

LILLY ELI & CO
Form 10-Q
April 30, 2012

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

Quarterly Report Under Section 13 or 15(d) of the

Securities Exchange Act of 1934

FOR THE QUARTER ENDED MARCH 31, 2012

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA
(State or other jurisdiction of
incorporation or organization)
LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285

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

(Address of principal executive offices)

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

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

Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of a large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting Company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

| Class | Number of Shares Outstanding |
|--------|------------------------------|
| Common | 1,160,415,307 |

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, | |
| | 2012 | 2011 |
| | (Dollars in millions, except | |
| | per-share data) | |
| Revenue | \$ 5,602.0 | \$ 5,839.2 |
| Cost of sales | 1,197.9 | 1,180.1 |
| Research and development | 1,151.5 | 1,124.0 |
| Marketing, selling, and administrative | 1,847.5 | 1,785.7 |
| Acquired in-process research and development (Note 4) | | 388.0 |
| Asset impairments, restructuring, and other special charges (Note 5) | 23.8 | 76.3 |
| Other net, expense (Note 13) | 46.0 | 11.2 |
| | 4,266.7 | 4,565.3 |
| Income before income taxes | 1,335.3 | 1,273.9 |
| Income taxes (Note 10) | 324.2 | 218.0 |
| Net income | \$ 1,011.1 | \$ 1,055.9 |
| Earnings per share basic and diluted (Note 9) | \$.91 | \$.95 |
| Dividends paid per share | \$.49 | \$.49 |

See Notes to Consolidated Condensed Financial Statements.

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

Consolidated Condensed Statements of Comprehensive Income

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

| | Three Months Ended | |
|--|-----------------------|------------|
| | March 31, 2012 | 2011 |
| | (Dollars in millions) | |
| Net income | \$ 1,011.1 | \$ 1,055.9 |
| Other comprehensive income, net of tax | 309.4 | 481.3 |
| Comprehensive income | \$ 1,320.5 | \$ 1,537.2 |

See Notes to Consolidated Condensed Financial Statements.

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

Consolidated Condensed Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES

| | March 31, 2012 | December 31, 2011 |
|---|-----------------------|--------------------|
| | (Dollars in millions) | |
| | (Unaudited) | |
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents (Note 6) | \$ 4,122.2 | \$ 5,922.5 |
| Short-term investments (Note 6) | 802.4 | 974.6 |
| Accounts receivable, net of allowances of \$108.4 (2012) and \$110.1 (2011) | 3,402.1 | 3,597.7 |
| Other receivables | 529.2 | 640.2 |
| Inventories | 2,424.2 | 2,299.8 |
| Prepaid taxes | 324.0 | 158.5 |
| Prepaid expenses and other | 998.5 | 654.9 |
| Total current assets | 12,602.6 | 14,248.2 |
| Other Assets | | |
| Investments (Note 6) | 4,521.1 | 4,029.8 |
| Goodwill and other intangibles net (Note 3) | 5,266.7 | 5,128.1 |
| Sundry | 2,093.2 | 2,493.4 |
| Total other assets | 11,881.0 | 11,651.3 |
| Property and Equipment | | |
| Land, buildings, equipment, and construction-in-progress | 14,765.7 | 14,594.0 |
| Less accumulated depreciation | (7,011.1) | (6,833.7) |
| Property and equipment, net | 7,754.6 | 7,760.3 |
| Total assets | \$ 32,238.2 | \$ 33,659.8 |
| Liabilities and Shareholders' Equity | | |
| Current Liabilities | | |
| Short-term borrowings and current maturities of long-term debt | \$ 10.6 | \$ 1,522.3 |
| Accounts payable | 1,246.3 | 1,125.2 |
| Employee compensation | 533.8 | 804.7 |
| Sales rebates and discounts | 1,619.8 | 1,771.3 |
| Dividends payable | | 542.3 |
| Income taxes payable | 388.8 | 261.6 |
| Other current liabilities | 2,754.4 | 2,903.5 |
| Total current liabilities | 6,553.7 | 8,930.9 |
| Other Liabilities | | |
| Long-term debt | 5,403.2 | 5,464.7 |
| Accrued retirement benefits (Note 11) | 2,766.5 | 3,068.5 |
| Long-term income taxes payable (Note 10) | 1,158.3 | 1,086.3 |
| Other noncurrent liabilities | 1,533.9 | 1,573.8 |
| Total other liabilities | 10,861.9 | 11,193.3 |

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

| | | |
|---|--------------------|--------------------|
| Shareholders' Equity (Notes 7 and 8) | | |
| Common stock | 725.8 | 724.1 |
| Additional paid-in capital | 4,858.2 | 4,886.8 |
| Retained earnings | 15,906.7 | 14,897.8 |
| Employee benefit trust | (3,013.1) | (3,013.1) |
| Accumulated other comprehensive loss | (3,549.2) | (3,858.6) |
| Noncontrolling interests | (11.5) | (6.1) |
| Cost of common stock in treasury | (94.3) | (95.3) |
| Total shareholders' equity | 14,822.6 | 13,535.6 |
| Total liabilities and shareholders' equity | \$ 32,238.2 | \$ 33,659.8 |

See Notes to Consolidated Condensed Financial Statements.

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

Consolidated Condensed Statements of Cash Flows

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

| | Three Months Ended | |
|---|-----------------------|------------|
| | March 31, | 2011 |
| | 2012 | 2011 |
| | (Dollars in millions) | |
| Cash Flows from Operating Activities | | |
| Net income | \$ 1,011.1 | \$ 1,055.9 |
| Adjustments to Reconcile Net Income to Cash Flows from Operating Activities: | | |
| Depreciation and amortization | 385.9 | 340.9 |
| Change in deferred income taxes | 132.1 | 92.5 |
| Stock-based compensation expense | 28.2 | 37.9 |
| Acquired in-process research and development, net of tax | | 252.2 |
| Other changes in operating assets and liabilities | (698.7) | (595.6) |
| Other operating activities, net | (6.1) | (7.7) |
| | | |
| Net Cash Provided by Operating Activities | 852.5 | 1,176.1 |
| Cash Flows from Investing Activities | | |
| Net purchases of property and equipment | (130.7) | (101.4) |
| Net change in short-term investments | 457.6 | 539.0 |
| Proceeds from sales and maturities of noncurrent investments | 1,423.2 | 211.9 |
| Purchases of noncurrent investments | (2,156.1) | (238.3) |
| Purchase of product rights | | (29.6) |
| Purchase of in-process research and development | | (388.0) |
| Cash paid for acquisitions, net of cash acquired | (195.4) | |
| Other investing activities, net | (50.9) | (34.3) |
| | | |
| Net Cash Used for Investing Activities | (652.3) | (40.7) |
| Cash Flows from Financing Activities | | |
| Dividends paid | (544.6) | (543.2) |
| Net change in short-term borrowings | (12.4) | (116.2) |
| Repayment of long-term debt | (1,500.0) | (54.6) |
| Other financing activities, net | | 0.2 |
| | | |
| Net Cash Used in Financing Activities | (2,057.0) | (713.8) |
| | | |
| Effect of exchange rate changes on cash and cash equivalents | 56.5 | 91.6 |
| | | |
| Net (decrease) increase in cash and cash equivalents | (1,800.3) | 513.2 |
| | | |
| Cash and cash equivalents at January 1 | 5,922.5 | 5,993.2 |

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

Cash and Cash Equivalents at March 31

\$ 4,122.2

\$ 6,506.4

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 2012 and 2011 was \$127.0 million and \$65.3 million, respectively.

