are already experiencing this with Gemzar.

Zyprexa Litigation

We are a defendant in approximately 50 Zyprexa product liability lawsuits in the U.S. covering approximately

130 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 40 of the lawsuits, covering about 40 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). We have trials scheduled in Texas and California state courts in September 2011. 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 have 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 RICO statute, 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. Plaintiffs sought review of this decision by the U.S. Supreme Court, which has denied plaintiffs' request for review. 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 120 lawsuits involving approximately 400 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 340 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court, and we have a trial with a group of these claimants scheduled in that court in October 2011.

Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES). 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 updated our 2011 earnings per share guidance to be in a range of \$3.85 to \$3.95, reflecting the restructuring charges taken in the first six months of 2011, continued strong volume growth in revenue, the appreciation of several foreign currencies versus the U.S. dollar, the prompt approvals of linagliptin in multiple markets and the partial impairment of the acquired in-process research and development asset related to liprotamase. 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 now expect total revenue to grow in the mid-single digits, which assumes we maintain our patent exclusivity for U.S. Strattera sales, and also 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 severe erosion of U.S. Gemzar sales. We still anticipate that the impact of U.S. health care reform will lower 2011 revenue by \$400 million to \$500 million. We expect these reductions in revenue to be offset by sales growth of Alimta, Cialis, Cymbalta, Effient, Humalog, and animal health products.

We now anticipate that gross margin as a percent of revenue will decline between two and three percentage points. Marketing, selling, and administrative expenses are now 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 now expected to be in the low single digits. Other net expense is now expected to be a net expense of between \$100 million and \$175 million. Cash flows are still expected to be sufficient to fund capital expenditures of between \$700 million and \$800 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 June 30, 2011, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the second 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, Gemzar, 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 is scheduled for October 2011. 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 is expected to schedule oral argument sometime this fall. 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.

We have been named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals. We have also been named in approximately 50 lawsuits filed in the same court by individual former employees making similar claims. We have also been named, along with several other companies, in a lawsuit filed by certain of these individuals in U.S. District Court for the Southern District of Indiana in April 2009, alleging possible harm caused by exposure to pesticides related to our former agricultural chemical manufacturing facility in Cosmopolis, Brazil. In November 2010, the case was dismissed with prejudice by the Court. The plaintiffs have filed a motion to reconsider, which has been denied, and the period for appeal has expired.

In 2004 we, along with several other pharmaceutical companies, were named in a lawsuit in California state court brought by approximately 20 California pharmacies alleging that pharmaceutical companies prevented commercial importation of prescription drugs from outside the United States and used Canadian pharmaceutical prices as an agreed floor for prices in the United States in violation of antitrust laws. The case sought restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative conduct. Summary judgment was granted to us and the other defendants and in July 2008, the California Court of Appeals affirmed that decision. In July 2010, the California Supreme Court overturned the lower court decision and remanded the case to the state court. In March 2011, the state court again granted summary judgment for us and the other defendants. Plaintiffs have appealed this decision. We believe the lawsuit has no 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.

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 June 30, 2011:

Period	Total		Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
	Number of Shares Purchased	Average Price Paid per Share	(c)	(d)
	(a)	(b)	(in thousands)	(in millions)
April 2011		\$		\$419.2
May 2011				419.2
June 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 \$3.0 billion share repurchase program announced in March 2000. As of June 30, 2011, we have purchased \$2.58 billion related to this program. During the first six 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: July 29, 2011

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

Date: July 29, 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