

LILLY ELI & CO
Form 10-Q
October 29, 2010

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
Quarterly Report Under Section 13 or 15(d) of the
Securities Exchange Act of 1934
FOR THE QUARTER ENDED SEPTEMBER 30, 2010
COMMISSION FILE NUMBER 001-6351
ELI LILLY AND COMPANY
(Exact name of Registrant as specified in its charter)

INDIANA 35-0470950
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)
LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285
(Address of principal executive offices)

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

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

Yes No

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

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

(Do not check if a smaller
reporting company)

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

Yes No

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

Yes No

The number of shares of common stock outstanding as of October 20, 2010:

| Class | Number of Shares Outstanding |
|--------|------------------------------|
| Common | 1,153,143,311 |

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CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

Eli Lilly and Company and Subsidiaries

| | Three Months Ended | | Nine Months Ended | |
|--|---|------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions, except per-share data) | | | |
| Revenue | \$ 5,654.8 | \$ 5,562.0 | \$ 16,889.0 | \$ 15,901.8 |
| Cost of sales | 987.6 | 1,051.9 | 3,134.0 | 2,815.7 |
| Research and development | 1,219.8 | 1,122.1 | 3,446.1 | 3,109.8 |
| Marketing, selling, and administrative | 1,694.9 | 1,701.8 | 5,064.7 | 4,939.2 |
| Acquired in-process research and development (Note 3) | | | 50.0 | |
| Asset impairments, restructuring, and other special charges (Note 5) | 59.5 | 549.8 | 113.0 | 654.8 |
| Other - net, expense (income) (Note 13) | 21.7 | 66.9 | (34.4) | 161.7 |
| | 3,983.5 | 4,492.5 | 11,773.4 | 11,681.2 |
| Income before income taxes | 1,671.3 | 1,069.5 | 5,115.6 | 4,220.6 |
| Income taxes (Note 10) | 368.4 | 127.7 | 1,215.7 | 807.2 |
| Net income | \$ 1,302.9 | \$ 941.8 | \$ 3,899.9 | \$ 3,413.4 |
| Earnings per share - basic and diluted (Note 9) | \$ 1.18 | \$.86 | \$ 3.53 | \$ 3.11 |
| Dividends paid per share | \$.49 | \$.49 | \$ 1.47 | \$ 1.47 |

See Notes to Consolidated Condensed Financial Statements.

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CONSOLIDATED CONDENSED BALANCE SHEETS
Eli Lilly and Company and Subsidiaries

| | September 30, 2010 | December 31, 2009 |
|---|-----------------------|----------------------|
| | (Dollars in millions) | |
| | (Unaudited) | |
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents (Note 6) | \$ 5,908.8 | \$ 4,462.9 |
| Short-term investments (Note 6) | 231.3 | 34.7 |
| Accounts receivable, net of allowances of \$100.1 (2010) and \$109.9 (2009) | 3,336.0 | 3,343.3 |
| Other receivables | 538.8 | 488.5 |
| Inventories | 2,679.6 | 2,849.9 |
| Deferred income taxes | 297.8 | 271.0 |
| Prepaid expenses | 1,192.0 | 1,036.2 |
| TOTAL CURRENT ASSETS | 14,184.3 | 12,486.5 |
| OTHER ASSETS | | |
| Investments (Note 6) | 1,340.2 | 1,155.8 |
| Goodwill and other intangibles - net (Note 3) | 4,308.5 | 3,699.8 |
| Sundry | 2,129.4 | 1,921.4 |
| | 7,778.1 | 6,777.0 |
| PROPERTY AND EQUIPMENT | | |
| Land, buildings, equipment, and construction-in-progress | 14,416.8 | 15,100.0 |
| Less accumulated depreciation | (6,474.9) | (6,902.6) |
| | 7,941.9 | 8,197.4 |
| | \$29,904.3 | \$ 27,460.9 |
| LIABILITIES AND SHAREHOLDERS EQUITY | | |
| CURRENT LIABILITIES | | |
| Short-term borrowings | \$ 155.1 | \$ 27.4 |
| Accounts payable | 1,034.7 | 968.1 |
| Employee compensation | 748.6 | 894.2 |
| Sales rebates and discounts | 1,294.3 | 1,109.8 |
| Dividends payable | | 538.0 |
| Income taxes payable | 281.0 | 346.7 |
| Other current liabilities | 2,583.7 | 2,683.9 |
| TOTAL CURRENT LIABILITIES | 6,097.4 | 6,568.1 |
| Long-term debt | 6,982.0 | 6,634.7 |
| Accrued retirement benefit (Note 11) | 1,817.8 | 2,334.7 |

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| | | |
|--|------------|-------------|
| Long-term income taxes payable (Note 10) | 1,303.8 | 1,088.4 |
| Deferred income taxes | 84.5 | 84.8 |
| Other noncurrent liabilities | 1,213.3 | 1,224.9 |
| | 11,401.4 | 11,367.5 |
| SHAREHOLDERS' EQUITY (Notes 7 and 8) | | |
| Common stock | 721.3 | 718.7 |
| Additional paid-in capital | 4,743.2 | 4,635.6 |
| Retained earnings | 12,647.1 | 9,830.4 |
| Employee benefit trust | (3,013.2) | (3,013.2) |
| Deferred costs-ESOP | (58.1) | (77.4) |
| Accumulated other comprehensive loss | (2,529.8) | (2,471.9) |
| Noncontrolling interests | (7.6) | 1.6 |
| | 12,502.9 | 9,623.8 |
| Less cost of common stock in treasury | 97.4 | 98.5 |
| | 12,405.5 | 9,525.3 |
| | \$29,904.3 | \$ 27,460.9 |

See Notes to Consolidated Condensed Financial Statements.

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CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
Eli Lilly and Company and Subsidiaries

| | Nine Months Ended September 30, | |
|--|------------------------------------|------------------|
| | 2010 | 2009 |
| | (Dollars in millions) | |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net income | \$ 3,899.9 | \$ 3,413.4 |
| Adjustments to reconcile net income to cash flows from operating activities: | | |
| Depreciation and amortization | 989.7 | 922.0 |
| Change in deferred income taxes | 479.8 | 306.3 |
| Stock-based compensation expense | 175.2 | 264.4 |
| Acquired in-process research and development, net of tax | 32.5 | |
| Net marketing investigation charges paid | (92.3) | (1,185.3) |
| Other changes in operating assets and liabilities | (820.3) | (1,768.0) |
| Other, net | (35.8) | 364.1 |
| NET CASH PROVIDED BY OPERATING ACTIVITIES | 4,628.7 | 2,316.9 |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Net purchases of property and equipment | (443.4) | (508.2) |
| Net change in short-term investments | (200.6) | 563.2 |
| Proceeds from sales and maturities of noncurrent investments | 444.4 | 742.2 |
| Purchases of noncurrent investments | (518.2) | (329.3) |
| Purchase of product rights | (419.0) | |
| Cash paid for acquisitions, net of cash acquired | (328.7) | |
| Purchase of in-process research and development | (50.0) | |
| Other, net | (79.8) | (70.8) |
| NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES | (1,595.3) | 397.1 |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Dividends paid | (1,621.2) | (1,612.4) |
| Net change in short-term borrowings | 125.1 | (4,829.4) |
| Proceeds from issuance of long-term debt | 1.0 | 2,400.0 |
| Repayment of long-term debt | (0.7) | (400.0) |
| Other, net | 23.5 | 36.6 |
| NET CASH USED IN FINANCING ACTIVITIES | (1,472.3) | (4,405.2) |
| Effect of exchange rate changes on cash and cash equivalents | (115.2) | 42.7 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 1,445.9 | (1,648.5) |

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| | | |
|---|------------|------------|
| Cash and cash equivalents at January 1 | 4,462.9 | 5,496.7 |
| CASH AND CASH EQUIVALENTS AT SEPTEMBER 30 | \$ 5,908.8 | \$ 3,848.2 |

See Notes to Consolidated Condensed Financial Statements.

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CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)
Eli Lilly and Company and Subsidiaries

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------|------------------------------------|-----------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Net income | \$1,302.9 | \$ 941.8 | \$3,899.9 | \$3,413.4 |
| Other comprehensive income (loss), net of tax ¹ | 777.9 | 291.4 | (57.9) | 611.4 |
| Comprehensive income | \$2,080.8 | \$1,233.2 | \$3,842.0 | \$4,024.8 |

¹ The significant components of other comprehensive income (loss) were gains from foreign currency translation adjustments of \$727.0 million for the three months ended September 30, 2010 and losses of \$193.5 million for the nine months ended September 30, 2010. The significant components of other comprehensive income for the three months and nine months ended September 30, 2009 were gains from foreign

currency translation adjustments of \$189.1 million and \$381.8 million, respectively. In addition, net unrealized gains on investment securities of \$72.4 million and \$169.4 million were included in other comprehensive income for the three months and nine months ended September 30, 2009, respectively.

See Notes to Consolidated Condensed Financial Statements.

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We operate in one significant business segment - human pharmaceutical products. Operations of the animal health business segment are not material and share many of the same economic and operating characteristics as human pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the third quarters of 2010 and 2009 was \$58.2 million and \$59.3 million, respectively, and \$161.4 million and \$142.6 million for the nine months ended September 30, 2010 and 2009, respectively.

REVENUE BY CATEGORY

Worldwide revenue by category was as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|------------------------------------|-------------------------------------|-----------|------------------------------------|-------------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Revenue to unaffiliated customers: | | | | |
| Neuroscience | \$2,246.4 | \$2,252.1 | \$ 6,854.2 | \$ 6,515.5 |
| Endocrinology | 1,510.4 | 1,538.7 | 4,506.9 | 4,428.9 |
| Oncology | 980.3 | 895.6 | 2,837.1 | 2,531.1 |
| Cardiovascular | 517.6 | 509.9 | 1,569.3 | 1,419.1 |
| Animal health | 353.3 | 314.6 | 967.1 | 854.0 |
| Other pharmaceuticals | 46.8 | 51.1 | 154.4 | 153.2 |
| Total revenue | \$5,654.8 | \$5,562.0 | \$ 16,889.0 | \$ 15,901.8 |

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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, 2009. We issued our financial statements by filing with the Securities and Exchange Commission (SEC) and have evaluated subsequent events up to the time of the filing.

