

LILLY ELI & CO  
Form 10-Q  
July 30, 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 JUNE 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  
(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 July 20, 2010:

Class	Number of Shares Outstanding
Common	1,153,140,311

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(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions, except per-share data)			
Revenue	\$ 5,748.7	\$ 5,292.8	\$ 11,234.2	\$ 10,339.8
Cost of sales	1,023.9	947.4	2,146.4	1,763.8
Research and development	1,187.2	1,040.4	2,226.3	1,987.7
Marketing, selling, and administrative	1,755.4	1,708.2	3,369.8	3,237.4
Acquired in-process research and development (Note 3)			50.0	
Asset impairments, restructuring, and other special charges (Note 5)	27.3	105.0	53.5	105.0
Other - net, expense (income) (Note 13)	18.4	24.1	(56.1)	94.8
	4,012.2	3,825.1	7,789.9	7,188.7
Income before income taxes	1,736.5	1,467.7	3,444.3	3,151.1
Income taxes (Note 10)	387.6	309.2	847.3	679.5
Net income	\$ 1,348.9	\$ 1,158.5	\$ 2,597.0	\$ 2,471.6
Earnings per share - basic and diluted (Note 9)	\$ 1.22	\$ 1.06	\$ 2.35	\$ 2.25
Dividends paid per share	\$ .49	\$ .49	\$ .98	\$ .98

See Notes to Consolidated Condensed Financial Statements.

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**CONSOLIDATED CONDENSED BALANCE SHEETS**  
**Eli Lilly and Company and Subsidiaries**

	June 30, 2010	December 31, 2009
	(Dollars in millions)	
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 5,163.5	\$ 4,462.9
Short-term investments (Note 6)	33.1	34.7
Accounts receivable, net of allowances of \$105.6 (2010) and \$109.9 (2009)	3,065.2	3,343.3
Other receivables	587.8	488.5
Inventories	2,174.4	2,849.9
Deferred income taxes	314.4	271.0
Prepaid expenses	1,128.0	1,036.2
<b>TOTAL CURRENT ASSETS</b>	<b>12,466.4</b>	<b>12,486.5</b>
<b>OTHER ASSETS</b>		
Investments (Note 6)	1,064.7	1,155.8
Goodwill and other intangibles - net (Note 4)	4,036.0	3,699.8
Sundry	2,371.6	1,921.4
	7,472.3	6,777.0
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	14,044.2	15,100.0
Less accumulated depreciation	(6,259.8)	(6,902.6)
	7,784.4	8,197.4
	<b>\$27,723.1</b>	<b>\$ 27,460.9</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 26.7	\$ 27.4
Accounts payable	950.3	968.1
Employee compensation	585.5	894.2
Sales rebates and discounts	1,288.3	1,109.8
Dividends payable	545.7	538.0
Income taxes payable	435.3	346.7
Other current liabilities	2,492.8	2,683.9
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,324.6</b>	<b>6,568.1</b>
Long-term debt	6,862.2	6,634.7
Accrued retirement benefit (Note 11)	1,882.4	2,334.7

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Long-term income taxes payable (Note 10)	1,227.3	1,088.4
Deferred income taxes	80.7	84.8
Other noncurrent liabilities	1,110.6	1,224.9
	11,163.2	11,367.5
SHAREHOLDERS' EQUITY (Notes 7 and 8)		
Common stock	721.3	718.7
Additional paid-in capital	4,668.0	4,635.6
Retained earnings	11,343.7	9,830.4
Employee benefit trust	(3,013.2)	(3,013.2)
Deferred costs-ESOP	(73.3)	(77.4)
Accumulated other comprehensive loss	(3,307.6)	(2,471.9)
Noncontrolling interests	(6.2)	1.6
	10,332.7	9,623.8
Less cost of common stock in treasury	97.4	98.5
	10,235.3	9,525.3
	\$27,723.1	\$ 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