Revenue by Category

Worldwide revenue by category was as follows:

| | Three Months Ended March 31, | |
|------------------------------------|---------------------------------|------------|
| | 2012 | 2011 |
| | (Dollars in millions) | |
| Revenue to unaffiliated customers: | | |
| Pharmaceutical products | | |
| Neuroscience | \$ 1,903.7 | \$ 2,405.1 |
| Endocrinology | 1,690.9 | 1,589.0 |
| Oncology | 803.9 | 839.9 |
| Cardiovascular | 638.4 | 581.8 |
| Other pharmaceuticals | 74.4 | 53.6 |
| Total pharmaceutical products | 5,111.3 | 5,469.4 |
| Animal health | 490.7 | 369.8 |
| Total revenue | \$ 5,602.0 | \$ 5,839.2 |

Notes to Consolidated Condensed Financial Statements

Note 1: Basis of Presentation

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2011. We issued our financial statements by filing with the Securities and Exchange Commission (SEC) and have evaluated subsequent events up to the time of the filing.

Note 2: Implementation of New Financial Accounting Pronouncements

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

Note 3: Acquisitions

Acquisitions of Businesses

On February 17, 2012, we acquired all of the outstanding stock of ChemGen Corporation, a privately-held bioscience company specializing in the development and commercialization of innovative feed enzyme products that improve the efficiency of poultry, egg, and meat production, for total purchase consideration of approximately \$205 million. We have not yet finalized our acquisition accounting but we anticipate the majority of the value of the assets recorded will be marketed product intangibles. This transaction was not material to our consolidated condensed financial statements.

On July 7, 2011, we acquired the animal health business of Janssen Pharmaceutica NV, a Johnson & Johnson company, for total purchase consideration of \$307.8 million in cash. We obtained a portfolio of more than 50 marketed animal health products. In connection with this acquisition, we preliminarily recorded \$234.4 million of marketed product assets and \$29.6 million of acquired in-process research and development (IPR&D) assets, with \$43.8 million of other net assets. The final determination may result in asset and liability fair values that differ from the preliminary estimates, but it is not expected that these differences will be material to our financial results.

Note 4: Collaborations

We often enter into collaborative arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These collaborations often require milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the third party. Revenues related to products sold by us pursuant to these arrangements are included in net product sales, while other sources of revenue (e.g., royalties and profit share payments) are included in collaboration and other revenue. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments made to or reimbursements received from our collaboration partners. Each collaboration is unique in nature, and our more significant arrangements are discussed below. The following table summarizes the composition of our total revenue recognized from all transactions, including collaboration activity:

| | Three Months Ended | |
|-------------------|-----------------------|------------|
| | March 31, 2012 | 2011 |
| | (Dollars in millions) | |
| Net product sales | \$ 5,413.8 | \$ 5,689.9 |

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

| | | |
|---------------------------------|------------|------------|
| Collaboration and other revenue | 188.2 | 149.3 |
| Total revenue | \$ 5,602.0 | \$ 5,839.2 |

Erbix[®]

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

| | Three Months Ended | |
|---------------------------------|-----------------------|-----------------|
| | March 31, | |
| | 2012 | 2011 |
| | (Dollars in millions) | |
| Net product sales | \$ 34.0 | \$ 27.1 |
| Collaboration and other revenue | 79.3 | 76.9 |
| Total revenue | \$ 113.3 | \$ 104.0 |

Bristol-Myers Squibb Company

Pursuant to a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, we are co-developing Erbitux in the U.S. and Canada with BMS, exclusively, and in Japan with BMS and Merck. The companies have jointly agreed to expand the investment in the ongoing clinical development plan for Erbitux to further explore its use in additional tumor types. Under this arrangement, Erbitux research and development and other costs are shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties under the agreement. Collaborative reimbursements received by us for supply of clinical trial materials; for research and development; and for a portion of marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in collaboration and other revenue. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.

We are responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in the territory, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. Sales of Erbitux to BMS for commercial use are reported in net product sales.

Merck KGaA

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

Necitumumab

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

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

In November 2011, we agreed with Amylin Pharmaceuticals, Inc. (Amylin) to terminate our collaborative arrangement for the joint development, marketing, and selling of Byetta® (exenatide injection) and other forms of exenatide such as Bydureon (exenatide extended-release for injectable suspension). Under the terms of the termination agreement,

Amylin made a one-time, upfront payment to us of \$250.0 million. Amylin also agreed to make future revenue-sharing payments to us in an amount equal to 15 percent of their global net sales of exenatide products until Amylin has made aggregate payments to us of \$1.20 billion plus interest, which will accrue at 9.5 percent. Amylin issued a secured note in the amount of \$1.20 billion to us under which any revenue-sharing payments made to us will reduce amounts outstanding under the note. In general, Amylin's obligation for the revenue-sharing payments and the secured note will terminate if all exenatide products are withdrawn from the market due to safety or efficacy issues and are not sold for a period of four years. Amylin will also pay a \$150.0 million milestone to us contingent upon FDA approval of a once-monthly suspension version of exenatide that is currently in Phase II clinical trials.

Commercial operations were transferred to Amylin in the U.S. at the end of November 2011, although we continue to provide certain transition services. Outside the U.S., we will transfer responsibility for commercialization of exenatide to Amylin on a market-by-market basis over a period beginning no earlier than the second half of 2012 and that will not extend beyond December 31, 2013.

Payments received from Amylin are allocated 65 percent to the U.S., which is treated as a contract termination, and 35 percent to the business outside the U.S., which will be treated as the disposition of a business. The allocation was based upon relative fair values. Revenue-sharing payments will be recognized as income as Amylin records sales. The income allocated to the U.S. is recognized as collaboration and other revenue and the income allocated to the business outside the U.S. will be recognized as proceeds from the disposition of a business in other net, expense in our consolidated condensed income statement beginning at the time control of the business transfers to Amylin. The amounts we may receive pursuant to the revenue-sharing arrangement represent contingent consideration and, therefore, do not qualify for recognition as income until the contingency is resolved and the amount becomes fixed or determinable. As a consequence, the note has not been recognized in our consolidated condensed balance sheet.