Note 2: Implementation of New Financial Accounting Pronouncements

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

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

We adopted the FASB Statement on Transfers and Servicing, an amendment of previous authoritative guidance. The most significant amendments resulting from this Statement consist of the removal of the concept of a qualifying special-purpose entity (SPE) from previous authoritative guidance, and the elimination of the exception for qualifying SPEs from the Consolidation guidance regarding variable interest entities. This Statement was effective for us January 1, 2010, and had no effect on our consolidated financial position or results of operations.

We adopted the FASB Statement that amended the previous Consolidations guidance regarding variable interest entities and addressed the effects of eliminating the qualifying SPE concept from the guidance on Transfers and Servicing. This Statement responded to concerns about the application of certain key provisions of the previous guidance on Consolidations regarding variable interest entities, including concerns over the transparency of enterprises' involvement with variable interest entities. This Statement was effective for us January 1, 2010, and had no effect on our consolidated financial position or results of operations.

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Note 3: Acquisitions

2010 Acquisitions of Businesses

In 2010, we completed the acquisitions of Alnara Pharmaceuticals, Inc. (Alnara) and a group of animal health product lines, both of which have been accounted for as business combinations, and neither of which is material to our consolidated financial statements.

Under the acquisition method of accounting, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions are included in our consolidated financial statements from the date of acquisition. To determine the fair value of acquired developed product technology and in-process research and development (IPR&D), we utilized the income method, which applies a probability weighting, that considers the risk of development and commercialization, to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. The ongoing expenses with respect to acquired products in development are not material to our total research and development expense currently and are not expected to be material to our total research and development expense on an annual basis in the future.

Alnara Pharmaceuticals, Inc.

In July 2010, we acquired Alnara, a privately held company developing protein therapeutics for the treatment of metabolic diseases, for total purchase consideration of \$291.7 million, which includes an upfront payment of \$188.7 million. Up to \$200 million in additional payments that are contingent upon potential future regulatory and commercial milestones are included as consideration in the purchase price. Alnara's lead product in development is liprotamase, a non-porcine pancreatic enzyme replacement therapy. Liprotamase is under review by the U.S. Food and Drug Administration (FDA) for the treatment of exocrine pancreatic insufficiency.

The fair value of the contingent consideration was determined by utilizing a probability weighted estimated cash flow stream adjusted for the expected timing of each payment. Subsequent to the acquisition date, on a quarterly basis we remeasure the contingent consideration liability at current fair value with changes recorded in other net, expense (income) in the statement of operations.

Animal Health Product Lines

In May 2010, we acquired the European marketing rights to several animal health product lines divested by Pfizer Inc. as part of its acquisition of Wyeth, Inc. These products, including vaccines, parasiticides, and feed additives, serve both the production animal and companion animal markets. We also acquired a manufacturing facility in Sligo, Ireland, currently used in the production of animal vaccines.

In connection with these 2010 acquisitions, we preliminarily recorded a \$264.0 million acquired IPR&D asset (related to the Alnara acquisition), \$112.2 million of goodwill, \$76.2 million of developed product technology, and \$98.5 million of deferred tax liability. Certain estimated values are not yet finalized and are subject to change. We expect to finalize these amounts as soon as possible, but no later than one

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year from the acquisition date. The IPR&D is treated as an indefinite-lived intangible asset until completion or abandonment of the project, at which time the asset will be amortized over the estimated remaining useful life, which is anticipated to be 15 years, or written off, as appropriate. The amortization of the Alnara acquired IPR&D asset will not be deductible for tax purposes. The developed product technology will be amortized over 20 years.

Product Acquisition

In March 2010, we entered into a license agreement with Acrux Limited to acquire the exclusive rights to commercialize its proprietary testosterone solution with the proposed tradename Axiron . The product is currently under regulatory review by the FDA for the treatment of testosterone deficiency in men and has no alternative future use. The charge of \$50.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2010 and is deductible for tax purposes. In connection with this arrangement, our partner is entitled to future milestones and royalties based on sales if this product is approved for commercialization.

Note 4: Collaborations

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------------|-------------------------------------|-----------|------------------------------------|------------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Net product sales | \$5,486.8 | \$5,385.5 | \$16,408.6 | \$15,390.6 |
| Collaboration and other revenue | 168.0 | 176.5 | 480.4 | 511.2 |
| Total revenue | \$5,654.8 | \$5,562.0 | \$16,889.0 | \$15,901.8 |

Erbix®

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------------|-------------------------------------|----------|------------------------------------|----------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Net product sales | \$ 18.5 | \$ 22.3 | \$ 56.9 | \$ 72.3 |
| Collaboration and other revenue | 76.9 | 79.6 | 234.7 | 223.5 |
| Total revenue | \$ 95.4 | \$ 101.9 | \$ 291.6 | \$ 295.8 |

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Bristol-Myers Squibb Company

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

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

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

Merck KGaA

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

Necitumumab

In January 2010, we restructured the commercial agreement with BMS described above to allow for the co-development and co-commercialization of necitumumab, which is currently in Phase III clinical testing for non-small cell lung cancer. Within this restructured arrangement, we and BMS have agreed to share in 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,

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BMS will record sales and we will receive 45 percent of the profits for necitumumab, while we will provide 50 percent of the selling effort. In Japan, we and BMS will share costs and profits evenly.

Exenatide

We are in a collaborative arrangement with Amylin Pharmaceuticals (Amylin) for the joint development, marketing, and selling of Byetta® (exenatide injection) and other forms of exenatide such as exenatide once weekly (proposed tradename Bydureon). Byetta is presently approved as an adjunctive therapy to improve glycemic control in patients with type 2 diabetes who have not achieved adequate glycemic control using metformin, a sulfonylurea, or a combination of metformin and sulfonylurea; and in the U.S. only, as an adjunctive therapy in patients using a thiazolidinedione (with or without metformin) and as a monotherapy. Lilly and Amylin are co-promoting exenatide in the U.S. Amylin is responsible for manufacturing and primarily utilizes third-party contract manufacturers to supply Byetta. However, we are manufacturing Byetta pen delivery devices for Amylin. We are responsible for development and commercialization costs outside the U.S.

Under the terms of our arrangement, we report as collaboration and other revenue our 50 percent share of gross margin on Amylin's net product sales in the U.S. We report as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. The following table summarizes the revenue recognized with respect to Byetta:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------------|-------------------------------------|----------|------------------------------------|----------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Net product sales | \$ 39.1 | \$ 38.0 | \$ 126.0 | \$ 100.2 |
| Collaboration and other revenue | 63.6 | 77.8 | 199.3 | 228.0 |
| Total revenue | \$ 102.7 | \$ 115.8 | \$ 325.3 | \$ 328.2 |

We pay Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs are recorded in cost of sales. Under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide's gross margin, we also record 50 percent of U.S. research and development costs and marketing and selling costs in the respective line items on the consolidated condensed statements of operations. A New Drug Application (NDA) has been submitted to the FDA for Bydureon. In October 2010, we received a complete response letter from the FDA that requested a safety study to measure the potential for heart rhythm disturbances when exenatide is used at higher than average doses. Our goal is to submit a reply to the complete response letter by the end of 2011, pending discussions with the FDA. Based on the requirements for additional data, this will likely be considered a Class 2 resubmission requiring a six-month review. We are evaluating the financial impact, if any, of the FDA's request and it is possible that we may incur related charges in the fourth quarter. We have also submitted Bydureon for review by the European Medicines Agency and we anticipate action in the first half of 2011.

Amylin is constructing and will operate a manufacturing facility for Bydureon, and we have entered into a supply agreement in which Amylin will supply Bydureon to us for sales outside the U.S. The estimated total cost of the facility is approximately \$550 million. In 2008, we paid \$125.0 million to Amylin, which we will amortize to cost of sales over the estimated life of the supply agreement beginning with product launch. We would be required to reimburse Amylin for a portion of any future impairment of this facility, recognized in accordance with GAAP. A portion of the \$125.0 million payment we made to Amylin would be creditable against any amount we would owe as a result of impairment. We have also agreed to loan up

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to \$165.0 million to Amylin at an indexed rate. No amounts have been loaned pursuant to this arrangement. Draws must be made by June 30, 2011 and any borrowings must be repaid by June 30, 2014. We have also agreed to cooperate with Amylin in the development, manufacturing, and marketing of Bydureon in a dual-chamber cartridge pen configuration. We will contribute 60 percent of the total initial capital costs of the project, our portion of which will be approximately \$130 million. As of September 30, 2010, we had contributed approximately \$84 million.

Cymbalta®*Boehringer Ingelheim*

Beginning in 2002, we were in a collaborative arrangement with Boehringer Ingelheim (BI) to jointly develop, market and promote Cymbalta (duloxetine), a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, outside the U.S. and Japan. Pursuant to the terms of the agreement, we generally shared equally in development, marketing, and selling expenses, and paid BI a commission on sales in the co-promotion territories. We manufacture the product for all territories. Reimbursements or payments for the cost sharing of marketing, selling, and administrative expenses were recorded in the respective expense line items in the consolidated condensed statements of operations. The commission paid to BI was recorded in marketing, selling, and administrative expenses. In March 2010, the parties agreed to terminate this agreement, and we re-acquired the exclusive rights to develop and market duloxetine for all indications in countries outside the U.S. and Japan. In connection with the arrangement, we paid BI approximately \$400 million and will also pay to BI a percentage of our sales of duloxetine in these countries through 2012 as consideration for the rights acquired. We record these costs as intangible assets and will amortize to marketing, selling and administrative expenses over the life of the original agreement, which is through 2015.

Quintiles

We were in a collaborative arrangement with Quintiles Transnational Corp. (Quintiles) to jointly market and promote Cymbalta in the U.S. since Cymbalta's launch in 2004. Pursuant to the terms of the agreement, Quintiles shared in the costs to co-promote Cymbalta with us and receives a commission based upon net product sales. According to that agreement, Quintiles' obligation to promote Cymbalta expired during 2009, and we pay a lower commission for three years after completion of the promotion efforts specified in that agreement. The commissions paid to Quintiles are recorded in marketing, selling, and administrative expenses.