	Six Months Ended June 30,	
	2010	2009
	(Dollars in millions)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 2,597.0	\$ 2,471.6
Adjustments to reconcile net income to cash flows from operating activities:		
Net marketing investigation charges paid	(80.5)	(1,392.8)
Other changes in operating assets and liabilities	(703.5)	(1,194.9)
Depreciation and amortization	645.0	612.3
Change in deferred income taxes	317.2	340.1
Stock-based compensation expense	128.2	160.4
Acquired in-process research and development, net of tax	32.5	
Other, net	(66.3)	14.5
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>2,869.6</b>	<b>1,011.2</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net purchases of property and equipment	(279.3)	(333.9)
Net change in short-term investments	(2.6)	457.8
Proceeds from sales and maturities of noncurrent investments	383.0	367.4
Purchases of noncurrent investments	(252.2)	(122.8)
Purchase of product rights	(400.0)	
Cash paid for acquisition	(148.4)	
Purchase of in-process research and development	(50.0)	
Other, net	(57.3)	(39.1)
<b>NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>	<b>(806.8)</b>	<b>329.4</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(1,075.9)	(1,075.8)
Net change in short-term borrowings	(1.3)	(4,812.8)
Proceeds from issuance of long-term debt	0.7	2,400.0
Other, net	(2.0)	(3.4)
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(1,078.5)</b>	<b>(3,492.0)</b>
Effect of exchange rate changes on cash and cash equivalents	(283.7)	(23.0)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>700.6</b>	<b>(2,174.4)</b>

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Cash and cash equivalents at January 1	4,462.9	5,496.7
CASH AND CASH EQUIVALENTS AT June 30	\$ 5,163.5	\$ 3,322.3

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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Net income	\$1,348.9	\$1,158.5	\$2,597.0	\$2,471.6
Other comprehensive (loss) income, net of tax <sup>1</sup>	(530.7)	663.5	(835.7)	320.0
Comprehensive income	\$ 818.2	\$1,822.0	\$1,761.3	\$2,791.6

<sup>1</sup> The significant components of other comprehensive loss were losses from foreign currency translation adjustments of \$543.5 million and \$920.5 million for the three months and six months ended June 30, 2010, respectively. The significant components of other comprehensive income for the three months and six months ended June 30, 2009 were gains from foreign currency translation adjustments of \$596.4 million and

\$192.7 million, respectively. In addition, net unrealized gains on investment securities of \$94.2 million and \$97.0 million were included in other comprehensive income for the three months and six months ended June 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 second quarters of 2010 and 2009 was \$66.4 million and \$47.6 million, respectively, and \$103.1 million and \$83.3 million for the six months ended June 30, 2010 and 2009, respectively.

**REVENUE BY CATEGORY**

Worldwide revenue by category was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Revenue to unaffiliated customers:				
Neuroscience	\$2,363.7	\$2,185.7	\$ 4,607.8	\$ 4,263.4
Endocrinology	1,518.7	1,481.4	2,996.5	2,890.1
Oncology	949.0	838.2	1,856.8	1,635.5
Cardiovascular	532.0	454.1	1,051.7	909.2
Animal health	324.2	275.4	613.8	539.5
Other pharmaceuticals	61.1	58.0	107.6	102.1
Total revenue	\$5,748.7	\$5,292.8	\$ 11,234.2	\$ 10,339.8

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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 be material 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.

**Table of Contents****Note 3: Acquisitions**

In the second quarter of 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. This acquisition has been accounted for as a business combination with the purchase price being allocated primarily to product-related intangibles and property and equipment. This acquisition is not material to our consolidated financial statements.

**Acquisitions of Marketed Products and Products in Development**

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 U.S. Food and Drug Administration (FDA) for the treatment of testosterone deficiency in men and has no alternative future use. The charge of \$50.0 million for acquired in-process research and development (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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Net product sales	\$5,589.3	\$5,113.3	\$10,921.8	\$10,005.1
Collaboration and other revenue	159.4	179.5	312.4	334.7
Total revenue	\$5,748.7	\$5,292.8	\$11,234.2	\$10,339.8

**Erbitux®**

Prior to our acquisition in November 2008, ImClone Systems Inc. (ImClone) entered into several collaborations with respect to Erbitux, a product approved to fight cancer, while still in its development phase. 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

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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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Net product sales	\$ 21.5	\$23.9	\$ 38.4	\$ 50.0
Collaboration and other revenue	82.3	75.8	157.8	143.9
Total revenue	\$103.8	\$99.7	\$196.2	\$193.9

*Bristol-Myers Squibb Company*

Pursuant to a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, ImClone is 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 ImClone 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 between ImClone and 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 ImClone 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

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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, 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. 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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Net product sales	\$ 43.7	\$ 34.7	\$ 87.0	\$ 62.1
Collaboration and other revenue	63.2	79.9	135.7	150.2
Total revenue	\$ 106.9	\$ 114.6	\$ 222.7	\$ 212.3