Prior to termination of the collaboration, we and Amylin were co-promoting Byetta in the U.S. Amylin was responsible for manufacturing and primarily utilized third-party contract manufacturers to supply Byetta. We supplied Byetta pen delivery devices for Amylin and will continue to do so for a period that will not extend beyond December 31, 2013, unless we and Amylin agree otherwise. We are responsible for certain development costs related to certain clinical trials outside the U.S. that we were conducting as of the date of the termination agreement as well as commercialization costs outside the U.S. until the commercial operations are transferred to Amylin.

Under the terms of our prior arrangement, we reported as collaboration and other revenue our 50 percent share of gross margin on Amylin's net product sales in the U.S. We reported as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. We paid Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs were recorded in cost of sales. This arrangement for the commercial operations outside the U.S. will continue until those operations transfer to Amylin. Prior to its termination, under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide's gross margin, we also recorded approximately 50 percent of U.S. related research and development costs and marketing and selling costs in the respective line items on the consolidated condensed statements of operations.

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

| | Three Months Ended | |
|---------------------------------|-----------------------|-----------------|
| | March 31, 2012 | 2011 |
| | (Dollars in millions) | |
| Net product sales | \$ 48.5 | \$ 40.8 |
| Collaboration and other revenue | 51.3 | 61.0 |
| Total revenue | \$ 99.8 | \$ 101.8 |

In accordance with the prior arrangement and pursuant to Amylin's request, in the second quarter of 2011 we loaned Amylin \$165.0 million. Interest on this loan is to be received quarterly and all outstanding principal and interest is due five years from the date of the advance.

Cymbalta®

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

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

Reimbursements or payments for the cost sharing of marketing, selling, and administrative expenses were recorded in the respective expense line items in the consolidated condensed statements of operations. The commission paid to Boehringer was recorded in marketing, selling, and

administrative expenses. In March 2010, the parties agreed to terminate this agreement, and we reacquired the exclusive rights to develop and market duloxetine for all indications in countries outside the U.S. and Japan. In connection with the termination, we paid Boehringer approximately \$400 million and will also pay to Boehringer a percentage of our sales of duloxetine in these countries through 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. 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 \$115.8 million and \$56.3 million in the quarters ended March 31, 2012 and 2011, respectively.

Diabetes Collaboration

In January 2011, we and Boehringer entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are Boehringer's two oral diabetes agents, linagliptin and empagliflozin (BI 10773). Subsequently in 2011, linagliptin was approved and launched in the U.S. (tradename Tradjenta®), Japan (tradename Trazenta®), Europe (tradename Trajenta®), and other countries. Empagliflozin is currently in Phase III clinical testing. Also included in the agreement is our new insulin glargine product and our novel basal insulin analog, both of which began Phase III clinical testing in the second half of 2011; and an option granted to Boehringer to co-develop and co-commercialize our anti-TGF-beta monoclonal antibody, which is currently in Phase II clinical testing. Under the terms of the agreement, we made an initial one-time payment to Boehringer of \$388.0 million and recorded an acquired IPR&D charge, which was included as expense in the first quarter of 2011 and is deductible for tax purposes.

In connection with the approval of linagliptin in the U.S., Japan, and Europe, in 2011 we paid \$478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales. We may pay up to \$300.0 million in additional success-based regulatory milestones for empagliflozin. We will be eligible to receive up to a total of \$650.0 million in success-based regulatory milestones on our two insulin products. Should Boehringer elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to \$525.0 million in opt-in and success-based regulatory milestone payments. The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Revenue related to this collaboration has not been significant to date.

Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby both we and TPG were obligated to fund the Phase III development of solanezumab. Under the agreement, TPG's obligation to fund solanezumab costs was not material and ended in 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.

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 \$72.0 million and \$45.4 million for the first quarter ended March 31, 2012 and 2011, respectively.

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

We recognized asset impairments, restructuring, and other special charges of \$23.8 million in the first quarter of 2012, primarily consisting of a change in our estimates of returned product related to the withdrawal of Xigris[®] from the market during the fourth quarter of 2011.

We recognized severance costs of \$76.3 million in the first quarter of 2011 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.

Note 6: Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit-review procedures and insurance. Major financial institutions represent the largest component of our investments in corporate debt securities. In accordance with documented corporate policies, we limit the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

Accounting Policy for Risk-Management Instruments

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the assets, liabilities, and transactions being hedged. As derivative contracts are initiated, we designate the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized currently in earnings during the period of change.

We may enter into foreign currency forward contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are entered into with the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other net, expense. We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At March 31, 2012, we had outstanding foreign currency forward commitments to purchase 365.2 million U.S. dollars and sell 275.5 million euro, commitments to buy 871.5 million euro and sell 1.15 billion U.S. dollars, and commitments to purchase 380.2 million British pounds and sell 456.8 million euro, which will all settle within 35 days.

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

Interest rate swaps or collars that convert our fixed-rate debt or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. At March 31, 2012, approximately 100 percent of our total debt is at a fixed rate. We have converted approximately 60 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities.

The Effect of Risk-Management Instruments on the Consolidated Condensed Statement of Operations

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

| | Three Months Ended | |
|---|-----------------------|-----------|
| | March 31, 2012 | 2011 |
| | (Dollars in millions) | |
| Fair value hedges | | |
| Effect from hedged fixed-rate debt | \$ (65.9) | \$ (53.3) |
| Effect from interest rate contracts | 65.9 | 53.3 |
| 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 | (32.8) | 30.0 |

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

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

During the first quarters of 2012 and 2011, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.