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote Effient, an antiplatelet agent for the treatment of patients with acute coronary syndrome (ACS) who are being managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). The product was approved for marketing by the European Commission under the trade name Eflient® in February 2009, and the initial sales were recorded in the first quarter of 2009. The product was also approved for marketing by the FDA under the tradename Effient in July 2009, and the initial sales in the U.S. were recorded in the third quarter of 2009. Within this arrangement, we and D-S have agreed to co-promote under the same trademark 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. Under the agreement, we paid D-S an upfront license fee and milestones related to successful development and product launch. 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

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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 \$36.3 million and \$67.9 million in the third quarter and first nine months of 2010, respectively.

TPG-Axon Capital

In 2008, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of semagacestat and solanezumab, our two lead molecules for the treatment of mild to moderate Alzheimer's disease. In the third quarter of 2010, we halted the development of semagacestat based on preliminary results of Phase III clinical trials which resulted in a charge to research and development of approximately \$80 million. Under the agreement, both we and TPG are obligated to provide funding for the Alzheimer's clinical trials. Funding from TPG will not exceed \$250.0 million and could extend into 2014. At the date we halted the development of semagacestat, TPG's remaining obligation to fund solanezumab would not exceed approximately \$115 million. In exchange for their funding, TPG may receive success-based milestones totaling \$350.0 million and mid- to high-single digit royalties that are contingent upon the successful development of solanezumab. The royalties would be paid for approximately eight years after launch of the product. Reimbursements received from TPG for its portion of research and development costs incurred related to the Alzheimer's treatments are recorded as a reduction to the research and development expense line item on the consolidated condensed statements of operations. The reimbursement from TPG has not been and is not expected to be material in any period.

Summary of Collaboration-Related Commission and Profit Share Payments

The aggregate amount of commissions and profit share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$35.6 million and \$80.8 million in the quarters ended September 30, 2010 and 2009, respectively, and \$132.2 million and \$243.0 million in the nine months ended September 30, 2010 and 2009, respectively.

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

The components of the charges included in asset impairments, restructuring, and other special charges in our consolidated condensed statements of operations are described below.

We recognized asset impairments, restructuring, and other special charges of \$59.5 million and \$113.0 million in the third quarter and first nine months of 2010, respectively, as a result of our previously announced initiatives to reduce our cost structure and global workforce as well as previously announced strategic decisions. These charges primarily related to severance costs, which are expected to be paid in 2010. We anticipate additional charges in the fourth quarter of 2010 relating to these previously announced initiatives and strategic decisions.

We recognized asset impairment, restructuring, and other special charges of \$424.8 million in the third quarter of 2009 primarily due to the announced agreement to sell our Tippecanoe Laboratories manufacturing site to an affiliate of Evonik Industries AG (Evonik). In connection with the sale of the site, we entered into a nine-year supply and services agreement, whereby the Evonik affiliate manufactures final and intermediate step active pharmaceutical ingredient (API) for certain of our human and animal health products. The decision to sell the site was based upon a projected decline in utilization of the site due to several factors, including upcoming patent expirations on certain medicines made at the site; our strategic decision to purchase, rather than manufacture, many late-stage chemical intermediates; and the evolution of our pipeline toward more biotechnology medicines. In addition to the sale of the Tippecanoe site, in the third quarter of 2009 we announced a voluntary exit program for certain U.S. sales employees.

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Components of the third-quarter restructuring charge include non-cash asset impairment charges and other charges of \$363.7 million, and \$61.1 million in severance-related charges, substantially all of which was paid in 2010. The fair value of assets used in determining impairment charges is based on contracted sales prices.

In the second and third quarters of 2009, we incurred other special charges of \$105.0 million and \$125.0 million, respectively, relating to advanced discussions with the attorneys general for several states that were not part of a prior settlement with the Eastern District of Pennsylvania, seeking to resolve their Zyprexa[®]-related claims. The charges reflected the then-current probable and estimable exposures in connection with the states' claims. See Note 12 for additional information.

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 and purchase option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other net, expense (income). The purchased option contracts are used to hedge anticipated foreign currency transactions, primarily intercompany inventory activities expected to occur within the next year. These contracts are designated as cash flow hedges of those future transactions, and the impact on earnings is included in cost of sales.

We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward and purchase option contracts generally have maturities not exceeding 12 months. At September 30, 2010, we did not hold any foreign currency option contracts. At September 30, 2010, we had

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outstanding foreign currency forward commitments to purchase 1.66 billion U.S. dollars and sell 1.25 billion euro, and commitments to buy 866 million euro and sell 1.14 billion U.S. dollars, which will settle within 2 months.

In the normal course of business, our operations are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance. Interest rate swaps or collars that convert our fixed-rate debt or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. At September 30, 2010, approximately 90 percent of our total debt is at a fixed rate. We have converted approximately 70 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities. Costless collars outstanding at September 30, 2010, for the forecasted sale of equity securities with an approximate fair value of \$176 million mature during 2011.

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------|------------------------------------|-----------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Fair value hedges | | | | |
| Effect from hedged fixed-rate debt | \$ 122.5 | \$ 77.7 | \$ 359.2 | \$(233.3) |
| Effect from interest rate contracts | (122.5) | (77.7) | (359.2) | 233.3 |
| Cash flow hedges | | | | |
| Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss | 2.2 | 2.7 | 6.7 | 7.8 |
| Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments | 20.3 | 77.6 | (26.1) | 71.8 |

The effective portion of net losses on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was \$17.3 million and \$17.3 million for the three months and nine months ended September 30, 2010. The effective portion of net gains on interest rate contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was \$0.0 and \$37.8 million for the three months and nine months ended September 30, 2009, respectively, and was \$0.0 and \$0.0 for both periods in 2010.

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During the three months and nine months ended September 30, 2010 and 2009, net losses related to ineffectiveness and net losses related to the portion of our risk-management hedging instruments, fair value and cash flow hedges excluded from the assessment of effectiveness were not material.

We expect to reclassify \$12.0 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on floating rate debt from accumulated other comprehensive loss to earnings during the next 12 months.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 2010 and December 31, 2009 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:

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| 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) | |
| (Dollars in millions) | | | | | | |
| September 30, 2010 | | | | | | |
| Short-term investments | | | | | | |
| Commercial paper | \$ 200.0 | \$ 200.0 | \$ | \$ 200.0 | \$ | \$200.0 |
| Corporate debt securities | 13.3 | 13.5 | | 13.3 | | 13.3 |
| U.S. government and agencies | 17.2 | 17.2 | 17.2 | | | 17.2 |
| Other securities | 0.8 | 0.8 | | 0.8 | | 0.8 |
| Total | \$ 231.3 | \$ 231.5 | | | | |
| Noncurrent investments | | | | | | |
| Mortgage-backed | \$ 249.2 | \$ 286.8 | \$ | \$ 249.2 | \$ | \$249.2 |
| U.S. government and agencies | 237.8 | 235.6 | 237.8 | | | 237.8 |
| Corporate debt securities | 223.7 | 222.0 | | 223.7 | | 223.7 |
| Asset-backed | 61.3 | 71.4 | | 61.3 | | 61.3 |
| Other debt securities | 6.8 | 9.9 | | 3.4 | 3.4 | 6.8 |
| Marketable equity | 402.3 | 186.0 | 402.3 | | | 402.3 |
| Equity method and other investments | 159.1 | 159.1 | | | | (1) |
| Total | \$1,340.2 | \$1,170.8 | | | | |
| December 31, 2009 | | | | | | |
| Short-term investments | | | | | | |
| U.S. government and agencies | \$ 18.5 | \$ 18.8 | \$ 18.5 | \$ | \$ | \$ 18.5 |
| Corporate debt securities | 15.8 | 16.1 | | 15.8 | | 15.8 |
| Other securities | 0.4 | 0.4 | | 0.4 | | 0.4 |
| Total | \$ 34.7 | \$ 35.3 | | | | |

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| | | | | | | |
|--------------------------------------|-----------|-----------|-------|----------|------|---------|
| Noncurrent investments | | | | | | |
| Mortgage-backed | \$ 240.3 | \$ 310.0 | \$ | \$ 240.3 | \$ | \$240.3 |
| Corporate debt securities | 185.9 | 195.4 | | 185.9 | | 185.9 |
| U.S. government and agencies | 81.3 | 81.7 | 81.3 | | | 81.3 |
| Asset-backed | 78.7 | 94.1 | | 78.7 | | 78.7 |
| Other debt securities | 34.4 | 12.8 | | 3.6 | 30.8 | 34.4 |
| Marketable equity | 378.7 | 184.0 | 378.7 | | | 378.7 |
| Equity methods and other investments | 156.5 | 156.5 | | | | (1) |
| Total | \$1,155.8 | \$1,034.5 | | | | |

(1) Not applicable

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| Description | Carrying Amount | Fair Value Measurements Using | | | Fair Value |
|--|--------------------|---|---|--|---------------|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | |
| (Dollars in millions) | | | | | |
| Long-term debt, including current portion | | | | | |
| September 30, 2010 | \$(7,137.1) | \$ | \$ (7,516.2) | \$ | \$(7,516.2) |
| December 31, 2009 | (6,655.0) | | (6,827.8) | | (6,827.8) |

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| Description | Carrying Amount | Fair Value Measurements Using | | | Fair Value |
|--|--------------------|---|---|--|---------------|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | |
| (Dollars in millions) | | | | | |
| September 30, 2010 | | | | | |
| Risk-management instruments | | | | | |
| Interest rate contracts designated as hedging instruments | | | | | |
| Sundry | \$487.9 | \$ | \$ 487.9 | \$ | \$487.9 |
| Foreign exchange contracts not designated as hedging instruments | | | | | |
| Other receivables | 43.2 | | 43.2 | | 43.2 |
| Other current liabilities | (55.8) | | (55.8) | | (55.8) |
| Equity contracts designed as hedging instruments | | | | | |
| Other current liabilities | (11.4) | | (11.4) | | (11.4) |
| Other noncurrent liabilities | (5.9) | | (5.9) | | (5.9) |

December 31, 2009

| | | | | | |
|--|---------|----|----------|----|---------|
| Risk-management instruments | | | | | |
| Interest rate contracts designated as hedging instruments | | | | | |
| Sundry | \$134.9 | \$ | \$ 134.9 | \$ | \$134.9 |
| Other noncurrent liabilities | (6.2) | | (6.2) | | (6.2) |
| Foreign exchange contracts not designated as hedging instruments | | | | | |
| Other receivables | 8.8 | | 8.8 | | 8.8 |
| Other current liabilities | (10.7) | | (10.7) | | (10.7) |

The fair value of the contingent consideration liability related to the Alnara acquisition (see Note 3), a Level 3 measurement in the fair value hierarchy, was \$103.3 million as of September 30, 2010.