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 has been submitted to the FDA for Bydureon, the proposed brand name for exenatide once weekly, with the current Prescription Drug User Fee Act action date of October 22, 2010. Amylin is constructing and will operate a manufacturing facility for exenatide once weekly, and we have entered into a supply agreement in which Amylin will supply

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exenatide once weekly product to us for sales outside the U.S. The estimated total cost of the facility is approximately \$550 million. In 2008, we paid \$125.0 million to Amylin, which we will amortize to cost of sales over the estimated life of the supply agreement beginning with product launch. We would be required to reimburse Amylin for a portion of any future impairment of this facility, recognized in accordance with GAAP. A portion of the \$125.0 million payment we made to Amylin would be creditable against any amount we would owe as a result of impairment. We have also agreed to loan up to \$165.0 million to Amylin at an indexed rate, no amounts have been loaned pursuant to this arrangement and any borrowings have to be repaid by June 30, 2014. We have also agreed to cooperate with Amylin in the development, manufacturing, and marketing of exenatide once weekly 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, of which we have contributed approximately \$70 million as of June 30, 2010.

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 the exclusive rights to develop and market duloxetine for all indications in countries outside the U.S. and Japan were re-acquired by us. 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 rate on net product sales 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 Efient® 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



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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 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 \$22.9 million and \$31.6 million in the second quarter and first six 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. Under the agreement, both we and TPG will provide funding for the Alzheimer's clinical trials. Funding from TPG will not exceed \$325.0 million and could extend into 2014. In exchange for their funding, TPG may receive success-based milestones totaling \$330.0 million and mid- to high-single digit royalties that are contingent upon the successful development of the Alzheimer's treatments. The royalties will be paid for approximately eight years after launch of a product. Reimbursements received from TPG for its portion of research and development costs incurred related to the Alzheimer's treatments are recorded as a reduction to the research and development expense line item on the consolidated condensed statements of operations. The reimbursement from TPG has not been and is not expected to be material in any period.

### **Summary of Collaboration Related Commission and Profit Share Payments**

The aggregate amount of commission and profit share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$31.6 million and \$84.6 million in the quarters ended June 30, 2010 and 2009, respectively, and \$96.7 million and \$162.2 million in the six months ended June 30, 2010 and 2009, respectively.

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

We recognized asset impairments, restructuring and other special charges of \$27.3 million and \$53.5 million in the second quarter and first six 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 by the end of the third quarter of 2010.

In the second quarter of 2009, we incurred other special charges of \$105.0 million, related to advanced discussions with the attorneys general for several states that were not part of the Eastern District of Pennsylvania settlement, seeking to resolve their Zyprexa®-related claims. The charge represented the then-current probable and estimable exposures in connection with the states' claims. Refer to 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

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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 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 June 30, 2010, we did not hold any foreign currency option contracts. At June 30, 2010, we had outstanding foreign currency forward commitments to purchase 541 million British pounds and sell 652 million euro, commitments to purchase 781 million U.S. dollars and sell 596 million euro, and commitments to buy 933 million euro and sell 1.20 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 June 30, 2010, approximately 94 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.

**Table of Contents****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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Fair value hedges				
Effect from hedged fixed-rate debt	\$ 205.1	\$(179.8)	\$ 236.7	\$(319.4)
Effect from interest rate contracts	(205.1)	179.8	(236.7)	319.4
Cash flow hedges				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.3	2.6	4.5	5.1
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	(49.4)	6.8	(46.4)	5.8

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 ended June 30, 2010 and June 30, 2009, respectively, and was \$0.0 and \$37.8 million for the six months ended June 30, 2010 and June 30, 2009, respectively.

During the three months and six months ended June 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 \$11.9 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 June 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) (Dollars in millions)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>June 30, 2010</b>						
Short-term investments						
Corporate debt securities	\$ 12.2	\$ 12.4	\$	\$ 12.2	\$	\$ 12.2
U.S. government and agencies	19.9	19.9	19.9			19.9
Other securities	1.0	1.0		1.0		1.0
Total	\$ 33.1	\$ 33.3				
Noncurrent investments						
Corporate debt securities	\$ 185.3	\$ 191.1	\$	\$ 185.3	\$	\$185.3
Mortgage-backed	228.6	277.5		228.6		228.6
Asset-backed	57.0	69.7		57.0		57.0
U.S. government and agencies	76.1	75.2	76.1			76.1
Other debt securities	6.6	10.4		3.1	3.5	6.6
Marketable equity	351.5	185.1	351.5			351.5
Equity method and other investments	159.6	159.6				(1)
Total	\$1,064.7	\$ 968.6				
<b>December 31, 2009</b>						
Short-term investments						
Corporate debt securities	\$ 15.8	\$ 16.1	\$	\$ 15.8	\$	\$ 15.8
U.S. government and agencies	18.5	18.8	18.5			18.5
Other securities	0.4	0.4		0.4		0.4
Total	\$ 34.7	\$ 35.3				
Noncurrent investments						