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

Fair Value of Financial Instruments

The following tables summarize certain fair value information at March 31, 2012 and December 31, 2011 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

| Description | Carrying Amount | Amortized Cost | Fair Value Measurements Using | | | Fair Value |
|--|-------------------|-------------------|--|---|---|------------|
| | | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | |
| March 31, 2012 | | | | | | |
| Cash and cash equivalents | \$ 4,122.2 | \$ 4,122.2 | \$ 4,006.4 | \$ 115.8 | \$ | \$ 4,122.2 |
| Short-term investments | | | | | | |
| U.S. government and agencies | \$ 46.2 | \$ 46.2 | \$ 46.2 | \$ | \$ | \$ 46.2 |
| Corporate debt securities | 735.8 | 735.1 | | 735.8 | | 735.8 |
| Other securities | 20.4 | 20.4 | | 20.4 | | 20.4 |
| Short-term investments | \$ 802.4 | \$ 801.7 | | | | |
| Noncurrent investments | | | | | | |
| U.S. government and agencies | \$ 978.4 | \$ 976.1 | \$ 978.4 | \$ | \$ | \$ 978.4 |
| Corporate debt securities | 2,373.7 | 2,362.7 | | 2,373.7 | | 2,373.7 |
| Mortgage-backed | 476.2 | 506.8 | | 476.2 | | 476.2 |
| Asset-backed | 306.6 | 313.9 | | 306.6 | | 306.6 |
| Other securities | 11.1 | 11.1 | | 10.1 | 1.0 | 11.1 |
| Marketable equity | 201.6 | 109.3 | 201.6 | | | 201.6 |
| Equity method and other investments ⁽¹⁾ | 173.5 | 173.5 | | | | |
| Noncurrent investments | \$ 4,521.1 | \$ 4,453.4 | | | | |
| December 31, 2011 | | | | | | |
| Cash and cash equivalents | \$ 5,922.5 | \$ 5,922.5 | \$ 5,264.6 | \$ 657.9 | \$ | \$ 5,922.5 |
| Short-term investments | | | | | | |
| U.S. government and agencies | \$ 362.3 | \$ 362.3 | \$ 362.3 | \$ | \$ | \$ 362.3 |
| Corporate debt securities | 600.7 | 601.1 | | 600.7 | | 600.7 |
| Other securities | 11.6 | 11.6 | | 11.6 | | 11.6 |
| Short-term investments | \$ 974.6 | \$ 975.0 | | | | |
| Noncurrent investments | | | | | | |
| U.S. government and agencies | \$ 908.8 | \$ 901.3 | \$ 908.8 | \$ | \$ | \$ 908.8 |
| Corporate debt securities | 2,081.3 | 2,093.3 | | 2,081.3 | | 2,081.3 |

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

| | | | | |
|---|-------|-------|-------|-------|
| Mortgage-backed | 443.8 | 479.1 | 443.8 | 443.8 |
| Asset-backed | 245.0 | 253.2 | 245.0 | 245.0 |
| Other securities | 10.0 | 11.9 | 8.7 | 1.3 |
| Marketable equity | 180.8 | 107.5 | 180.8 | 180.8 |
| Equity methods and other investments ⁽¹⁾ | 160.1 | 160.1 | | |

Noncurrent investments \$ 4,029.8 \$ 4,006.4

⁽¹⁾ Fair value not applicable

| Description | Carrying Amount | Quoted Prices in Active Markets for Identical Assets (Level 1) | Fair Value Measurements Using | | | Fair Value |
|--|-----------------|--|---|---|--|--------------|
| | | | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | | |
| Long-term debt, including current portion | | | | | | |
| March 31, 2012 | \$ (5,413.8) | \$ | \$ (5,845.2) | \$ | | \$ (5,845.2) |
| December 31, 2011 | \$ (6,981.5) | \$ | \$ (7,451.5) | \$ | | \$ (7,451.5) |

| Description | Carrying Amount | Quoted Prices in Active Markets for Identical Assets (Level 1) | Fair Value Measurements Using | | | Fair Value |
|--|-----------------|--|---|---|--|------------|
| | | | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | | |
| March 31, 2012 | | | | | | |
| Risk-management instruments | | | | | | |
| Interest rate contracts designated as hedging instruments | | | | | | |
| Sundry | \$ 472.0 | \$ | \$ 472.0 | \$ | | \$ 472.0 |
| Foreign exchange contracts not designated as hedging instruments | | | | | | |
| Other receivables | 12.1 | | 12.1 | | | 12.1 |
| Other current liabilities | (5.3) | | (5.3) | | | (5.3) |
| December 31, 2011 | | | | | | |
| Risk-management instruments | | | | | | |
| Interest rate contracts designated as hedging instruments | | | | | | |
| Other receivables | \$ 6.1 | \$ | \$ 6.1 | \$ | | \$ 6.1 |
| Sundry | 531.7 | | 531.7 | | | 531.7 |
| Foreign exchange contracts not designated as hedging instruments | | | | | | |
| Other receivables | 16.2 | | 16.2 | | | 16.2 |
| Other current liabilities | (25.9) | | (25.9) | | | (25.9) |

The fair value of the contingent consideration liability related to prior acquisitions, a Level 3 measurement in the fair value hierarchy, was \$121.6 million as of March 31, 2012 and December 31, 2011, 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 \$4.19 billion of our investments in debt securities, measured at fair value, will mature within five years.

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

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

| | March 31, 2012 | December 31, 2011 |
|---|-----------------------|-------------------|
| | (Dollars in millions) | |
| Unrealized gross gains | \$ 124.8 | \$ 103.0 |
| Unrealized gross losses | 56.4 | 80.0 |
| Fair value of securities in an unrealized gain position | 3,159.0 | 2,498.9 |
| Fair value of securities in an unrealized loss position | 1,877.5 | 2,164.4 |

Other-than-temporary impairment losses on fixed income securities of \$3.7 million were recognized in the statement of operations for the first quarter of 2012 compared with \$0.5 million for the same period in 2011. The amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position include fixed-rate debt securities of varying maturities. The value of fixed income securities is sensitive to changes in the yield curve and other market conditions. Approximately 90 percent of the securities in a loss position are investment-grade debt securities. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of March 31, 2012.

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

| | Three Months Ended | |
|--------------------------------|-----------------------|----------|
| | March 31, 2012 | 2011 |
| | (Dollars in millions) | |
| Proceeds from sales | \$ 2,383.4 | \$ 260.9 |
| Realized gross gains on sales | 13.7 | 39.4 |
| Realized gross losses on sales | 2.7 | 3.5 |

Realized gains and losses on sales of available-for-sale securities are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

Note 7: Stock-Based Compensation

Our stock-based compensation expense consists primarily of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognized pretax stock-based compensation cost of \$30.9 million and \$37.9 million in the first quarter of 2012 and 2011, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings per share targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement period. As of March 31, 2012, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$42.6 million, which will be amortized over the weighted-average remaining requisite service period of approximately 17 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, 2012, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to

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

\$84.5 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, 2012, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to \$91.3 million, which will be amortized over the weighted-average remaining requisite service period of 27 months.

Note 8: Shareholders Equity

As of March 31, 2012, we have purchased \$2.58 billion of our previously announced \$3.00 billion share repurchase program. We did not acquire any shares pursuant to this program during the first three months of 2012, and we have no current plans to repurchase shares under this program for the remainder of 2012.