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 \$560 million of our investments in debt securities, measured at fair value, will mature within five years.

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

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| | September 30, 2010 | December 31, 2009 |
|---|-----------------------|----------------------|
| | (Dollars in millions) | |
| Unrealized gross gains | \$230.4 | \$ 222.4 |
| Unrealized gross losses | 61.2 | 101.7 |
| Fair value of securities in an unrealized gain position | 884.2 | 579.8 |
| Fair value of securities in an unrealized loss position | 322.2 | 449.4 |

Other-than-temporary impairment losses on fixed income securities of \$4.7 million and \$11.4 million were recognized in the statement of operations for the three months and nine months ended September 30, 2010, respectively, compared with \$10.7 million and \$18.3 million for the same periods in 2009. These losses primarily relate to credit losses on certain mortgage-backed securities. The amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position are composed of fixed-rate debt securities of varying maturities. The value of fixed income securities is sensitive to changes in the yield curve and other market conditions, which led to the decline in value in 2008. Approximately 60 percent of the securities in a loss position are investment-grade debt securities. The majority of these securities first moved into an unrealized loss position during 2008. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of September 30, 2010.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--------------------------------|-------------------------------------|---------|------------------------------------|-----------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Proceeds from sales | \$59.9 | \$426.6 | \$427.6 | \$1,027.2 |
| Realized gross gains on sales | 7.8 | 39.5 | 82.4 | 56.8 |
| Realized gross losses on sales | 1.6 | 4.5 | 3.9 | 5.5 |

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.

In September 2010, we borrowed \$125.0 million of short-term floating-rate debt due in 2011.

Note 7: Stock-Based Compensation

Our stock-based compensation expense consists primarily of performance awards (PAs) and shareholder value awards (SVAs). We recognized pretax stock-based compensation cost of \$46.8 million and \$104.0 million in the third quarter of 2010 and 2009, respectively. In the first nine months of 2010 and 2009, we recognized pretax stock-based compensation expense of \$175.2 million and \$264.4 million, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings per share

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targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of September 30, 2010, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$66.1 million, which will be amortized over the weighted-average remaining requisite service period of approximately 10 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of September 30, 2010, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$57.3 million, which will be amortized over the weighted-average remaining requisite service period of approximately 22 months.

Note 8: Shareholders' Equity

As of September 30, 2010, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first nine months of 2010, we did not acquire any shares pursuant to this program, nor do we expect any share repurchases under this program for the remainder of 2010.

Note 9: Earnings Per Share

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

Note 10: Income Taxes

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in major taxing jurisdictions for years before 2005. The IRS began its examination of tax years 2005-2007 during the third quarter of 2008. In the third quarter of 2009, we settled an IRS administrative appeals matter from the 2001-2004 IRS audit. Considering the status of the 2005-2007 IRS examination at that time and the settlement of the IRS administrative appeals matter from the 2001-2004 audit, gross unrecognized tax benefits were reduced approximately \$190 million in the third quarter of 2009. Additionally, in the third quarter of 2009, our income tax expense was reduced by \$54.4 million, and a cash payment of \$52.8 million was paid, after utilization of applicable tax credit carryovers.

The IRS continues its examination of tax years 2005-2007. In the first quarter of 2010, we began the process of advancing the examination procedures to tax years 2008-2009 for certain matters currently being examined in the 2005-2007 audit cycle. Management believes it is reasonably possible that both the 2005-2007 audit and the examination of certain matters for tax years 2008-2009 could conclude within the next 12 months, both of which could cause a significant change in the total amount of unrecognized tax benefits. However, the ultimate resolution of these tax matters is dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the range of the reasonably possible changes in unrecognized tax benefits that could occur within the next 12 months, nor is it possible to reliably estimate total future cash flows related to these unrecognized tax benefits.

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

Note 11: Retirement Benefits

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

| | Defined Benefit Pension Plans | | | |
|---|-------------------------------|---------|-------------------|----------|
| | Three Months Ended | | Nine Months Ended | |
| | September 30, | | September 30, | |
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Components of net periodic benefit cost | | | | |
| Service cost | \$ 54.7 | \$ 59.3 | \$ 165.5 | \$ 179.0 |
| Interest cost | 107.9 | 104.6 | 323.7 | 312.0 |
| Expected return on plan assets | (158.8) | (149.9) | (476.4) | (435.3) |
| Amortization of prior service cost | 1.7 | 1.8 | 5.0 | 5.4 |
| Recognized actuarial loss | 41.2 | 21.2 | 123.5 | 63.0 |
| Net periodic benefit cost | \$ 46.7 | \$ 37.0 | \$ 141.3 | \$ 124.1 |

| | Retiree Health Benefit Plans | | | |
|---|------------------------------|---------|-------------------|---------|
| | Three Months Ended | | Nine Months Ended | |
| | September 30, | | September 30, | |
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Components of net periodic benefit cost | | | | |
| Service cost | \$ 14.1 | \$ 13.4 | \$ 42.2 | \$ 40.1 |
| Interest cost | 30.3 | 29.2 | 90.2 | 87.7 |
| Expected return on plan assets | (30.6) | (29.5) | (92.0) | (88.4) |
| Amortization of prior service cost | (9.3) | (9.0) | (27.9) | (27.0) |
| Recognized actuarial loss | 21.3 | 17.2 | 63.8 | 51.5 |
| Net periodic benefit cost | \$ 25.8 | \$ 21.3 | \$ 76.3 | \$ 63.9 |

On a global basis, we have contributed substantially all of the \$100 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2010. In addition, we have contributed \$400.0 million of discretionary funding in the aggregate to several of our global post-retirement benefit plans in 2010. We do not anticipate making any substantial contributions throughout the remainder of the year.

Note 12: Contingencies

We are a party to various legal actions, government investigations, and environmental proceedings. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, the resolution of all such matters will not have

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a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

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

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

Gemzar® : Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); and Sun Pharmaceutical Industries Inc. (Sun) each submitted one or more ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. Sandoz Inc. (Sandoz), APP Pharmaceuticals, LLC (APP), Actavis Elizabeth LLC and Actavis Totowa LLC (Actavis), Dr. Reddy's Laboratories, Inc.

(Dr. Reddy's), and Accord Healthcare Inc. (Accord) have similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006), Hospira (October 2006, January 2008, and March 2010), APP (December 2009), Fresenius (February 2010), Actavis (June 2010), Sandoz (August 2010), and Dr. Reddy's (October 2010), and against Accord in the U.S. District Court for the Middle District of North Carolina (October 2010), seeking rulings that our patents are valid and are being infringed. In November 2007, Sun filed a declaratory judgment action in the U.S. District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent, and the opinion was affirmed by a panel of the Court of Appeals for the Federal Circuit. We are seeking reconsideration of this decision. In March 2010, the district court in Indiana upheld the validity of our compound patent. The court also ruled in our favor on all invalidity theories brought forward by Teva on our method-of-use patent, except for obviousness-type double patenting. The court applied collateral estoppel with regard to this theory, given the ruling in the Sun case. We expect the balance of these cases to follow the final outcomes in the Teva and Sun Cases. Teva's ANDAs have been approved by the FDA, and other generic companies have tentative or final marketing approval for generic gemcitabine. Therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010.

Alimta®: Teva Parenteral Medicines, Inc. (Teva); APP; and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of

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the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. Trial is scheduled for November 2010 against Teva and APP.

Evista®: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. In September 2009, the court upheld our method-of-use patents (the last expires in 2014) and the court held that our particle-size patents (expiring 2017) are invalid. Both rulings were upheld by the appeals court in September 2010. InvaGen Pharmaceuticals, Inc. (InvaGen) submitted an ANDA in 2008 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against InvaGen in January 2009 in the U.S. District Court for the Southern District of Indiana That action has been stayed pending the outcome of the Teva appeal. Watson Laboratories Inc. (Watson) also submitted an ANDA in March of 2010 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against Watson in May 2010 in the U.S. District Court for the Southern District of Indiana.

Strattera®: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. In August 2010, the court ruled that our patent is invalid. Several companies have received final approval to market generic atomoxetine, but the Court of Appeals for the Federal Circuit granted an injunction prohibiting the launch of generic atomoxetine until the court renders an opinion. The appeal is scheduled to be heard by the court in December 2010. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals, and we are considering our legal options.

We believe each of these Hatch-Waxman challenges is without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the U.S.:

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novapharm suit, finding our patent invalid. However, in July 2010 the appeals court set aside the decision and remitted the limited issues of utility and sufficiency of disclosure to the trial court.

In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the

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decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to withdraw from the market or were subject to injunction. We have negotiated settlements of the damages arising from infringement with most of the generic companies.

We have received challenges in a number of other countries, including Spain, Austria, Australia, Portugal, and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenges, but additional actions against multiple generic companies are now pending. In March 2010, the District Court of Hague ruled against us and revoked our compound patent in the Netherlands. We have appealed this decision. We have also successfully defended Zyprexa patents in Austria and Portugal.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations.

Zyprexa Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims) 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. Almost all of the federal lawsuits 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).

Since June 2005, we have entered into agreements with various claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle a substantial majority of the claims. The agreements cover a total of approximately 32,690 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In 2005, we settled and paid more than 8,000 claims for \$690.0 million, plus \$10.0 million to cover administration of the settlement.