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Corporate debt securities	\$ 185.9	\$ 195.4	\$	\$ 185.9	\$	\$185.9
Mortgage-backed	240.3	310.0		240.3		240.3
Asset-backed	78.7	94.1		78.7		78.7
U.S. government and agencies	81.3	81.7	81.3			81.3
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			
		Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs	Significant Unobservable Inputs	Fair Value
		Assets (Level 1)	(Level 2)	(Level 3)	
(Dollars in millions)					
<b>Long-term debt, including current portion</b>					
June 30, 2010	\$(6,880.3)	\$	\$ (7,193.0)	\$	\$(7,193.0)
December 31, 2009	(6,655.0)		(6,827.8)		(6,827.8)

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)			
<b>June 30, 2010</b>					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Sundry	\$365.4	\$	\$ 365.4	\$	\$365.4
Foreign exchange contracts not designated as hedging instruments					
Other receivables	81.3		81.3		81.3
Other current liabilities	(63.0)		(63.0)		(63.0)

**December 31, 2009**

Risk-management instruments  
Interest rate contracts designated as  
hedging instruments

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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)

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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 \$235 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:

	June 30, 2010	December 31, 2009
	(Dollars in millions)	
Unrealized gross gains	\$ 177.2	\$ 222.4
Unrealized gross losses	81.3	101.7
Fair value of securities in an unrealized gain position	633.9	579.8
Fair value of securities in an unrealized loss position	292.4	449.4

Other-than-temporary impairment losses on fixed income securities of \$5.7 million and \$6.7 million were recognized in the statement of operations for the three months and six months ended June 30, 2010, respectively, compared with \$2.3 million and \$7.6 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 June 30, 2010.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Proceeds from sales	\$ 189.0	\$ 313.0	\$ 367.7	\$ 600.6
Realized gross gains on sales	11.4	12.4	74.6	17.3
Realized gross losses on sales	0.5	0.3	2.3	1.0

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.



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### **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 \$54.4 million and \$94.3 million in the second quarter of 2010 and 2009, respectively. In the first six months of 2010 and 2009, we recognized pretax stock-based compensation expense of \$128.2 million and \$160.4 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 targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of June 30, 2010, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$122.8 million, which will be amortized over the weighted-average remaining requisite service period of approximately 13 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of June 30, 2010, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$68.3 million, which will be amortized over the weighted-average remaining requisite service period of approximately 24 months.

### **Note 8: Shareholders' Equity**

As of June 30, 2010, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first half 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

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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 estimate reliably total future cash flows related to these unrecognized tax benefits.

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 are 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.

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## Note 11: Retirement Benefits

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

	Defined Benefit Pension Plans			
	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 53.0	\$ 59.0	\$ 110.8	\$ 119.7
Interest cost	107.7	104.1	215.8	207.5
Expected return on plan assets	(160.0)	(143.1)	(317.6)	(285.4)
Amortization of prior service cost	1.6	1.8	3.4	3.6
Recognized actuarial loss	41.6	20.1	82.3	41.7
Net periodic benefit cost	\$ 43.9	\$ 41.9	\$ 94.7	\$ 87.1

	Retiree Health Benefit Plans			
	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 12.3	\$ 10.4	\$ 28.0	\$ 26.7
Interest cost	30.2	29.8	59.9	58.5
Expected return on plan assets	(30.6)	(29.5)	(61.3)	(58.9)
Amortization of prior service cost	(9.3)	(9.0)	(18.6)	(18.0)
Recognized actuarial loss	20.9	17.2	42.5	34.3
Net periodic benefit cost	\$ 23.5	\$ 18.9	\$ 50.5	\$ 42.6

On a global basis, as of June 30, 2010, we have contributed substantially all of the \$100 million required to satisfy minimum funding requirements to our defined benefit pension plans. In addition, we have contributed \$300 million of discretionary funding to our global post-retirement benefit plans. 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 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):

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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 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, and one alleges the patent having claims directed to the active ingredient is unenforceable. 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 patents 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.