Note 9: Earnings Per Share

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

Note 10: Income Taxes

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

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

Note 11: Retirement Benefits

Net pension and retiree health benefit expense included the following components:

| | Defined Benefit Pension Plans Three Months Ended | | Retiree Health Benefit Plans Three Months Ended | |
|---|---|-------------------|--|-------------------|
| | March 31, 2012 | March 31, 2011 | March 31, 2012 | March 31, 2011 |
| (Dollars in millions) | | | | |
| Components of net periodic benefit cost | | | | |
| Service cost | \$ 63.0 | \$ 58.9 | \$ 16.4 | \$ 14.8 |
| Interest cost | 113.0 | 111.8 | 28.5 | 29.5 |
| Expected return on plan assets | (171.1) | (171.6) | (31.8) | (32.0) |
| Amortization of prior service cost | .9 | 2.2 | (8.8) | (10.8) |
| Recognized actuarial loss | 70.9 | 49.5 | 23.7 | 22.2 |
| Net periodic benefit cost | \$ 76.7 | \$ 50.8 | \$ 28.0 | \$ 23.7 |

On a global basis, we have contributed approximately \$30 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2012. In addition, we have contributed \$300 million of discretionary funding to our global post-retirement benefit plans in 2012. During the remainder of 2012, we expect to make contributions to our defined benefit pension plans of approximately \$40 million to satisfy minimum funding requirements. We do not anticipate making any additional discretionary contributions in 2012.

Note 12: Contingencies

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

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as specifically noted below with respect to the Alimta[®] Hatch-Waxman Act patent challenges, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

We are engaged in U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984). Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patents and data-based pediatric exclusivity period (compound patent licensed from the Trustees of Princeton University and expiring in 2017, concomitant nutritional supplement use patent expiring in 2022) and alleging the patents are invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. In July 2011, the district court entered judgment in our favor, upholding that patent's validity. The generic manufacturers have appealed this decision. In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP, Pliva Hrvatska D.O.O., and Barr seeking rulings that our concomitant nutritional supplement use patent is valid and infringed. No trial date has yet been set. In January 2012 and April 2012, we filed similar lawsuits against Accord Healthcare Inc. and Apotex Inc., respectively.

We believe the Hatch-Waxman challenges to the Alimta patents are without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

Zyprexa® Litigation

We are a defendant in approximately 20 Zyprexa product liability lawsuits in the U.S. covering approximately 80 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 15 of the lawsuits, covering about 15 plaintiffs, are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596). We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

Byetta Litigation

We have been named as a defendant in approximately 115 lawsuits involving approximately 490 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 520 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court. We believe these claims are without merit and are prepared to defend against them vigorously.

Diethylstilbestrol Litigation

In approximately 100 U.S. lawsuits against us involving approximately 115 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed diethylstilbestrol (DES) during pregnancy in the 1950s and 1960s. Approximately 85 of these claimants allege that they were indirectly exposed in utero to the medicine and later developed breast cancer as a consequence. In December 2009, a lawsuit was filed in U.S. District Court in Washington, D.C. against Lilly 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 was dismissed in April 2012. Certain parties in this case participated in court-ordered mediation on April 20, 2012 which did not result in a decision. Five cases involving similar allegations are scheduled for trial in January 2013. We believe these claims are without merit and are prepared to defend against them vigorously.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims in the future. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. The DES claims are covered by insurance, subject to deductibles and coverage limits. There is no assurance that we will be able to fully collect from our insurance carriers in the future.

Note 13: Other - Net, Expense

Other - net, expense comprised the following:

| | Three Months Ended | |
|--------------------|-----------------------|-------------------|
| | March 31, 2012 | March 31, 2011 |
| | (Dollars in millions) | |
| Interest expense | \$ 45.3 | \$ 45.8 |
| Interest income | (26.1) | (15.5) |
| Other | 26.8 | (19.1) |
| Other-net, expense | \$ 46.0 | \$ 11.2 |

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

Operating Results

Executive Overview

Financial Results

Worldwide total revenue was \$5.60 billion, a decrease of 4 percent compared with the first quarter of 2011. The decrease was primarily driven by the loss of patent exclusivity for Zyprexa, partially offset by growth in Cymbalta, Forteo®, Effient, diabetes care, and our animal health portfolio. The decrease in revenues, lower gross margin, and an increase in the effective tax rate, were partially offset by the acquired in-process research and development (IPR&D) charge in the first quarter 2011 described below. As a result, net income decreased 4 percent to \$1.01 billion, and earnings per share decreased 4 percent to \$0.91 per share, in the first quarter of 2012 as compared to \$1.06 billion, or \$0.95 per share, in the first quarter of 2011.

2012

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

We recognized asset impairments, restructuring, and other special charges of \$23.8 million (pretax), or \$.01 per share, primarily related to changes in returns reserve estimates for the withdrawal of Xigris in the fourth quarter of 2011.

2011

Collaborations (Note 4)

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

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

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.

Late-Stage Pipeline

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

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

There are many difficulties and uncertainties inherent in pharmaceutical research and development (R&D) and the introduction of new products. A high rate of failure is inherent in new drug discovery and development. The process to bring a drug from the discovery phase to regulatory approval can take 12 to 15 years or longer and cost more than \$1 billion. Failure can occur at any point in the process, including late in the process after substantial investment. As a result, most research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Delays and uncertainties in the U.S. Food and Drug Administration (FDA) approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. Consequently, it is very difficult to predict which products will ultimately be approved and the sales growth of those products.

We manage R&D spending across our portfolio of molecules, and a delay in, or termination of, any one project will not necessarily cause a significant change in our total R&D spending. Due to the risks and uncertainties involved in the R&D process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our R&D projects, nor can we reliably estimate the future potential revenue that will be generated from a successful R&D project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated R&D expense. While we do accumulate certain R&D costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total R&D costs by project, by preclinical versus clinical spend, or by therapeutic category.

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

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

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

Empagliflozin-BI10773 (Q3 2010) a sodium glucose co-transporter (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim)

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

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

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

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

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

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

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

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

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

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

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

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

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

Florbetapir On April 6, 2012, the FDA approved Amyvid (florbetapir), a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline. Beginning in June, a limited number of radiopharmacies will be distributing Amyvid.

Linagliptin In January 2012, the FDA approved Jentadueto, a combination of linagliptin and metformin for the treatment of adults with type 2 diabetes (in collaboration with Boehringer Ingelheim).

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

Solanezumab In January 2012, an independent Data Monitoring Committee (DMC) recommended that we continue the two ongoing Phase III randomized pivotal trials for solanezumab without modifications, based on pre-planned interim safety and futility analyses. The DMC also recommended that we make a protocol modification to EXPEDITION-XT, the open-label extension study of the two Phase III trials, making the protocol for the open-label extension more consistent with the current protocol for the pivotal studies. We expect to report the results of the two Phase III pivotal trials in the second half of 2012.