In 2007, we settled and paid more than 18,000 claims for approximately \$500 million.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 100 lawsuits in the U.S. covering approximately 185 plaintiffs, of which about 75 lawsuits covering about 80 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, the earliest trial groups have been tentatively scheduled for December 2010. We also have trials scheduled in California in February 2011 and in Texas state court in August 2011.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by

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the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures, and practices.

In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We have reached agreements to settle the Zyprexa-related claims of all of these states except Minnesota, with which we are in advanced discussions. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the then-current probable and estimable exposures in connection with these claims.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order and Judge Weinstein's order denying our motion for summary judgment in September 2008. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs' overpricing claim. Plaintiffs are seeking a reconsideration of this decision.

We cannot determine with certainty the additional number of lawsuits and claims that may be asserted. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta. Approximately half of these claims are covered by insurance, subject to deductibles and coverage limits.

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

Environmental Matters

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, we have been designated as one of several potentially responsible parties with respect to fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup. We also continue remediation of certain of our own sites. We have accrued for estimated Superfund cleanup costs, remediation, and certain other environmental matters. This takes into account, as applicable, available information regarding site conditions, potential cleanup methods, estimated costs, and the extent to which other parties can be expected to contribute to payment of those costs. We have limited liability insurance coverage for certain environmental liabilities.

Note 13: Other - Net, Expense (Income)

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-------------------------------|-------------------------------------|---------|------------------------------------|----------|
| | 2010 | 2009 | 2010 | 2009 |
| | (Dollars in millions) | | | |
| Interest expense | \$ 47.2 | \$ 59.2 | \$ 142.3 | \$ 211.1 |
| Interest income | (16.3) | (15.2) | (37.9) | (61.4) |
| Other | (9.2) | 22.9 | (138.8) | 12.0 |
| Other - net, expense (income) | \$ 21.7 | \$ 66.9 | \$ (34.4) | \$ 161.7 |

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**OPERATING RESULTS****Executive Overview****I. Financial Results**

Our worldwide revenue increased 2 percent and 6 percent to \$5.65 billion and \$16.89 billion for the third quarter and first nine months of 2010, respectively, driven primarily by the increase in revenue related to the collective growth of Alimta, Humulin®, Cymbalta, and animal health products for the third quarter and, in addition for the first nine months of 2010, Zyprexa, Cialis® and Humalog®. Net income for the third quarter and the first nine months of 2010 increased 38 percent and 14 percent, to \$1.30 billion and \$3.90 billion, respectively, compared with the same periods of 2009. Earnings per share for the third-quarter and the first nine months of 2010 increased 37 percent and 14 percent to \$1.18 per share and \$3.53 per share, respectively, compared with the same periods of 2009. Net income

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for the third quarter and first nine months of 2010 and 2009 was affected by the following highlighted items:
2010

Due to the enactment of health care reform in the U.S. in March 2010, total revenue decreased by approximately \$25 million (pretax), or \$.02 per share, in the third quarter, and approximately \$155 million (pretax), or \$.11 per share, in the first nine months of 2010, as a result of higher rebates. We also recorded a one-time non-cash deferred income tax charge in the first quarter of \$85.1 million, or \$.08 per share, associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan.

We recognized asset impairments, restructuring, and other special charges of \$59.5 million (pretax), or \$.03 per share, in the third quarter, and \$113.0 million (pretax), or \$.07 per share, for the first nine months of 2010, respectively, primarily related to our previously announced initiatives to reduce our cost structure and global workforce as well as previously announced strategic decisions.

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

2009

We recognized asset impairments, restructuring, and other special charges of \$424.8 million (pretax), which decreased earnings per share by \$.26 in the third quarter for asset impairments and restructuring primarily related to the sale of our Tippecanoe manufacturing site to an affiliate of Evonik Industries AG.

We incurred pretax charges of \$105.0 million, or \$.06 per share, in the second quarter, and \$125.0 million, or \$.07 per share, in the third quarter, representing the currently probable and estimable exposures in connection with the claims of several states that did not participate in the EDPA settlement related to Zyprexa.

II. Late-Stage Pipeline

Our long-term success depends, to a great extent, on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies. We currently have nearly 70 potential new drugs in human testing and a larger number of projects in earlier stages of development.

Our new molecular entities currently in Phase III clinical trial testing include the following:

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

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

Necitumumab A fully human monoclonal antibody being investigated as a treatment for non-small cell lung cancer

NERI IV A potent and highly selective norepinephrine reuptake inhibitor being investigated as a treatment for major depression and attention-deficit hyperactivity disorder.

Ramucirumab A monoclonal antibody being investigated as a treatment metastatic for breast and gastric cancers

Solanezumab An amyloid beta (Aβ) antibody for the treatment of Alzheimer's disease

Tasisulam A small-molecule compound for the treatment of melanoma

Our new molecular entities that have been submitted for regulatory review include the following:

Arxxant A potential treatment for diabetic retinopathy

Axiron A testosterone solution to be applied via an underarm applicator, a potential treatment for testosterone deficiency

Liprotamase A non-porcine pancreatic enzyme replacement therapy

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The following are presented to provide updates on our late-stage pipeline developments that have occurred this year:
Third Quarter

We and our partner, MacroGenics, Inc., announced that an independent Data Monitoring Committee (DMC) completed a planned analysis of one-year safety and efficacy data of the Protégé Phase 3 clinical trial of teplizumab, an investigational biologic under development for the treatment of individuals with recent-onset type 1 diabetes. The DMC concluded that the primary efficacy endpoint of the study was not met. The DMC, noting that all administration of experimental drug had been completed, commented that appropriate safety monitoring is warranted. No unanticipated safety issues were identified in the DMC's review. The companies have decided to suspend further enrollment and dosing of patients in two other ongoing clinical trials of teplizumab in type 1 diabetes. In October 2010 we notified MacroGenics of our intent to terminate our collaboration agreement for the development of teplizumab. We are evaluating the financial impact of halting the development of teplizumab.

The FDA issued a complete response letter regarding the NDA for Bydureon. In the complete response letter, the FDA requested a safety study to measure the potential for heart rhythm disturbances when exenatide is used at higher than average doses. Additionally, the FDA has now requested the results of the already completed DURATION-5 study to evaluate the efficacy, and the labeling of the safety and effectiveness, of the commercial formulation of Bydureon. We, along with our partners Amylin Pharmaceuticals, Inc. and Alkermes, Inc., have set a goal to submit our reply to the complete response letter by the end of 2011, pending discussions with the FDA. Based on the requirements for additional data, this will likely be considered a Class 2 resubmission requiring a six-month review.

We completed our acquisition of Alnara Pharmaceuticals, Inc., a privately-held company developing protein therapeutics for the treatment of metabolic diseases. Alnara's lead product in development is liprotamase, a non-porcine pancreatic enzyme replacement therapy. Liprotamase is under review by the FDA for the treatment of exocrine pancreatic insufficiency.

We halted development of semagacestat, a gamma secretase inhibitor being studied as a potential treatment for Alzheimer's disease, because preliminary results from two ongoing long-term Phase III studies showed the compound did not slow disease progression and was associated with worsening of clinical measures of cognition and the ability to perform activities of daily living.

The FDA Anesthetic and Life Support Drugs Advisory Committee voted 8-6 in favor of expanding the pain indications for Cymbalta to a broader population that will be further defined by the FDA, if approved.

Second Quarter

We, along with our partner, Kowa Pharmaceuticals America Inc., announced the U.S. launch of Livalo®. In addition to a proper diet, Livalo is used for the treatment of high cholesterol (primary hyperlipidemia or mixed dyslipidemia) in adults.

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First Quarter

We entered into an exclusive worldwide license agreement for the potential commercialization of Acrux's experimental testosterone solution (proposed tradename Axiron). The New Drug Application for Axiron is currently under regulatory review by the FDA for the treatment of testosterone deficiency (hypogonadism) in men.

We, along with our partners Amylin and Alkermes, Inc., submitted Bydureon for review by the European Medicines Agency.

III. Legal, Regulatory, and Other Matters

In September 2009, we set a goal to reduce our expected cost structure by \$1 billion by the end of 2011. This savings will come from a series of actions, including reducing a targeted 5,500 positions by the end of 2011 (excluding strategic additions in high-growth emerging markets and Japan, as well as additions for acquisitions), outsourcing activities, and consolidating certain activities to become more efficient. We expect the majority of the savings to occur in the marketing, selling, and administrative line item in the consolidated statement of operations, and to a lesser extent, cost of sales and research and development.

The U.S. District Court for the Southern District of Indiana has upheld our compound patent for Gemzar (exclusivity based on this patent expires on November 15, 2010). The U.S. District Court for the Eastern District of Michigan granted a motion for partial summary judgment in August 2009, invalidating our U.S. method-of-use patent for Gemzar (expiring in 2013) and on July 28, 2010, the Court of Appeals for the Federal Circuit affirmed that decision. We have asked for reconsideration of this decision by the Federal Circuit court. Nevertheless, some of the generic companies have tentative or final marketing approval for generic gemcitabine, and therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010, following the expiration of the compound patent.

The U.S. District Court for the District of New Jersey ruled that the method-of-use patent for Strattera, which expires in 2017, is invalid. We are currently appealing this decision to the U.S. Court of Appeals for the Federal Circuit, and a hearing is scheduled in December 2010. The Appeals Court has granted an injunction that prevents the launch of generic atomoxetine until a ruling is rendered. Several generic companies have tentative approval to market generic atomoxetine.

