LILLY ELI & CO
Form 10-Q
April 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 MARCH 31, 2011

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA	35-0470950
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285

(Address of principal executive offices)

Registrant's telephone number, including area code (317) 276-2000

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months and (2) has been subject to such filing requirements for the past 90 days.

Yes x 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 x 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 x

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 x No ¨

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

Class	Number of Shares Outstanding
Common	1,157,666,449

PART I. Financial Information

Item 1. Financial Statements

Consolidated Condensed Statements of Operations

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended March 31,	
	2011	2010
	(Dollars in millions, except per-share data)	
Revenue	$ 5,839.2	$ 5,485.5
Cost of sales	1,180.1	1,122.5
Research and development	1,124.0	1,039.1
Marketing, selling, and administrative	1,785.7	1,614.4
Acquired in-process research and development (Note 3 and Note 4)	388.0	50.0
Asset impairments, restructuring, and other special charges (Note 5)	76.3	26.2
Other - net, expense (income) (Note 13)	11.2	(74.5)
	4,565.3	3,777.7
Income before income taxes	1,273.9	1,707.8
Income taxes (Note 10)	218.0	459.7
Net income	$ 1,055.9	$ 1,248.1
Earnings per share - basic and diluted (Note 9)	$ .95	$ 1.13
Dividends paid per share	$ .49	$ .49

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Balance Sheets

Eli Lilly and Company and Subsidiaries

	March 31, 2011	December 31, 2010
	(Dollars in millions)	
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	$ 6,506.4	$ 5,993.2
Short-term investments (Note 6)	206.7	733.8
Accounts receivable, net of allowances of $112.7 (2011) and $100.4 (2010)	3,694.3	3,493.8
Other receivables	488.8	664.3
Inventories	2,767.2	2,517.7
Prepaid taxes	550.1	828.3
Prepaid expenses and other	1,140.8	608.9
Total current assets	15,354.3	14,840.0
Other Assets		
Investments (Note 6)	1,898.7	1,779.5
Goodwill and other intangibles - net (Note 3)	4,731.3	4,818.8
Sundry	1,743.3	1,622.4
	8,373.3	8,220.7
Property and Equipment		
Land, buildings, equipment, and construction-in-progress	14,540.1	14,486.6
Less accumulated depreciation	(6,572.4)	(6,545.9)
	7,967.7	7,940.7
	$ 31,695.3	$ 31,001.4
Liabilities and Shareholders Equity		
Current Liabilities		
Short-term borrowings	$ 1,539.9	$ 156.0
Accounts payable	1,183.2	1,072.2
Employee compensation	524.0	851.8
Sales rebates and discounts	1,489.5	1,372.6
Dividends payable		540.0
Income taxes payable	315.2	457.5
Other current liabilities	2,600.0	2,651.3
Total current liabilities	7,651.8	7,101.4
Other Liabilities		
Long-term debt	5,132.4	6,770.5
Accrued retirement benefit (Note 11)	1,866.4	1,887.4
Long-term income taxes payable (Note 10)	1,224.3	1,234.8
Other noncurrent liabilities	1,886.2	1,594.5
	10,109.3	11,487.2
Shareholders Equity (Notes 7 and 8)		

Common stock	724.1	721.3
Additional paid-in capital	4,736.8	4,798.5
Retained earnings	13,785.3	12,732.6
Employee benefit trust	(3,013.1)	(3,013.2)
Deferred costs-ESOP	(10.9)	(52.4)
Accumulated other comprehensive loss	(2,188.8)	(2,670.1)
Noncontrolling interests	(3.9)	(7.5)
	14,029.5	12,509.2
Less cost of common stock in treasury	95.3	96.4
	13,934.2	12,412.8
	$ 31,695.3	$ 31,001.4

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Statement of Cash Flows

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended March 31,	
	2011	2010
	(Dollars in millions)	
Cash Flows from Operating Activities		
Net income	$ 1,055.9	$ 1,248.1
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	340.9	299.4
Change in deferred income taxes	92.5	230.5
Stock-based compensation expense	37.9	73.7
Acquired in-process research and development, net of tax	252.2	32.5
Net marketing investigation charges paid		(56.5)
Other changes in operating assets and liabilities	(595.6)	(815.1)
Other operating activities, net	(7.7)	(54.6)
Net Cash Provided by Operating Activities	1,176.1	958.0
Cash Flows from Investing Activities		
Net purchases of property and equipment	(101.4)	(125.1)
Net change in short-term investments	539.0	(0.8)
Proceeds from sales and maturities of noncurrent investments	211.9	191.0
Purchases of noncurrent investments	(238.3)	(57.2)
Purchase of product rights	(29.6)	
Purchase of in-process research and development	(388.0)	(50.0)
Other investing activities, net	(34.3)	(10.5)
Net Cash Used for Investing Activities	(40.7)	(52.6)
Cash Flows from Financing Activities		
Dividends paid	(543.2)	(539.2)
Net change in short-term borrowings	(116.2)	(7.9)
Repayment of long-term debt	(54.6)	
Other financing activities, net	0.2	0.1
Net Cash Used in Financing Activities	(713.8)	(547.0)
Effect of exchange rate changes on cash and cash equivalents	91.6	(96.1)
Net Increase in Cash and Cash Equivalents	513.2	262.3
Cash and cash equivalents at January 1	5,993.2	4,462.9