Legal, Regulatory, and Other Matters

The enactment of the Patient Protection and Affordable Care Act (PPACA) and The Health Care and Education Reconciliation Act of 2010 in March 2010 brought significant changes to U.S. health care. These changes began to affect our financial results in the first quarter of 2010 and will continue to have significant impact on our results in the future. The U.S. Supreme Court has agreed to decide the constitutionality of the PPACA, including the Medicaid expansion and the individual mandate for health insurance scheduled to take effect in 2014. Oral arguments took place in March 2012 and a decision is expected in June 2012. We are unable to predict the impact to our consolidated results of operations, liquidity, and financial position should the Supreme Court rule that all or part of the PPACA is unconstitutional.

The continuing prominence of U.S. budget deficits as both a policy and political issue increases the risk that taxes, fees, rebates, or other measures that would further reduce pharmaceutical companies' revenue or increase expenses may be enacted. Certain other federal and state health care proposals continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. We also expect pricing pressures at state levels could become more severe. These federal and state proposals, or state price pressures, could have a material adverse effect on our consolidated results of operations.

The Obama administration has proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. There also have been tax proposals under discussion or introduced in the U.S. Congress that could change the manner in which, and the rate at which, income of U.S. companies would be taxed. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, will continue to be a topic of discussion for Congress and the Obama administration. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations.

International operations also are generally subject to extensive price and market regulations, 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 pressures on national and regional health care budgets as a result of austerity measures being pursued in a number of countries.

Revenue

Revenue decreased 4 percent, to \$5.60 billion, compared with the first quarter of 2011. This 4 percent revenue decline was comprised of a decrease of 7 percent due to lower volume, partially offset by an increase of 4 percent in prices. Foreign exchange rates had a negligible impact (numbers do not add due to rounding). The decrease in volume was driven by the loss of patent exclusivity for Zyprexa in most major markets, partially offset by volume gains for other products. Total revenue in the U.S. remained relatively flat at \$3.08 billion due to the loss of patent exclusivity for Zyprexa, offset by higher prices and, to a lesser extent, increased volume in other products. Revenue outside the U.S. decreased \$245.9 million, or 9 percent, for the first quarter of 2012 driven by the loss of patent exclusivity for Zyprexa, partially offset by increased volume in other products including Cymbalta, Forteo, Humalog®, Effient, and the animal health portfolio.

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

The following table summarizes our revenue activity for the three months ended March 31, 2012 and 2011:

| Product | Three Months Ended March 31, 2012 | | | Three Months Ended March 31, 2011 | Percent Change from 2011 |
|--|--------------------------------------|-------------------|--------------------|--|--------------------------------|
| | U.S. ¹ | Outside U.S. | Total ² | Total | |
| | (Dollars in millions) | | | | |
| Cymbalta | \$ 857.6 | \$ 257.3 | \$ 1,114.9 | \$ 908.8 | 23% |
| Alimta | 256.6 | 350.2 | 606.8 | 579.9 | 5% |
| Humalog | 348.4 | 241.9 | 590.3 | 525.4 | 12% |
| Zyprexa | 202.8 | 359.9 | 562.7 | 1,281.9 | (56)% |
| Animal health products | 269.6 | 221.1 | 490.7 | 369.8 | 33% |
| Cialis® | 178.8 | 283.0 | 461.8 | 434.4 | 6% |
| Humulin® | 155.1 | 152.6 | 307.7 | 289.8 | 6% |
| Forteo | 121.9 | 149.4 | 271.3 | 216.1 | 26% |
| Evista® | 171.7 | 84.5 | 256.2 | 266.1 | (4)% |
| Strattera® | 104.8 | 54.1 | 158.9 | 138.7 | 15% |
| Effient | 89.8 | 26.0 | 115.8 | 56.3 | NM |
| Other pharmaceutical products | 166.7 | 310.0 | 476.7 | 622.7 | (23)% |
| Total net product sales | 2,923.8 | 2,490.0 | 5,413.8 | 5,689.9 | (5)% |
| Collaboration and other revenue ³ | 161.1 | 27.1 | 188.2 | 149.3 | 26% |
| Total revenue | \$ 3,084.9 | \$ 2,517.1 | \$ 5,602.0 | \$ 5,839.2 | (4)% |

NM Not Meaningful

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

² Numbers may not add due to rounding.

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

Product Highlights

U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the U.S. for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, increased 24 percent during the first three months of 2012. The increase was due to higher prices and increased demand. Sales outside the U.S. increased 18 percent during the first three months of 2012 compared with the same period in 2011, driven by increased demand.

U.S. sales of Alimta, a treatment for various cancers, increased 10 percent during the first three months of 2012 due to increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 1 percent for the same period due to increased demand, partially offset by lower prices in Japan.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 15 percent for the first quarter of 2012 due to higher prices. Sales outside the U.S. increased 9 percent for the first three months of 2012, driven by increased demand.

U.S. sales of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, decreased 66 percent in the first three months of 2012. Sales outside the U.S. decreased 47 percent. The decreases in both the U.S. and outside the U.S. were due to the loss of patent exclusivity in the U.S. and most major international markets outside of Japan. We expect further erosion of Zyprexa sales throughout 2012.

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

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 13 percent for the first quarter of 2012, driven by increased demand. Sales outside the U.S. increased 2 percent, driven by increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 20 percent during the first three months of 2012, driven primarily by higher prices. Sales outside the U.S. decreased 5 percent during the first three months of 2012, driven by the unfavorable impact of foreign exchange rates, lower prices, and decreased volume.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men, increased 9 percent during the first quarter of 2012, driven by higher prices, largely offset by decreased demand. Sales outside the U.S. increased 43 percent the first quarter of 2012, due primarily to increased demand in Japan.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 1 percent during the first three months of 2012, driven by decreased demand, largely offset by higher prices. Sales outside the U.S. decreased 8 percent for the first quarter of 2012, driven by decreased volume in Japan.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. in adults, increased 21 percent during the first three months of 2012, due to higher prices. Sales outside the U.S. increased 4 percent for the first three months of 2012, driven primarily by increased demand, partially offset by lower prices.

U.S. sales of Effient, a product for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention (PCI), including patients undergoing angioplasty, atherectomy, or stent placement, increased 114 percent during the first three months of 2012 due to increased demand and higher prices. Sales outside the U.S. increased 82 percent due to increased demand.

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 9 percent, to \$113.3 million, during the first quarter of 2012.