The enactment of the Patient Protection and Affordable Care Act and The Health Care and Education Reconciliation Act of 2010 in March 2010 brings significant changes to U.S. health care. These changes began to affect our financial results in the first quarter of 2010 and will continue to have significant impact on our results in the future. Changes to the rebates for prescription drugs sold to Medicaid beneficiaries, which increase the minimum statutory rebate for branded drugs from 15.1 percent to 23.1 percent, were generally effective in the first quarter of 2010. This rebate has been expanded to managed-Medicaid, a program that provides for the delivery of Medicaid benefits via managed care organizations, under arrangements between those organizations and state Medicaid agencies. Additionally, a prescription drug discount program for outpatient drugs in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities) has been expanded. Also, there are changes to the tax treatment of subsidies paid by the government to employers, such as us, who provide their retirees with a drug benefit at least equivalent to the Medicare Part D drug benefit. Beginning in 2013, the federal government will tax the subsidy it provides to such employers. While this tax will not take effect for three more years, accounting rules dictate that we adjust our deferred tax asset through a one-time non-cash charge upon enactment of the tax law change, which we recorded in the first quarter of 2010. In addition, the federal government created an expedited regulatory approval pathway for biosimilars or follow-on biologics (copies of biological compounds) in the U.S. Biologics will have up to 12.5 years of data-package protection following launch.

Beginning in 2011, drug manufacturers will provide a discount of 50 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the doughnut hole (the coverage gap in

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Medicare prescription drug coverage). The doughnut hole will be phased out by the federal government between 2011 and 2020. Additionally, beginning in 2011, a nondeductible annual fee will be imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. This fee is allocated to companies based on their prior calendar year market share for branded prescription drug sales into these government programs. Regulations have not been drafted to implement the various elements of this legislation. A guidance project is currently underway within the IRS and U.S. Treasury concerning the implementation of this nondeductible annual fee. However, guidance has not yet been publicly released to implement the pharmaceutical fee legislation.

In its budget submission to Congress in February 2010, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. Some provisions changing taxation of international income were enacted in August, 2010, which did not have a material effect on results of operations. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, continues to be a topic of discussion for Congress. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations. On October 25, 2010, Puerto Rico enacted income and excise tax legislation affecting to our Puerto Rican operations which will become effective on January 1, 2011. We are currently evaluating the impact on our consolidated results of operations in future years.

Certain other federal and state health care proposals may continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These proposals include legalizing the importation of prescription drugs and other cost-control strategies. We expect pricing pressures at state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

International operations also are generally subject to extensive price and market regulations, and several European countries have recently required either price decreases or rebate increases in response to economic pressures. There are proposals for cost-containment measures pending in a number of additional countries, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual property protection. These proposals are expected to increase in both frequency and impact, given the effect of the downturn in the global economy on local governments.

Revenue

Revenue for the third quarter and the first nine months of 2010 increased 2 percent and 6 percent to \$5.65 billion and \$16.89 billion, respectively, driven primarily by the increase in revenue related to the collective growth of Alimta, Humulin, Cymbalta, and animal health products for the third quarter and, in addition for the first nine months of 2010, Zyprexa, Cialis and Humalog. Revenue in the U.S. of \$3.15 billion remained essentially flat for the third quarter and increased \$413.0 million, or 5 percent during the first nine months of 2010, compared with the same periods of 2009 due to higher prices and, to a lesser extent, increased volume, offset in part by approximately \$25 million and approximately \$155 million in the third quarter and first nine months of 2010, respectively, in higher rebates resulting from U.S. health care reform. Third-quarter 2010 total revenue would have been reduced by approximately \$65 million due to the impact of U.S. health care reform, but was reduced only by approximately \$25 million, due primarily to the issuance of government guidance that clarified the implementation of certain aspects of health care reform legislation, resulting in a reduction of a prior accrual.

Revenue outside the U.S. increased \$88.4 million, or 4 percent, and \$574.3 million, or 8 percent, for the third quarter and first nine months of 2010, respectively, compared with the same periods of 2009 due to increased demand and, to a lesser extent for the first nine months of 2010, the positive impact of

Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. In the third quarter and first nine months of 2010, Zyprexa sales in the U.S. increased 6 percent and 8 percent, respectively, compared with the same periods of 2009, driven by higher prices, partially offset by the impact of wholesaler buying patterns. Sales outside the U.S. decreased 7 percent and remained essentially flat for the third quarter and first nine months of 2010, respectively, with the third quarter decrease driven by the unfavorable impact of foreign exchange rates and lower prices. The results in the first nine months of 2010 were driven by the favorable impact of foreign exchange rates offset by lower prices. We will lose effective exclusivity for Zyprexa in the U.S. in October 2011. We will also lose effective exclusivity in most of Europe in 2011. In the five major European countries, which in the aggregate have approximately \$850 million of sales for the first nine months of 2010, we will lose effective exclusivity in April 2011 (Spain) and September 2011 (France, Germany, Italy, and the United Kingdom). As a result, we expect generic olanzapine to be introduced to the market following the expiration of these patents. While it is difficult to predict the precise impact on Zyprexa sales, the introduction of generics will result in a rapid and severe decline in our Zyprexa sales which will have a material adverse effect on results of operations and cash flows. In Japan, our second-largest market for Zyprexa, with over \$300 million of sales for the first nine months of 2010, our patent expires in December 2015.

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U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, decreased 1 percent for the third quarter and increased 7 percent during the first nine months of 2010, with the third quarter decrease driven primarily by the impact of wholesaler buying patterns, partially offset by higher prices. The increase in the first nine months of 2010 was due primarily to higher prices. Sales outside the U.S. increased 18 percent and 27 percent during the third quarter and first nine months of 2010, respectively, compared with the same periods in 2009, driven primarily by increased demand resulting from recent launches in Japan and Canada.

U.S. sales of Alimta, a treatment for various cancers, increased 14 percent and 23 percent during the third quarter and first nine months of 2010, respectively, due to increased demand and higher prices. Sales outside the U.S. increased 28 percent and 54 percent for the same periods, due to increased demand. Demand outside the U.S. was favorably impacted by the continued strong growth of the non-small cell lung cancer indication in Japan.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 7 percent for the third quarter and increased 1 percent during first nine months of 2010, respectively, with the third quarter decrease driven in part by the impact of wholesaler buying patterns. The increase for the first nine months of 2010 was due to higher prices. Sales outside the U.S. increased 8 percent and 12 percent for the third quarter and first nine months of 2010, respectively, driven by increased demand and higher prices, offset partially in the third quarter by the unfavorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction, decreased 3 percent for the third quarter and increased 2 percent during the first nine months of 2010, with the third quarter decrease driven primarily by the impact of wholesaler buying patterns, partially offset by higher prices. The increase for the first nine months of 2010 was due to higher prices. Sales outside the U.S. increased 6 percent and 15 percent for the same periods, with the third quarter increase driven by increased demand and higher prices, offset partially by the unfavorable impact of foreign exchange rates. The increase for the first nine months was due to increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

U.S. sales of Gemzar, a product approved to treat various cancers, increased 15 percent and 5 percent during the third quarter and first nine months of 2010, respectively, with the increase due to higher prices and the favorable impact of wholesaler buying patterns. Sales outside the U.S. decreased 25 percent and 35 percent for the third quarter and first nine months of 2010, respectively, due to lower demand and lower prices as a result of the entry of generic competition in most major markets other than Japan. The U.S. Gemzar method-of-use patent has been held invalid by the Court of Appeals for the Federal Circuit, and various generic manufacturers have tentative or final FDA approval to market generic gemcitabine. Therefore, we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010, following the expiration of the compound patent on November 15, 2010. While it is difficult to predict the precise impact on Gemzar sales, the introduction of generics would result in a rapid and severe decline in our U.S. Gemzar sales.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 14 percent and 17 percent during the third quarter and first nine months of 2010, respectively, driven by increased volume resulting from the new partnership with Walmart for Humulin ReliOn® and, to a lesser extent, higher prices. Sales outside the U.S. increased 2 percent and remained essentially flat for the third quarter and first nine months of 2010, respectively, with the third quarter results driven by increased demand, partially offset by lower prices and the unfavorable impact of foreign exchange rates. The favorable impact of foreign exchange rates and higher demand for the first nine months of 2010 was offset by lower prices.

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U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 5 percent and 1 percent during the third quarter and first nine months of 2010, respectively, due to lower demand, partially offset by higher prices. Sales outside the U.S. increased 6 percent for the third quarter and decreased 1 percent for the first nine months of 2010, respectively, with third quarter increases driven primarily by increased demand. The decrease during the first nine months of 2010 was due to lower demand and, to a lesser extent, lower prices, partially offset by the favorable impact of foreign exchange rates.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, decreased 12 percent and 6 percent during the third quarter and first nine months of 2010, respectively, driven primarily by lower demand, partially offset by higher prices. Sales outside the U.S. increased 4 percent and 10 percent for the third quarter and first nine months of 2010, respectively, with the increase in the third quarter due to higher prices and, to a lesser extent, increased demand, partially offset by the unfavorable impact of foreign exchange rates. The increase during the first nine months of 2010 was due to increased demand and, to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 20 percent and 12 percent during the third quarter and first nine months of 2010, respectively, due primarily to lower demand, and to a lesser extent, lower net effective selling prices. Sales outside the U.S. increased 11 percent and 12 percent for the third quarter and first nine months of 2010, respectively, with the increase for the third quarter driven by increased demand, partially offset by lower prices. Demand outside the U.S. was favorably impacted by continued strong demand in Japan. The U.S. District Court for the District of New Jersey ruled that the U.S. method-of-use patent for Strattera, which expires in 2017, is invalid. We are currently appealing this decision to the U.S. Court of Appeals for the Federal Circuit, with a hearing scheduled in December 2010. The Appeals Court has granted an injunction that prevents the launch generic atomoxetine until a ruling is rendered. While it is difficult to predict the precise impact on Strattera sales, the introduction of generics would result in a rapid and severe decline in our U.S. Strattera sales.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, decreased 18 percent and 10 percent to \$168.8 million and \$535.6 million during the third quarter and first nine months of 2010, respectively, due to competitive pressures in the U.S. and German markets. We report as revenue our 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues decreased 11 percent and 1 percent to \$102.7 million and \$325.3 million during the third quarter and first nine months of 2010, respectively.

We report as revenue for Erbitux, a product approved to treat various cancers, the net royalties received from our collaboration partners and our product sales. Our revenues decreased 6 percent and 1 percent to \$95.4 million and \$291.6 million during the third quarter and first nine months of 2010, respectively.