Cash and Cash Equivalents at March 31	$ 6,506.4	$ 4,725.2

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Statements of Comprehensive Income

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended March 31,	
	2011	2010
	(Dollars in millions)	
Net income	$ 1,055.9	$ 1,248.1
Other comprehensive income (loss), net of tax[1]	481.3	(305.0)
Comprehensive income	$ 1,537.2	$ 943.1

[1] The significant components of other comprehensive income (loss) were income of $444.5 million and losses of $377.0 million from foreign currency translation adjustments for the three months ended March 31, 2011 and 2010, 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 first quarters of 2011 and 2010 was $65.3 million and $36.8 million, respectively.

Revenue by Category

Worldwide revenue by category was as follows:

	Three Months Ended March 31,	
	2011	2010
	(Dollars in millions)	
Revenue to unaffiliated customers:		
Neuroscience	$ 2,405.1	$ 2,244.1
Endocrinology	1,589.0	1,477.8
Oncology	839.9	907.7
Cardiovascular	581.8	519.7
Animal health	369.8	289.6
Other pharmaceuticals	53.6	46.6
Total revenue	$ 5,839.2	$ 5,485.5

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 nondeductible 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 first quarter of 2011 we recorded $43.8 million 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

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 might 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 March 31,	
	2011	2010
	(Dollars in millions)	
Net product sales	$ 5,689.9	$ 5,332.5
Collaboration and other revenue	149.3	153.0
Total revenue	$ 5,839.2	$ 5,485.5

Erbitux®

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

	Three Months Ended March 31,	
	2011	2010
	(Dollars in millions)	
Net product sales	$ 27.1	$ 17.0
Collaboration and other revenue	76.9	75.5
Total revenue	$ 104.0	$ 92.5

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 on-going 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 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 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

8

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 tradename Bydureon). Lilly 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 March 31,	
	2011	2010
	(Dollars in millions)	
Net product sales	$ 40.8	$ 43.2
Collaboration and other revenue	61.0	72.5
Total revenue	$ 101.8	$ 115.7

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. Our goal is to submit a reply to the complete response letter in the second half of 2011. Based on the requirements for additional data, this will likely be considered a Class 2 resubmission requiring a six-month review.

We have also submitted Bydureon for review by the European Medicines Agency (EMA) and in April 2011, the Committee for Medicinal Products for Human Use (CHMP) of the EMA issued a positive opinion recommending approval of Bydureon in the European Union for the treatment of type 2 diabetes in combination with certain oral therapies. The CHMP s positive opinion is referred to the European Commission, which has the authority to approve medicines for the European Union. The European Commission usually makes a decision on CHMP recommendations within two to three months.

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 plan to loan 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 March 31, 2011, we have contributed approximately $95 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 re-acquired the exclusive rights to develop and market duloxetine for all indications in countries outside the U.S. and Japan. In connection with the arrangement, 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 $56.3 million and $8.8 million in the first quarter of 2011 and 2010, respectively.

Diabetes Collaboration

In January 2011, we and BI entered into a global agreement 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, which has been submitted to the FDA, EMA and Japanese regulatory authorities, and BI10773, which is currently in Phase III clinical testing; our two basal insulin analogues, LY2605541 and LY2963016, both expected to begin Phase III clinical testing in 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 for acquired IPR&D related to this arrangement, which is included as expense in the first quarter of 2011 and is deductible for tax purposes. We may pay up to a total of 625.0 million in success-based regulatory milestones for linagliptin and BI10773. We will be eligible to receive up to a total of $650.0 million in success-based regulatory milestones on our two basal analogue insulins. 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 will share ongoing development costs equally. Upon successful regulatory approval of any product resulting from the collaboration, the companies will share equally in the product's commercialization costs and gross margin. 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 incurred subsequent to 2010 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 related to the Alzheimer s treatments are 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 and is not expected to be 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 $45.4 million and $65.1 million in the quarters ended March 31, 2011 and 2010, respectively.

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

We recognized severance costs of $76.3 million in the first quarter of 2011, and severance and exit costs of $26.2 million in the first quarter of 2010 as a result of the 2009 initiative to reorganize global operations, streamline various functions of the business, and reduce total employees, as well as other previously announced strategic actions to reduce our cost structure and global workforce. All costs 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.