Animal health product sales in the U.S. increased 33 percent during the first quarter of 2012 due primarily to increased demand and the favorable impact from customer buying patterns. Sales outside the U.S. increased 32 percent during the first quarter of 2012, driven primarily by the impact of the acquisition of the Janssen animal health assets in Europe.

Gross Margin, Costs, and Expenses

For the first quarter of 2012, gross margin as a percent of total revenue decreased by 1.2 percentage points, to 78.6 percent. The decrease was primarily due to lower sales of Zyprexa following its patent expiration in most major markets, partially offset by the impact of foreign exchange rates on international inventories sold.

Marketing, selling, and administrative expenses increased 3 percent, to \$1.85 billion, for the first quarter of 2012, driven by the diabetes collaboration with Boehringer Ingelheim (BI) and increased expense for newer pharmaceutical and animal health products, partially offset by lower administrative expenses. Research and development expenses were \$1.15 billion for the first quarter of 2012. Compared with the same period of 2011, research and development expenses increased 2 percent, driven by expenses related to the diabetes collaboration with BI and other late-stage clinical trial costs.

No acquired IPR&D charges were incurred in the first three months of 2012, compared with \$388.0 million for the same period in 2011, all of which was associated with the diabetes collaboration with BI. We incurred \$23.8 million of asset impairments, restructuring, and other special charges in the first quarter of 2012, compared with \$76.3 million for the same period in 2011. See Notes 4 and 5 to the consolidated condensed financial statements for additional information.

Other net expense was a net expense of \$46.0 million, compared with net expense of \$11.2 million in the first quarter of 2011. The increase was driven by the recognition in the first quarter of 2011 of a gain on an equity investment and an insurance recovery, partially offset by increased interest income in the first quarter of 2012.

The effective tax rate was 24.3 percent in the first quarter of 2012, compared with an effective tax rate of 17.1 percent in the first quarter of 2011. The increase in the effective tax rate was driven primarily by the tax benefit in 2011 of the IPR&D charge described above, as well as the expiration of the R&D tax credit in the U.S. at the end of 2011.

Financial Condition

As of March 31, 2012, cash, cash equivalents, and short-term investments totaled \$4.92 billion compared with \$6.90 billion at December 31, 2011. The decrease was due primarily to the maturity and repayment of long-term debt of \$1.50 billion and dividends paid of \$544.6 million.

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

Total debt as of March 31, 2012 decreased by \$1.57 billion compared with December 31, 2011, to \$5.41 billion, due primarily to the previously mentioned long-term debt maturity and payment of \$1.50 billion. Our current debt ratings from Standard & Poor's and Moody's are AA- and A2, respectively.

As of the first quarter of 2012, the U.S. economy continues to show signs of recovery, though at a moderate pace. This is in contrast to Europe, where the Eurozone gross domestic product will likely decrease in 2012, with the peripheral nations continuing to weigh on the region. While worries in Europe persist, several positive actions this quarter were aimed at calming fears, including the Greek Private Sector Involvement bond exchange, the European Central Bank's second three-year Long-Term Refinancing Operations and the agreement of Eurozone finance ministers to increase the size of the bailout package by 500 billion euro. This quarter also saw Japan announce its first trade deficit in more than three decades, while concern over oil prices created unease. Meanwhile, U.S. economic data in the first quarter generally exceeded expectations, with several key indicators signaling a strengthening recovery dampened, however, by the continued lag of the housing market. Given the fragility of the economic recovery and the continued anxiety regarding Europe, the Federal Reserve has maintained its view that accommodative policy is likely to be warranted through 2014. Fiscal austerity efforts, domestically and abroad (most notably in Spain, Italy and Greece), driven by sluggish growth and high sovereign debt levels, play a key role in the global economic recovery. We continue to monitor the potential impacts of the economic environment; the creditworthiness of our wholesalers and other customers, including foreign government backed agencies and suppliers; the uncertain impact of recent health care legislation; the federal government's involvement in the U.S. economy; and various international government funding levels. Currently, we believe economic conditions in Europe will not have a material impact on our liquidity.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including debt service, capital expenditures, and dividends in 2012. 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 2012 section, may affect our operating results and cash generated from operations.

We depend on patents or other forms of intellectual property protection for most of our revenues, cash flows, and earnings. Through 2014, we expect to lose U.S. patent protection for Cymbalta (June 2013) and Evista (March 2014). Cymbalta could receive an additional six months of exclusivity, based on completion of pediatric studies.

Zyprexa and Gemzar have already lost exclusivity in the U.S. and Europe. In the U.S., Gemzar lost exclusivity in November 2010 and Zyprexa lost exclusivity in October 2011. In addition, we face U.S. patent litigation over Alimta, and it is possible we could lose our exclusivity prior to the expiration of the relevant patents. Refer to the Hatch-Waxman patent litigation discussion in Note 12 and in the Legal and Regulatory Matters section below. The loss of exclusivity for Alimta, Cymbalta, or Evista 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. The U.S. patent for Humalog expires in May 2013. Humalog is currently protected in Europe only by formulation patents. We do not currently expect the loss of patent protection for Humalog to result in a rapid and severe decline in revenue. To date, no biosimilar version of Humalog has been approved in the U.S. or Europe; however, it is difficult to predict the likelihood and impact of biosimilars entering the market. Our goal is to mitigate the effect of these exclusivity losses on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, in the emerging markets, in Japan, and in our animal health business. Our expected growth in the emerging markets and Japan is attributable to both the growth of these markets and launches of patent-protected products in these markets.

Legal and Regulatory Matters

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as specifically noted below with respect to the Alimta[®] Hatch-Waxman Act patent challenges, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

We are engaged in U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984). Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patents and data-based pediatric exclusivity period (compound patent licensed from the Trustees of Princeton University and expiring in 2017, concomitant nutritional supplement use patent expiring in 2022) and alleging the patents are invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. In July 2011, the district court entered judgment in our favor, upholding

that patent's validity. The generic manufacturers have appealed this decision. In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP, Pliva Hrvatska D.O.O., and Barr seeking rulings that our concomitant nutritional supplement use patent is valid and infringed. No trial date has yet been set. In January 2012 and April 2012, we filed similar lawsuits against Accord Healthcare Inc. and Apotex Inc., respectively.

We believe the Hatch-Waxman challenges to the Alimta patents are without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

Zyprexa® Litigation

We are a defendant in approximately 20 Zyprexa product liability lawsuits in the U.S. covering approximately 80 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 15 of the lawsuits, covering about 15 plaintiffs, are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596). We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

Byetta Litigation

We have been named as a defendant in approximately 115 lawsuits involving approximately 490 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 520 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court. We believe these claims are without merit and are prepared to defend against them vigorously.