Animal health product sales in the U.S. increased 12 percent during the third quarter and first nine months of 2010, respectively, due primarily to increased sales of Comfortis. Sales outside the U.S. increased 13 percent and 15 percent during the third quarter and first nine months of 2010, respectively, driven primarily by increased demand.

Gross Margin, Costs, and Expenses

For the third quarter of 2010, gross margins as a percentage of total revenue increased by 1.4 percentage points, to 82.5 percent. For the first nine months of 2010, gross margins as a percentage of total revenue

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decreased by 0.9 percentage points, to 81.4 percent. The increase for the third quarter was driven primarily by manufacturing productivity improvements and increased prices. The decrease for the first nine months of 2010 was primarily due to the impact of changes in foreign currencies compared to the U.S. dollar on international inventories sold, which increased cost of sales in the first nine months of 2010, but substantially decreased cost of sales in the first nine months of 2009.

Marketing, selling, and administrative expenses were essentially flat at \$1.69 billion for the third quarter, and increased 3 percent to \$5.06 billion for the first nine months of 2010. For the third quarter, higher marketing and selling expenses outside the U.S. were offset by lower administrative expenses and company-wide cost containment efforts. The increase for the first nine months of 2010 was driven by higher marketing and selling expenses outside the U.S. that were partially offset by lower litigation and administrative expenses and company-wide cost containment. Research and development expenses were \$1.22 billion and \$3.45 billion for the third quarter and first nine months of 2010, respectively. Compared with the same periods of 2009, research and development expenses grew 9 percent and 11 percent for the third quarter and first nine months of 2010, respectively, due primarily to a charge of approximately \$80 million related to the termination of the development of semagacestat and increased costs of late-stage clinical trials.

Acquired IPR&D charges were \$50.0 million in the first nine months of 2010, all of which was associated with the in-license from Acrux in the first quarter. We did not have any acquired IPR&D charges in either the third quarter or first nine months of 2009. We incurred \$59.5 million and \$113.0 of asset impairments, restructuring, and other special charges in the third quarter and first nine months of 2010, respectively, compared with \$549.8 million and \$654.8 million for the same periods in 2009. See Notes 3 and 5 to the consolidated condensed financial statements for additional information.

Other - net, expense (income) improved \$45.2 million and \$196.1 million, to a net expense of \$21.7 million and net income of \$34.4 million for the third quarter and first nine months of 2010, respectively, primarily due to an insurance recovery in the third quarter of 2010 associated with the theft of product at the company's Enfield distribution center in March 2010, as well as lower net interest expense, and, for the first nine months of 2010, damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany and a gain related to the disposition of investment securities acquired in the ImClone acquisition.

The effective tax rate was 22.0 percent and 23.8 percent in the third quarter and first nine months of 2010, respectively, compared with an effective tax rate of 11.9 percent and 19.1 percent in the third quarter and first nine months of 2009, respectively. The effective tax rate for 2010 reflects the expiration of the R&D tax credit in the U.S. The increase in the effective tax rate was driven primarily by the deductibility in the U.S, which has a statutory tax rate higher than our global effective rate, of the asset impairment and restructuring charges in the third quarter of 2009 associated with the sale of the Tippecanoe site and, for the first nine months of 2010, by a one-time deferred tax charge of \$85.1 million associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan as part of U.S. health care reform.

Earnings per share growth of 37 percent and 14 percent in the third quarter and first nine months of 2010, respectively, was higher than revenue growth of 2 percent and 6 percent for the same periods primarily due to lower asset impairments, restructuring, and other special charges.

FINANCIAL CONDITION

As of September 30, 2010, cash, cash equivalents, and short-term investments totaled \$6.14 billion compared with \$4.50 billion at December 31, 2009. The increase in cash is driven by cash flow from operations of \$4.63 billion, partially offset by dividends paid of \$1.62 billion, acquisitions of

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\$797.7 million, purchases of noncurrent investments of \$518.2 million and net purchases of property and equipment of \$443.4 million.

Total debt as of September 30, 2010 increased by \$475.0 million compared with December 31, 2009, to \$7.14 billion, which was due to the approximately \$353 million increase in the fair value of hedged debt and an increase in short-term debt of approximately \$125 million. Our current debt ratings from Standard & Poor's and Moody's are AA- and A1, respectively. Our Moody's long-term debt rating is under review for possible downgrade.

As of the third quarter of 2010, the U.S. and global economic recoveries proceed but face continued headwinds. Recent U.S. economic data continues to reflect a tepid recovery. Given persistently high unemployment and little sign of near-term inflation risk, the U.S. Federal Reserve is maintaining low interest rates to stimulate lending and economic growth. High sovereign debt levels and efforts at fiscal austerity in the U.S. and other developed countries continue to be a concern for many economists and are predicted to slow economic recovery globally. Given this backdrop, both private and public health care payers are facing heightened fiscal challenges and are taking steps to reduce the costs of care, including pressures for increased pharmaceutical discounts and rebates in the U.S., price cuts in government systems outside the U.S., and efforts to drive greater use of generic drugs globally. We continue to monitor the potential near-term impact of the economic environment on prescription trends, the creditworthiness of our wholesalers and other customers and suppliers, the uncertain impact of recent health care legislation, the federal government's involvement in the economy, and various international government funding levels.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including debt service, capital expenditures, acquisition activity, costs associated with litigation and government investigations, and dividends in 2010. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. Our access to credit markets has not been adversely affected given the high credit quality of our short- and long-term debt. We currently have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program and matures in May 2011. Various risks and uncertainties, including those discussed in the Financial Expectations for 2010 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. In the next three years we will lose effective exclusivity for Zyprexa in October 2011 in the U.S. and in most major European countries in October 2011, and for Humalog in major European countries beginning in November 2010. Gemzar has already lost effective exclusivity in major European countries and we expect to lose effective exclusivity in the U.S. in November 2010. In addition, we face U.S. patent litigation over several key patent-protected products whose exclusivity extends beyond 2012, including Alimta, Cymbalta, Evista, and Strattera, and it is possible we could lose our effective exclusivity for one or more of these products prior to the end of 2012. See the Hatch Waxman patent litigation discussion in Note 12 and in the Legal and Regulatory Matters section below. Revenue from each of these products contributes materially to our results of operations, liquidity, and financial position, and the loss of exclusivity would result in a rapid and severe decline in revenue from the affected product, which would have a material adverse effect on our results of operations. However, our goal is to partially mitigate the effect on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, the emerging markets, Japan, and our animal health segment and the previously announced goal to reduce our expected cost structure by \$1 billion by the end of 2011.

Table of Contents**LEGAL AND REGULATORY MATTERS**

We are a party to various legal actions and government investigations. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

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

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

Gemzar: Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); and Sun Pharmaceutical Industries Inc. (Sun) each submitted one or more ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. Sandoz Inc. (Sandoz), APP Pharmaceuticals, LLC (APP), Actavis Elizabeth LLC and Actavis Totowa LLC (Actavis), Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), and Accord Healthcare Inc. (Accord) have similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006), Hospira (October 2006, January 2008, and March 2010), APP (December 2009), Fresenius (February 2010), Actavis (June 2010), Sandoz (August 2010), and Dr. Reddy's (October 2010), and against Accord in the U.S. District Court for the Middle District of North Carolina (October 2010), seeking rulings that our patents are valid and are being infringed. In November 2007, Sun filed a declaratory judgment action in the U.S. District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent, and the opinion was affirmed by a panel of the Court of Appeals for the Federal Circuit. We are seeking reconsideration of this decision. In March 2010, the district court in Indiana upheld the validity of our compound patent. The court also ruled in our favor on all invalidity theories brought forward by Teva on our method-of-use patent, except for obviousness-type double patenting. The court applied collateral estoppel with regard to this theory, given the ruling in the Sun case. We expect the balance of these cases to follow the final outcomes in the Teva and Sun Cases. Teva's ANDAs have been approved by the FDA, and other generic companies have tentative or final marketing approval for generic gemcitabine. Therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010.

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Alimta: Teva Parenteral Medicines, Inc. (Teva); APP; and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. Trial is scheduled for November 2010 against Teva and APP.

Evista: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. In September 2009, the court upheld our method-of-use patents (the last expires in 2014) and the court held that our particle-size patents (expiring 2017) are invalid. Both rulings were upheld by the appeals court in September 2010. InvaGen Pharmaceuticals, Inc. (InvaGen) submitted an ANDA in 2008 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against InvaGen in January 2009 in the U.S. District Court for the Southern District of Indiana That action has been stayed pending the outcome of the Teva appeal. Watson Laboratories Inc. (Watson) also submitted an ANDA in March of 2010 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against Watson in May 2010 in the U.S. District Court for the Southern District of Indiana.

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. In August 2010, the court ruled that our patent is invalid. Several companies have received final approval to market generic atomoxetine, but the Court of Appeals for the Federal Circuit granted an injunction prohibiting the launch of generic atomoxetine until the court renders an opinion. The appeal is scheduled to be heard by the court in December 2010. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals, and we are considering our legal options.

We believe each of these Hatch-Waxman challenges is without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the U.S.:

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novopharm suit, finding our patent invalid. However, in July 2010 the appeals court set aside the decision and remitted the limited issues of utility and sufficiency of disclosure to the trial court.

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In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to withdraw from the market or were subject to injunction. We have negotiated settlements of the damages arising from infringement with most of the generic companies.

We have received challenges in a number of other countries, including Spain, Austria, Australia, Portugal, and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenges, but additional actions against multiple generic companies are now pending. In March 2010, the District Court of Hague ruled against us and revoked our compound patent in the Netherlands. We have appealed this decision. We have also successfully defended Zyprexa patents in Austria and Portugal.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations.

Zyprexa Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims) 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. Almost all of the federal lawsuits 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).

Since June 2005, we have entered into agreements with various claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle a substantial majority of the claims. The agreements cover a total of approximately 32,690 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In 2005, we settled and paid more than 8,000 claims for \$690.0 million, plus \$10.0 million to cover administration of the settlement.