10

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 March 31, 2011, we had outstanding foreign currency forward commitments to purchase 1.43 billion U.S. dollars and sell 1.03 billion euro, commitments to buy 841.0 million euro and sell 1.18 billion U.S. dollars, commitments to purchase 175.0 million British pounds and sell 202.0 million euro, and commitments to purchase 261.0 million U.S. dollars and sell 21.37 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 March 31, 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 March 31,	
	2011	2010
	(Dollars in millions)	
Fair value hedges		
Effect from hedged fixed-rate debt	$ (53.3)	$ 31.6
Effect from interest rate contracts	53.3	(31.6)
Cash flow hedges		
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.2	2.2
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	30.0	3.0

The effective portion of net losses on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $10.0 million for the first quarter of 2011.

We expect to reclassify $12.0 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 first quarters of 2011 and 2010, net losses related to ineffectiveness and net losses related to the portion of our risk-management hedging instruments, fair value and cash flow hedges excluded from the assessment of effectiveness were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at March 31, 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: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
			(Dollars in millions)			
March 31, 2011						
Cash and cash equivalents	$ 6,506.4	$ 6,506.4	$ 2,515.0	$ 3,991.4	$	$ 6,506.4
Short-term investments						
Commercial paper	$ 50.0	$ 50.0	$	$ 50.0	$	$ 50.0
U.S. government and agencies	61.6	61.5	61.6			61.6
Corporate debt securities	82.4	81.8		82.4		82.4
Other securities	12.7	12.7		12.7		12.7
Short-term investments	$ 206.7	$ 206.0				
Noncurrent investments						
U.S. government and agencies	$ 323.1	$ 326.3	$ 323.1	$	$	$ 323.1
Corporate debt securities	418.3	417.4		418.3		418.3
Mortgage-backed	345.0	378.9		345.0		345.0
Asset-backed	155.6	164.5		155.6		155.6
Other debt securities	43.6	44.9		40.8	2.8	43.6
Marketable equity	456.3	183.4	456.3			456.3
Equity method and other investments[1]	156.8	156.8				
Investments	$ 1,898.7	$ 1,672.2				
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						
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	6.4
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: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
			(Dollars in millions)		
Long-term debt, including current portion					
March 31, 2011	$ (6,668.0)	$	$ (6,906.3)	$	$ (6,906.3)
December 31, 2010	$ (6,788.7)	$	$ (7,030.0)	$	$ (7,030.0)

Description	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
			(Dollars in millions)		
March 31, 2011					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Other receivables	$ 27.0	$	$ 27.0	$	$ 27.0
Sundry	198.0		198.0		198.0
Foreign exchange contracts not designated as hedging instruments					
Other receivables	13.0		13.0		13.0
Other current liabilities	(30.3)		(30.3)		(30.3)
Equity contracts designed as hedging instruments					
Other current liabilities	(45.6)		(45.6)		(45.6)
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 $148.1 million and $163.5 million as of March 31, 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 $960.0 million of our investments in debt securities, measured at fair value, will mature within five years.

A summary of the fair value of available-for-sale securities in an unrealized gain or loss position and the amount of unrealized gains and losses (pretax) in accumulated other comprehensive loss follows:

	March 31, 2011	December 31, 2010
	(Dollars in millions)	
Unrealized gross gains	$ 281.3	$ 262.6
Unrealized gross losses	54.1	61.1
Fair value of securities in an unrealized gain position	1,049.5	1,031.8
Fair value of securities in an unrealized loss position	764.9	758.1

Other-than-temporary impairment losses on fixed income securities of $0.5 million were recognized in the statement of operations for the first quarter of 2011 compared with $1.0 million for the same period 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 80 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 March 31, 2011.

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

	Three Months Ended March 31,	
	2011	2010
	(Dollars in millions)	
Proceeds from sales	$ 260.9	$ 178.7
Realized gross gains on sales	39.4	63.2
Realized gross losses on sales	3.5	1.8

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 $37.9 million and $73.7 million in the first quarter of 2011 and 2010, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings per share targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of March 31, 2011, the total remaining unrecognized compensation cost related to nonvested PAs amounted to $57.1 million, which will be amortized over the weighted-average remaining requisite service period of approximately 15 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 March 31, 2011, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to $82.7 million, which will be amortized over the weighted-average remaining requisite service period of approximately 26 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 March 31, 2011, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to $80.2 million, which will be amortized over the weighted-average remaining requisite service period of 29 months.

Note 8: Shareholders Equity

As of March 31, 2011, we have purchased $2.58 billion of our previously announced $3.0 billion share repurchase program. During the first three 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 2005. 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 2008-09. 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 have been 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. We anticipate a cash payment of approximately $200 million will be paid in the second quarter of 2011 related to tax years 2005-2006.