Diethylstilbestrol Litigation

In approximately 100 U.S. lawsuits against us involving approximately 115 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed diethylstilbestrol (DES) during pregnancy in the 1950s and 1960s. Approximately 85 of these claimants allege that they were indirectly exposed in utero to the medicine and later developed breast cancer as a consequence. In December 2009, a lawsuit was filed in U.S. District Court in Washington, D.C. against Lilly 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 was dismissed in April 2012. Certain parties in this case participated in court-ordered mediation on April 20, 2012 which did not result in a decision. Five cases involving similar allegations are scheduled for trial in January 2013. We believe these claims are without merit and are prepared to defend against them vigorously.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims in the future. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. The DES claims are covered by insurance, subject to deductibles and coverage limits. There is no assurance that we will be able to fully collect from our insurance carriers in the future.

Financial Expectations for 2012

We have raised our 2012 earnings per share guidance and now expect to be in the range of \$3.14 to \$3.29. All other elements of our 2012 financial guidance remain unchanged. We anticipate that total revenue will be between \$21.8 billion and \$22.8 billion. This includes an expected decline of more than \$3 billion in Zyprexa sales due to patent expirations in most markets outside of Japan. The reduction in revenue due to Zyprexa patent expirations is expected to be partially offset by growth in key franchises including Cymbalta, Cialis, Humalog, Humulin, and Forteo, as well as continued growth of newer products such as Effient, Axiron®, and Tradjenta. We also anticipate continued strong, double-digit revenue growth from our Elanco Animal Health business. Both Japan and emerging markets are expected to post continued strong underlying volume growth; however, overall revenue growth in these markets in 2012 will be adversely affected by pricing actions in Japan and by the expected impact of patent expirations, including Zyprexa, in some emerging market countries.

We anticipate that gross margin as a percent of revenue will be approximately 77 percent. Marketing, selling, and administrative expenses are expected to decline and be in the range of \$7.4 billion to \$7.8 billion. Research and development expense is expected to be flat to increasing and in the range of \$5.0 billion to \$5.3 billion. Other net, expense is expected to be in a range between net expense of \$50 million and net income of \$100 million. Operating cash flows are expected to be more than sufficient to fund capital expenditures of approximately \$800 million, as well as anticipated business development activity and our current 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 2011 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, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services and chief financial officer, evaluated our disclosure controls and procedures as of March 31, 2012, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the first quarter of 2012, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We are pursuing a multi-year initiative to outsource some accounting transaction-processing activities, migrating to a consistent enterprise financial system across the organization, and moving certain activities to newly-established captive shared services centers. In addition, we are in the process of reducing financial human resources at various locations around the world. None of these initiatives is in response to any identified deficiency or weakness in our internal control over financial reporting. These initiatives are expected to continue to enhance our internal control over financial reporting, but in the short term may increase our risk.

Part II. Other Information

Item 1. Legal Proceedings

See 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

The product liability litigation involving Zyprexa, Byetta, and diethylstilbestrol. That information is incorporated into this Item by reference.

Strattera Patent Litigation

Actavis Elizabeth LLC, Apotex Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals Inc., Sandoz Inc., Sun Pharmaceutical Industries Limited, and Teva Pharmaceuticals USA, Inc. each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent and data-based pediatric exclusivity period (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against the seven companies in the U.S. District Court for the District of New Jersey. In August 2010, the district court ruled that our patent was invalid; however, in July 2011, the Court of Appeals for the Federal Circuit overturned that decision, upholding the patent. The deadline for any further appeal has passed. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it had the right to launch a generic atomoxetine product, based on the district court ruling in the Actavis case. Following the Federal Circuit decision in Actavis, Zydus and Lilly entered into a consent judgment under which Zydus has dismissed its declaratory judgment action and consented to the validity of Lilly's patent.

Other Product Liability Litigation

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

Along with several other manufacturers, we have been named as a defendant in approximately 150 cases in the U.S. involving approximately 760 claimants related to the analgesic Darvon and related formulations of propoxyphene. These cases generally allege various cardiac injuries. In November 2011, a lawsuit was filed in the U.S. District Court for the Eastern District of Louisiana (*Ballard, et al. v. Eli Lilly and Company et al.*) against Lilly and other manufacturers as a putative class action seeking to assert product liability claims on behalf of U.S. residents who ingested propoxyphene and allegedly sustained personal injuries. We transferred the U.S. regulatory approvals and all marketing rights to our propoxyphene products in 2002 to aaiPharma Inc., which subsequently transferred all such approvals and marketing rights to Xanodyne Pharmaceuticals, Inc. We believe these claims are without merit and are prepared to defend against them vigorously.

We have been named as a defendant in a U.S. lawsuit involving a claimant alleging that the antidepressant Prozac caused or contributed to birth defects in the daughter of a woman who ingested the drug during pregnancy. We are aware of approximately 315 additional claims related to birth defects, which have not yet been filed. We believe these claims are without merit and are prepared to defend against them vigorously.

We have been named along with Takeda Chemical Industries, Ltd., and Takeda affiliates (together "Takeda") as a defendant in product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until September 2006. Under our agreement with Takeda, we will be indemnified by Takeda for our losses and expenses in connection with the U.S. litigation in accordance with the terms of the agreement. We have also been named along with Takeda as a defendant in a purported product liability class action in Ontario, Canada (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*) related to Actos, which we promoted in Canada until 2009. We believe these claims are without merit and are prepared to defend against them vigorously.

Other Matters

We are also a defendant in other litigation and investigations, including product liability, patent, employment, and premises liability litigation, of a character we regard as normal to our business.

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended March 31, 2012:

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

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

February 2012
March 2012

419.2
419.2

Total

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.00 billion share repurchase program announced in March 2000. As of March 31, 2012, we have purchased \$2.58 billion related to this program. We did not acquire any shares pursuant to this program during the first three months of 2012, and we have no current plans to repurchase shares under this program for the remainder of 2012.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

- EXHIBIT 11. Statement re: Computation of Earnings per Share
- EXHIBIT 12. Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges
- EXHIBIT 31.1 Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer
- EXHIBIT 31.2 Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer
- EXHIBIT 32. Section 1350 Certification
- EXHIBIT 101. Interactive Data File

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ELI LILLY AND COMPANY
(Registrant)

Date: April 30, 2012

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

Date: April 30, 2012

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

Index to Exhibits

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

Exhibit

- | | |
|--------------|---|
| EXHIBIT 11. | Statement re: Computation of Earnings per Share |
| EXHIBIT 12. | Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges |
| EXHIBIT 31.1 | Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer |
| EXHIBIT 31.2 | Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer |
| EXHIBIT 32. | Section 1350 Certification |
| EXHIBIT 101. | Interactive Data File |