In 2007, we settled and paid more than 18,000 claims for approximately \$500 million.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 100 lawsuits in the U.S. covering approximately 185 plaintiffs, of which about 75 lawsuits covering about 80 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, the earliest trial groups have been tentatively scheduled for December 2010. We also have trials scheduled in California in February 2011 and in Texas state court in August 2011.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act

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for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures, and practices.

In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We have reached agreements to settle the Zyprexa-related claims of all of these states except Minnesota, with which we are in advanced discussions. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the then-current probable and estimable exposures in connection with these claims.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order and Judge Weinstein's order denying our motion for summary judgment in September 2008. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs' overpricing claim. Plaintiffs are seeking a reconsideration of this decision.

We cannot determine with certainty the additional number of lawsuits and claims that may be asserted. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta. Approximately half of these claims are covered by insurance, subject to deductibles and coverage limits.

Product Liability Insurance

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

FINANCIAL EXPECTATIONS FOR 2010

We have raised our 2010 earnings per share guidance to a range of \$4.55 to \$4.65, excluding any potential fourth quarter restructuring charges primarily related to previously announced cost structure and global workforce reductions. This new guidance also does not include any potential charges related to the recent news on Bydureon and teplizumab.

We also have revised certain other elements of our full-year 2010 financial guidance. We now expect volume-driven revenue growth in the mid-single digits, driven primarily by Alimta, Cymbalta, Humalog, Cialis, Effient and animal health products. For 2010, we now expect that U.S. health care reform will reduce revenue by approximately \$225 million to \$275 million. We still anticipate that gross margin as a percent of revenue will be flat to increasing. Marketing, selling, and administrative expenses are still projected to grow in the low-single digits while research and development expenses are still projected to grow in the low-double digits. Other-net, expense (income) is now expected to be a net expense of between \$0 and \$50.0 million. Cash flows are still expected to be sufficient to fund capital expenditures (now estimated to be approximately \$700 million), as well as anticipated business development activity and our dividend.

We caution investors that any forward-looking statements or projections made by us, including those above, are based on management's belief at the time they are made. However, they are subject to risks and uncertainties. Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the implementation of U.S. health care reform; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired IPR&D charges; foreign exchange rates and global macroeconomic conditions; changes in effective tax rates; wholesaler inventory changes; other regulatory developments, litigation, patent disputes, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2009 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/sec.cfm>.

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Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures.* Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's disclosure controls and procedures, which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the commission (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2010, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the third quarter of 2010, 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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

See Part I, Item 2, Management's Discussion and Analysis, Legal and Regulatory Matters, for information on various legal proceedings, including but not limited to:

The U.S. patent litigation involving Alimta, Cymbalta, Evista, Gemzar, and Strattera

The patent litigation outside the U.S. involving Zyprexa

The various federal and state investigations relating to our sales, marketing, and promotional practices

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

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We refer to Part I, Item 3, of our Form 10-K annual report for 2009 for the discussion of product liability litigation involving diethylstilbestrol (DES), vaccines containing the preservative thimerosal, and Byetta. In the DES litigation, we have been named as a defendant in approximately 25 suits involving approximately 50 claimants seeking to recover damages on behalf of children and grandchildren of women who were prescribed DES during pregnancy in the 1950s and 1960s. In December 2009, a lawsuit was filed in the U.S. District Court in Washington, D.C., against us and other manufacturers (*Michele Fecho, et al v. Eli Lilly and Company, et al*) seeking to assert product liability claims on behalf of a putative class of men and women allegedly exposed to the medicine who claim to have later developed breast cancer. In the thimerosal litigation, we have been named as a defendant in approximately 200 suits involving approximately 270 claimants. In addition, we have been named a defendant in approximately 100 lawsuits involving approximately 340 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 40 additional claimants who have not yet filed suit.

Table of Contents*Other Patent Litigation*

Cialis: In July 2005, Vanderbilt University filed a lawsuit in the United States District Court in Delaware against ICOS Corporation seeking to add three of its scientists as co-inventors on the Cialis compound and method-of-use patents. In January 2009, the district court judge ruled in our favor, declining to add any of these scientists as an inventor on either patent. The plaintiff appealed this ruling to the Court of Appeals for the Federal Circuit, which affirmed the lower court ruling in April 2010, and, in June 2010, further denied a rehearing of the case. The plaintiffs have petitioned for review of this decision by the U.S. Supreme Court. An unfavorable final outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Shareholder Derivative Litigation

Since January 2008, we have been served with seven shareholder derivative lawsuits: *Lambrecht, et al. v. Taurel, et al.*, filed January 17, 2008, in the U.S. District Court for the Southern District of Indiana; *Staeher, et al. v. Eli Lilly and Company, et al.*, filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; *Waldman, et al., v. Eli Lilly and Company, et al.*, filed February 11, 2008, in the U.S. District Court for the Eastern District of New York; *Solomon v. Eli Lilly and Company, et al.*, filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; *Robbins v. Taurel, et al.*, filed April 9, 2008, in the U.S. District Court for the Eastern District of New York; *City of Taylor General Employees Retirement System v. Taurel, et al.*, filed April 15, 2008, in the U.S. District Court for the Eastern District of New York; and *Zemprelli v. Taurel, et al.*, filed June 24, 2008, in the U.S. District Court for the Southern District of Indiana. All seven lawsuits are nominally filed on behalf of the company, against various current and former directors and officers and allege that the named officers and directors harmed the company through the improper marketing of Zyprexa, and in certain suits, Evista and Prozac. We have reached an agreement with plaintiffs' counsel to settle this litigation, which was approved by the U.S. District Court for the Southern District of Indiana and all cases have been dismissed in all courts. Under the settlement, we have agreed to implement or maintain certain enhancements in our corporate governance, compliance, and risk management systems. We also agreed not to oppose plaintiffs' counsel's request for fees and expenses of \$8.75 million.

Employment Matters

In April 2006, three former employees and one current employee filed a complaint against the company in the U.S. District Court for the Southern District of Indiana (*Welch, et al. v. Eli Lilly and Company*, filed April 20, 2006) alleging racial discrimination. During the litigation, plaintiffs amended their complaint twice, and the lawsuit at one point involved 145 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). Although the case was originally filed as a putative class action, in September 2009, plaintiffs withdrew their request for class certification. In September 2010, the court severed the remaining individual claims and ordered that any plaintiff wishing to continue litigation must file an individual action within 90 days; any individual claim not refiled within 90 days will be dismissed with prejudice.

We have also been named as a defendant in a lawsuit filed in the U.S. District Court for the Northern District of New York (*Schaefer-LaRose, et al. v. Eli Lilly and Company*, filed November 14, 2006) claiming that our pharmaceutical sales representatives should have been categorized as non-exempt rather than exempt employees, and claiming that the company owes them back wages for overtime worked, as well as penalties, interest, and attorneys' fees. Other pharmaceutical industry participants face similar lawsuits. The case was transferred to the U.S. District Court for the Southern District of Indiana in August 2007. In February 2008, the Indianapolis court conditionally certified a nationwide opt-in collective action under the Fair Labor Standards Act of all current and former employees who served as a Lilly pharmaceutical sales representative at any time from November 2003 to the present. As of the close of the opt-in period, fewer than 400 of the over 7,500 potential plaintiffs elected to participate in the lawsuit. In September 2009, the

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District Court granted our motion for summary judgment with regard to Ms. Schaefer-LaRose's claims and ordered the plaintiffs to demonstrate why the entire collective action should not be decertified within 30 days. Plaintiffs have filed a motion for reconsideration of the summary judgment decision and have also opposed decertification. In October 2010, the court denied plaintiffs motion for reconsideration but decided not to decertify the collective action at this time. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

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

Other Matters

Between 2003 and 2005, various municipalities in New York sued us and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the municipalities overpaid their portion of the cost of pharmaceuticals. The suits seek monetary and other relief, including civil penalties and treble damages. Similar suits were filed against us and many other manufacturers by the states of Mississippi, Iowa, Utah, Oklahoma, and Kansas. These suits are pending either in the U.S. District Court for the District of Massachusetts or in various state courts. All of these suits are in early stages or discovery is ongoing. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, 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 the consolidated results of operations in any one accounting period.

Item 1a. Risk Factors

Our business is subject to increasing government price controls and other health care cost containment measures.

Government health care cost-containment measures can significantly affect our sales and profitability. In many countries outside the United States, government agencies strictly control, directly or indirectly, the prices at which our products are sold. In the United States, we are subject to substantial pricing pressures from state Medicaid programs and private insurance programs and pharmacy benefit managers, including those operating under the Medicare Part D pharmaceutical benefit, and we expect implementation of recently-enacted U.S. health care reform legislation to increase these pricing pressures. In addition, many state legislative proposals would further negatively affect our pricing and/or reimbursement for our products. We expect pricing pressures from both governments and private payers inside and outside the United States to become more severe. See Management's Discussion and Analysis Executive Overview Legal, Regulatory, and Other Matters.

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2010:

| Period | Total Number of Shares Purchased (a) (in thousands) | Average Price Paid per Share (b) | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c) (in thousands) | Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d) (in millions) |
|----------------|---|--|---|--|
| July 2010 | 1 | \$ 33.50 | | \$ 419.2 |
| August 2010 | | | | 419.2 |
| September 2010 | | | | 419.2 |
| Total | 1 | | | |

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of September 30, 2010, we have purchased \$2.58 billion related to this program. During the first nine months of 2010, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2010.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

| | |
|--------------|---|
| EXHIBIT 3. | Bylaws as amended October 18, 2010, incorporated by reference from Exhibit 3 to the Company's Report on Form 8-K filed October 21, 2010 |
| EXHIBIT 10. | 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 18, 2012 |
| EXHIBIT 11. | Statement re: Computation of Earnings per Share |
| EXHIBIT 12. | Statement re: Computation of Ratio of Earnings to Fixed Charges |
| EXHIBIT 31.1 | Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer |

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|-----------------|---|
| 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 |

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SIGNATURES

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

ELI LILLY AND COMPANY

(Registrant)

Date: October 29, 2010

/s/ James B. Lootens

James B. Lootens

Corporate Secretary

Date: October 29, 2010

/s/ Arnold C. Hanish

Arnold C. Hanish

Vice President, Finance and Chief Accounting
Officer

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