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 March 31,		Retiree Health Benefit Plans Three Months Ended March 31,	
	2011	2010	2011	2010
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$ 58.9	$ 57.8	$ 14.8	$ 15.7
Interest cost	111.8	108.1	29.5	29.7
Expected return on plan assets	(171.6)	(157.6)	(32.0)	(30.7)
Amortization of prior service cost	2.2	1.8	(10.8)	(9.3)
Recognized actuarial loss	49.5	40.7	22.2	21.6
Net periodic benefit cost	$ 50.8	$ 50.8	$ 23.7	$ 27.0

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. While it is not possible to determine the outcome of these matters, 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):

Cymbalta: Seventeen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity (and some also allege nonenforceability) of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia. In November 2008 we filed lawsuits in U.S. District Court for the Southern District of Indiana against Actavis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; and Wockhardt Limited, seeking rulings that the compound patent claims are valid, infringed, and enforceable. We filed similar lawsuits in the same court against Sun Pharma Global, Inc. in December 2008 and against Anchen Pharmaceuticals, Inc. in August 2009. These cases were consolidated and actions against all but Wockhardt Limited were stayed pursuant to stipulations by the defendants to be bound by the outcome of the litigation through appeal. In March 2011, Wockhardt stipulated to entry of final judgment against it and in favor of Lilly on all pending issues, which was so ordered by the court. In April 2011, the court issued an order which dismissed the lawsuit, prohibits the remaining defendants from selling generic duloxetine until our compound patent expires, and requires them to notify the FDA they are not seeking approval of generic duloxetine products during the patent term. Because all parties stipulated to this order, no appeal of this decision is possible.

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. We are seeking review of this decision by the U.S. Supreme Court. 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 November 2010, the district court ruled from the bench that judgment would be entered in Lilly s favor, upholding the patent s validity. Plaintiffs may appeal this decision once the judgment is entered.

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 is invalid. Several companies have received final approval to market generic atomoxetine, but the Court of Appeals for the Federal Circuit granted an injunction prohibiting the launch of generic atomoxetine until the court renders an opinion. The appeal was heard by the court in December 2010 and we are waiting for a ruling. 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 each of these Hatch-Waxman challenges is 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 any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

Zyprexa® Litigation

We are a defendant in approximately 60 Zyprexa product liability lawsuits in the U.S. covering approximately 140 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 at 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 state court in August 2011 and in California state court 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 are seeking review of this decision by the U.S. Supreme Court. An unfavorable outcome in this case could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Byetta Litigation

We have been named as a defendant in approximately 110 lawsuits involving approximately 370 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 40 additional claimants who have not yet filed suit. Approximately 80 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court, and we have a trial 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), thimerosal, and Darvon®. Over 75 percent of 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 March 31,	
	2011	2010
	(Dollars in millions)	
Interest expense	$ 45.8	$ 47.6
Interest income	(15.5)	(10.6)
Other	(19.1)	(111.5)
Other-net, expense (income)	$ 11.2	$ (74.5)

Other income for the first three 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

We achieved revenue growth of 6 percent in the first quarter of 2011, which was driven primarily by the collective growth of Cymbalta, animal health products, Zyprexa, and Alimta, offset by a decline in Gemzar revenue. This revenue growth as well as improved gross margins and a lower effective tax rate were more than offset by the items noted below. As a result, net income decreased 15 percent to $1.06 billion, and earnings per share decreased 16 percent to $0.95 per share, in the first quarter of 2011 as compared to $1.25 billion, or $1.13 per share, in the first quarter of 2010.

2011

As a result of the enactment of health care reform in the U.S. during 2010, in the first quarter of 2011, total revenue was reduced by $89.0 million (pretax), or $.06 per share, as a result of higher rebates and subsidies. Marketing, selling and administrative charges increased by $43.8 million (pretax), or $.04 per share, as a result of the mandatory pharmaceutical manufacturers fee.

We incurred acquired in-process research and development (IPR&D) charges associated with the diabetes collaboration with Boehringer Ingelheim of $388.0 million (pretax), which decreased earnings per share by $.23.

We recognized asset impairments, restructuring, and other special charges of $76.3 million (pretax), or $.06 per share related to severance costs from previously announced strategic actions.

2010

Due to the enactment of health care reform in the U.S. in March 2010, total revenue was reduced by $62.4 million (pretax), or $.04 per share, as a result of higher rebates, and we recorded a one-time non-cash charge 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 with of $50.0 million (pretax), which decreased earnings per share by $.03.

We recognized asset impairments, restructuring, and other special charges of $26.2 million (pretax) 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, which decreased earnings per share by $.02.

Late-Stage Pipeline

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

There are many difficulties and uncertainties inherent in pharmaceutical research and development and the introduction of new products. 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 is 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 therapeutic category.

The following new molecular entities are currently in Phase III clinical trial testing:

BAFF antibody an anti-BAFF monoclonal antibody for the treatment of rheumatoid arthritis and lupus

BI10773 an SGLT-2 inhibitor for the treatment of diabetes (in collaboration with Boehringer Ingelheim)

Enzastaurin a small molecule for the treatment of diffuse large B-cell lymphoma

GLP-1 Fc a glucagon-like peptide 1 analog for the treatment of type 2 diabetes

mGlu2/3 a prodrug receptor agonist for the treatment of schizophrenia

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

NERI a potent and highly selective norepinephrine reuptake inhibitor for the treatment of major depression

Ramucirumab a monoclonal antibody for the treatment of metastatic breast, gastric, liver, NSCLC, and colorectal cancers

Solanezumab an amyloid beta (Aß) antibody for the treatment of Alzheimer s disease

The following new molecular entities have been submitted for regulatory review:

Arxxant a potential treatment for diabetic retinopathy

Florbetapir a molecular imaging tool for the detection of beta-amyloid plaque in the brain. The absence of beta-amyloid plaque in the brain makes a diagnosis of Alzheimer s disease unlikely.

Linagliptin a DPP-4 inhibitor for the treatment of diabetes (in collaboration with Boehringer Ingelheim)

Liprotamase 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:

BI10773 and linagliptin. In January 2011, we announced a global agreement with Boehringer Ingelheim to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development. Included are Boehringer Ingelheim s two oral diabetes agents, linagliptin and BI10773, as well as our two basal insulin analogues, LY2605541 and LY2963016, along with an option to co-develop and co-commercialize Lilly s anti-TGF-beta monoclonal antibody.

Florbetapir. In March 2011, we received a complete response letter from the FDA for the NDA for Amyvid (florbetapir) which 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.

Liprotamase. In April 2011, we received a complete response letter from the FDA for the NDA for liprotamase which communicated the need for us to conduct an additional clinical trial prior to a re-submission. We will be working diligently to address the agency s questions.

mGlu2/3. In February 2011, we began the first Phase III clinical trial for our mGlu2/3 prodrug for schizophrenia.

Necitumumab. In February 2011, 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 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 same DMC also noted that patients who have already received two or more cycles of necitumumab appear to have a lower ongoing risk for these safety concerns. These patients may choose to remain on the trial, after being informed of the additional potential risks. Investigators will continue to assess patients after two cycles to determine if there is a potential benefit from treatment. The DMC also reviewed another Phase III study, called SQUIRE, evaluating necitumumab as a potential treatment for squamous non-small cell lung cancer, and recommended it could continue without any modifications.

Pending Acquisitions

We have reached an agreement with Johnson & Johnson Company to acquire the animal health business of its Janssen Pharmaceutica NV subsidiary (Janssen). Upon deal closing, our animal health division, Elanco, would obtain a portfolio of about 50 marketed animal health products. Closing of the transaction is contingent upon clearance from European regulatory authorities and is subject to other customary closing conditions. We along with Janssen have notified the appropriate European works councils of our intentions and expect the transaction to close in mid-2011. 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, is invalid. Our appeal to the U.S. Court of Appeals for the Federal Circuit was heard in December 2010, and we are awaiting a ruling. The Court of Appeals has granted an injunction that prevents the launch of generic atomoxetine until a ruling is rendered. Several generic companies have tentative approval to market generic atomoxetine, and, should the appeal be unsuccessful, we would anticipate a rapid and severe decline in U.S. Strattera sales due to generic competition.

The enactment of the Patient Protection and Affordable Care Act 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. 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, were generally 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. 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; some proposals would strengthen the pharmaceutical business model while others under consideration might pose some risks.

Beginning in 2011, drug manufacturers will provide 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 will be 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.

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. In addition, the constitutionality of U.S. health care reform is being challenged. We expect pricing pressures at state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

21

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 increased 6 percent, to $5.84 billion, driven primarily by the collective growth of Cymbalta, animal health products, Zyprexa, and Alimta, offset by a decline in Gemzar revenue. Worldwide volume increased 5 percent; the favorable impact of foreign exchange rates contributed 1 percent of revenue growth; and pricing had a negligible impact on revenue growth. Revenue in the U.S. increased by $42.4 million, or 1 percent, for the first quarter of 2011 compared with the first quarter of 2010 primarily due to higher prices, partially offset by lower volume. First-quarter total revenue was reduced by $89.0 million and $62.4 million in 2011 and 2010, respectively, due to the impact of U.S. health care reform.

Revenue outside the U.S. increased $311.2 million, or 13 percent, for the first quarter of 2011 due to increased volume and, to a lesser extent, the positive impact of foreign exchange rates, partially offset by lower prices.

The following table summarizes our revenue activity for the three months ended March 31, 2011 and 2010:

	Three Months Ended March 31, 2011			Three Months Ended March 31,	
Product	U.S.[1]	Outside U.S.	Total[2]	2010 Total	Percent Change from 2010
			(Dollars in millions)		
Zyprexa	$ 597.1	$ 684.8	$ 1,281.9	$ 1,215.0	6
Cymbalta	691.1	217.6	908.8	803.2	13
Alimta	233.0	346.9	579.9	527.4	10
Humalog®	303.8	221.6	525.4	506.4	4
Cialis®	157.8	276.6	434.4	408.3	6
Animal health products	202.4	167.4	369.8	289.6	28
Humulin®	129.4	160.4	289.8	257.8	12
Evista®	174.2	92.0	266.1	241.6	10
Forteo®	111.7	104.4	216.1	194.5	11
Gemzar	59.3	96.8	156.1	287.8	(46)
Strattera	86.6	52.1	138.7	146.4	(5)
Other pharmaceutical products	213.4	309.5	522.9	454.5	15
Total net product sales	2,959.8	2,730.1	5,689.9	5,332.5	7
Collaboration and other revenue[3]	116.4	32.9	149.3	153.0	(2)
Total revenue	$ 3,076.2	$ 2,763.0	$ 5,839.2	$ 5,485.5	6

[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 2 percent in the first three months of 2011, driven by higher prices, partially offset by lower volume. Sales outside the U.S. increased 8 percent driven primarily by higher volume, and to a lesser extent the favorable impact of foreign exchange rates. 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 $280 million in sales for the first quarter of 2011, we will lose effective exclusivity in April 2011 (Spain) and September 2011 (France, Germany, Italy, and the United Kingdom). 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 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 more than $100 million of sales in the first quarter of 2011, 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 6 percent during the first three months of 2011. The increase was due to higher prices, and to a lesser extent, increased demand. Sales outside the U.S. increased 43 percent during the first three months of 2011 compared with the same period in 2010, driven primarily by increased demand resulting from recent launches in Japan and other international markets.

U.S. sales of Alimta, a treatment for various cancers, increased 5 percent during the first three months of 2011 due to higher prices and increased demand. Sales outside the U.S. increased 14 percent for the same period due to increased demand in Japan and other international markets.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 2 percent for the first quarter of 2011 due to lower net effective selling prices, partially offset by increased demand. Sales outside the U.S. increased 13 percent for the first three months of 2011, driven by increased demand.

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 5 percent for the first quarter of 2011 driven primarily by higher prices, partially offset by decreased volume. Sales outside the U.S. increased 7 percent, driven by increased demand and, to a lesser extent, higher prices.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 13 percent during the first three months of 2011, driven by increased demand resulting from the partnership with Walmart for Humulin® ReliOn®. Sales outside the U.S. increased 12 percent during the first three months of 2011, driven by increased demand, partially offset by lower prices.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, increased 10 percent during the first three months of 2011, due to higher prices, partially offset by decreased demand. Sales outside the U.S. increased 10 percent for the first quarter of 2011, driven by increased demand in Japan and to a lesser extent the favorable impact of foreign exchange rates, partially offset by lower prices.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men, decreased 4 percent during the first quarter of 2011 driven by decreased demand, partially offset by higher prices. Sales outside the U.S. increased 34 percent the first quarter of 2011 due primarily to increased demand resulting from the recent launch in Japan.

U.S. sales of Gemzar, a product approved to treat various cancers, decreased 66 percent, 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 15 percent for the first three months of 2011 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.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. adults, decreased 16 percent during the first three months of 2011 due to lower net effective selling prices and decreased demand. Sales outside the U.S. increased 20 percent for the first three months of 2011, driven primarily by continued strong demand in Japan. 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, is invalid. We are currently appealing this decision to the U.S. Court of Appeals for the Federal Circuit. The Court of Appeals has granted an injunction that prevents the launch of generic atomoxetine until a ruling is rendered. While it is difficult to predict the precise impact on Strattera sales, if our appeal is unsuccessful, we expect that the introduction of generics would result in a rapid and severe decline in our U.S. Strattera sales.

We report as revenue for Erbitux, a product approved to treat various cancers, the net royalties received from our collaboration partners and our product sales. Our revenues increased 12 percent, to $104.0 million, during the first quarter of 2011, due primarily to the timing of the sale of manufactured product to partners for development purposes.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, decreased 12 percent, to $165.4 million, during the first quarter of 2011 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

12 percent, to $101.8 million, during the first quarter of 2011.

Animal health product sales in the U.S. increased 28 percent during the first quarter of 2011 due to increased demand for food animal products and the U.S. launch of Trifexis , a monthly oral parasiticide for dogs. Sales outside the U.S. increased 27 percent during the first quarter of 2011, driven by increased demand and the impact of the acquisition of certain Pfizer animal health assets in Europe.

Gross Margin, Costs, and Expenses

For the first quarter of 2011, gross margins as a percentage of total revenue increased by 0.3 percentage points, to 79.8 percent.

Marketing, selling, and administrative expenses increased 11 percent to $1.79 billion for the first quarter of 2011. The increase was driven by increased administrative expenses in the U.S., as well as higher marketing and selling expenses outside the U.S. Higher administrative expenses in the U.S. included $43.8 million related to the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform, as well as higher litigation expenses. Research and development expenses were $1.12 billion for the first quarter of 2011. Compared with the same period of 2010, research and development expenses grew 8 percent due primarily to increased late-stage clinical trial costs.

Acquired IPR&D charges were $388.0 million in the first three months of 2011, all of which was associated with the diabetes collaboration with Boehringer Ingelheim, compared with $50.0 million for the same period in 2010. We incurred $76.3 million of asset impairments, restructuring, and other special charges in the first quarter of 2011, compared with $26.2 million for the same period 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 $11.2 million, compared to $74.5 million of other income in the first quarter of 2010. The first quarter of 2010 included damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany, as well as a gain related to the disposition of investment securities acquired in the ImClone acquisition.

The effective tax rate was 17.1 percent in the first quarter of 2011, compared with an effective tax rate of 26.9 percent in the first quarter of 2010. The effective tax rate in the first quarter of 2010 was driven upward by the 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, as well as the lapse of the U.S. R&D tax credit. The effective tax rate for the first quarter of 2011 reflects the tax benefit of the in-process research and development charge associated with the diabetes collaboration with Boehringer Ingelheim as well as the extension of the R&D tax credit in the U.S. and the excise tax legislation enacted in Puerto Rico.

Financial Condition

As of March 31, 2011, cash, cash equivalents, and short-term investments totaled $6.71 billion compared with $6.73 billion at December 31, 2010. Cash, cash equivalents, and short-term investments remained relatively flat between the periods due to an increase of cash flow from operations of $1.18 billion, offset by dividends paid of $543.2 million, acquisitions of $417.6 million, and net purchases of property and equipment of $101.4 million.

Total debt as of March 31, 2011 decreased by $254.2 million compared with December 31, 2010, to $6.67 billion, which was due to the repayment of $125.0 million in short-term floating rate debt, a decrease of approximately $75 million in other debt, and the approximately $55 million decrease in the fair value of hedged debt. Our current debt ratings from Standard & Poor s and Moody s are AA- and A2, respectively.

As of the first quarter of 2011, the U.S. and global economic recoveries proceed but face continued headwinds and renewed volatility. U.S. economic data in the first quarter was mixed but overall reflects a steady pace of economic recovery, with gradual but sustained improvement in labor market data counter-balanced by an increase in commodity prices spurred by ongoing geopolitical events in the Middle East and North Africa. While core inflation remains at low levels, concerns have arisen about the potential impact of commodity inflation on consumer sentiment, consumer spending, inflation expectations and ultimately core inflation. The U.S. Federal Reserve has maintained its accommodative monetary policy, though internal debate is growing with regard to the timing and manner of a return to more normal monetary policy. High sovereign debt levels and mounting 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 globally. 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 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 has not been adversely affected. 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, Cymbalta, and Strattera, and it is possible we could lose our effective exclusivity for one or more 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

We are a party to various legal actions and government investigations. The most significant of these are described below. While it is not possible to determine the outcome of these matters, 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):

Cymbalta: Seventeen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity (and some also allege nonenforceability) of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia. In November 2008 we filed lawsuits in U.S. District Court for the Southern District of Indiana against Actavis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; and Wockhardt Limited, seeking rulings that the compound patent claims are valid, infringed, and enforceable. We filed similar lawsuits in the same court against Sun Pharma Global, Inc. in December 2008 and against Anchen Pharmaceuticals, Inc. in August 2009. These cases were consolidated and actions against all but Wockhardt Limited were stayed pursuant to stipulations by the defendants to be bound by the outcome of the litigation through appeal. In March 2011, Wockhardt stipulated to entry of final judgment against it and in favor of

Lilly on all pending issues, which was so ordered by the court. In April 2011, the court issued an order which dismissed the lawsuit, prohibits the remaining defendants from selling generic duloxetine until our compound patent expires, and requires them to notify the FDA they are not seeking approval of generic duloxetine products during the patent term. Because all parties stipulated to this order, no appeal of this decision is possible.

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. We are seeking review of this decision by the U.S. Supreme Court. 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 November 2010, the district court ruled from the bench that judgment would be entered in Lilly s favor, upholding the patent s validity. Plaintiffs may appeal this decision once the judgment is entered.

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 is invalid. Several companies have received final approval to market generic atomoxetine, but the Court of Appeals for the Federal Circuit granted an injunction prohibiting the launch of generic atomoxetine until the court renders an opinion. The appeal was heard by the court in December 2010 and we are waiting for a ruling. 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 each of these Hatch-Waxman challenges is 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 any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

Zyprexa Litigation

We are a defendant in approximately 60 Zyprexa product liability lawsuits in the U.S. covering approximately 140 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 at 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 state court in August 2011 and in California state court 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 are seeking review of this decision by the U.S. Supreme Court. An unfavorable outcome in this case could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Byetta Litigation

We have been named as a defendant in approximately 110 lawsuits involving approximately 370 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 40 additional claimants who have not yet filed suit. Approximately 80 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court, and we have a trial 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), thimerosal, and Darvon. Over 75 percent of 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 lowered our 2011 earnings per share guidance to be in a range of $3.86 to $4.01, reflecting the restructuring charge taken in the first quarter of 2011. 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. Due to the recent appreciation of foreign currencies versus the U.S. dollar, we now expect total revenue to grow in the low-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.

Due to the recent appreciation of foreign currencies versus the U.S. dollar, we now anticipate that gross margin as a percent of revenue will decline approximately three percentage points. Marketing, selling, and administrative expenses are still projected to grow in the low- to mid-single digits and include an estimated $150 million to $200 million in non-tax deductible expense for the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform, while research and development expense growth is still expected to be relatively flat. Other net, expense is still expected to be a net expense of between $50 million and $150 million. Cash flows are still expected to be sufficient to fund capital expenditures of between $800 million and $900 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 March 31, 2011, and concluded that they are effective.

27

(b) *Changes in Internal Controls*. During the first 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, Cymbalta, 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 Novapharm 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. 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 Product Liability Litigation

We refer to Part I, Item 3, of our Form 10-K annual report for 2010 for the discussion of product liability litigation involving diethylstilbestrol (DES) and vaccines containing the preservative thimerosal. In the DES litigation, we have been named as a defendant in approximately 20 suits involving approximately 100 claimants seeking to recover damages on behalf of children and grandchildren of women who were prescribed DES during pregnancy in the 1950s and 1960s. In December 2009, a lawsuit was filed in the U.S. District Court in Washington, D.C., against us and other manufacturers (*Michele Fecho, et al v. Eli Lilly and Company, et al*) seeking to assert product liability claims on behalf of a putative class of men and women allegedly exposed to the medicine who claim to have later developed breast cancer. This case has since been transferred to Federal Court in Boston. In the thimerosal litigation, we have been named as a defendant in approximately 60 suits involving approximately 80 claimants. We, along with several other manufacturers, have been named as defendants in approximately 15 cases relating to Darvon and related formulations of propoxyphene. These cases allege various cardiac injuries. One case was filed in the Southern District of Mississippi as a putative class action. We transferred the NDA and all marketing rights to propoxyphene in the U.S. in 2002.

Other Marketing Practices Investigations

In August 2003, we received notice that the staff of the SEC is conducting an investigation into the compliance by Polish subsidiaries of certain pharmaceutical companies, including Lilly, with the U.S. Foreign Corrupt Practices Act of 1977. The staff has issued subpoenas to us requesting production of documents related to the investigation. In connection with that matter, staffs of the SEC and the Department of Justice (DOJ) have asked us to voluntarily provide additional information related to certain activities of Lilly affiliates in a number of other countries. The SEC staff has also issued subpoenas related to activities in these countries. We are in advanced discussions with the SEC to resolve their investigation.

28

Other Matters

In 2004 we, along with several other pharmaceutical companies, were named in a lawsuit in California state court brought by approximately 20 California pharmacies alleging that pharmaceutical companies prevented commercial importation of prescription drugs from outside the 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 may appeal this decision. We believe the lawsuit has no merit and are prepared to defend against it vigorously.

During routine inspections in 2006 and 2007, the U.S. Environmental Protection Agency (EPA) identified potential gaps in our leak detection and repair (LDAR) program. In addition, in 2006 we voluntarily reported to the state and city environmental agencies that we had exceeded an annual limit for air emissions. In response to these events, we have implemented numerous corrective actions and enhancements to our LDAR program. This matter was resolved in February 2011, and we paid a fine of $0.3 million related to the settlement.

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.

In January 2009, as part of the of a government investigation related to our U.S. marketing and promotional practices with respect to Zyprexa, we entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company s systems, processes, policies, procedures, and practices.

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 March 31, 2011:

Period	Total Number of Shares Purchased (a) (in thousands)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c) (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d) (in millions)
January 2011		$		$419.2
February 2011				419.2
March 2011	1	34.39		419.2
Total	1			

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 March 31, 2011, we have purchased $2.58 billion related to this program. During the first three 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.

29

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 10.	The Eli Lilly and Company Executive Officer Incentive Plan
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: April 29, 2011

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

Date: April 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 10.	The Eli Lilly and Company Executive Officer Incentive Plan (Incorporated by reference from Appendix B of the Company s Report on Form DEF 14A filed on March 7, 2011)
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