Gemzar®: Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sisor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); Actavis Elizabeth LLC and Actavis Totowa LLC (Actavis); and Sun Pharmaceutical Industries Inc. (Sun) each submitted one or more abbreviated marketing applications 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) and APP Pharmaceuticals, LLC (APP) 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), and Actavis (June 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. The status of these cases is as follows:

In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We appealed this decision, and on July 28, 2010, a panel of the Court of Appeals for the Federal Circuit affirmed the district court's ruling. We disagree with the decision and will consider other legal options, including seeking reconsideration by the full Federal Circuit. Nevertheless, some of the generic companies, including Sun and Teva, 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 on November 15, 2010.

The trial against Teva was held in September 2009. 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. Teva's ANDAs have been approved by the FDA.

Two suits against Hospira have been administratively closed, and the parties have agreed to be bound by the results of the Teva suit. The remaining suit is in the early stages.

APP filed a motion to dismiss our suit, based on the decision in the Sun case. APP's ANDA has received tentative approval from the FDA, but APP is prohibited from entering the market by a 30-month stay, which expires in May 2012.

The Fresenius and Actavis cases are in the early stages.

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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. The trial against Teva was completed in March 2009. In September 2009, the court upheld our method-of-use patents (the last expires in 2014) and Teva has appealed that ruling. In addition, the court held that our particle-size patents (expiring 2017) are invalid, and we have appealed that ruling. 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. The court has ruled on all pending summary judgment motions, and granted our infringement motion. The remaining invalidity defenses were heard at trial in May 2010. We are waiting for a decision. Several companies have received tentative approval to market generic atomoxetine, but are prohibited from entering the market by a 30-month stay that expires in November 2010. An adverse court decision prior to November 2010 would terminate the stay and enable one or more companies to launch generic atomoxetine.

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

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the Novapharm suit, finding our patent invalid. We appealed this decision, and in July 2010 the appeals court set aside the decision and remitted it 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 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.

*Xigris® and Evista:* In June 2002, Ariad Pharmaceuticals, Inc. (Ariad), the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. Following jury and bench trials on separate issues, the U.S. District Court of Massachusetts entered final judgment in September 2007 that Ariad's claims were valid, infringed, and enforceable, and finding damages in the amount of \$65 million plus a 2.3 percent royalty on net U.S. sales of Xigris and Evista since the time of the jury decision. However, the court deferred the requirement to pay any damages until after all rights to appeal are exhausted. In April 2009, the Court of Appeals for the Federal Circuit overturned the District Court judgment, concluding that Ariad's asserted patent claims are invalid. The Court of Appeals reheard the case en banc in December 2009 and affirmed the panel decision in March 2010. No further appeals are possible.

### *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 32,670 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.

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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 145 lawsuits in the U.S. covering approximately 235 plaintiffs, of which about 120 cases covering about 130 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 October and December 2010. We also have trials scheduled in Texas state court in October and December 2010.

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 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 and paid \$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 Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. 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

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certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. While the Second Circuit Court of Appeals heard oral arguments on the appeal in December 2009, no opinions have been rendered. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees who were prescribed Zyprexa on similar grounds as described in the New York cases. In December 2009, the court granted our summary judgment motion dismissing the case. The Pennsylvania Employees Trust Fund has agreed to dismiss its appeal.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits was certified for residents of Quebec, and a second was certified in Ontario and includes all Canadian residents except for residents of Quebec and British Columbia. The allegations in the Canadian actions were similar to those in the product liability litigation pending in the U.S. We have reached agreement to resolve all Zyprexa class-action litigation in Canada. No additional charges were recorded as a result of this agreement.

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.

### **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 attain 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.



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Note 13: Other - Net, Expense (Income)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(Dollars in millions)			
Interest expense	\$ 47.5	\$ 64.3	\$ 95.1	\$ 151.9
Interest income	(11.0)	(18.8)	(21.6)	(46.2)
Other	(18.1)	(21.4)	(129.6)	(10.9)
Other - net, expense (income)	\$ 18.4	\$ 24.1	\$ (56.1)	\$ 94.8

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

## 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 9 percent to \$5.75 billion and \$11.23 billion for the second quarter and first six months of 2010, respectively, driven primarily by the increase in revenue related to the collective growth of Alimta, Cymbalta, Zyprexa, Cialis® and Humalog®. Net income for the second-quarter and the first six months of 2010 increased 16 percent and 5 percent, to \$1.35 billion and \$2.60 billion, respectively, compared with the same periods of 2009. Earnings per share for the second-quarter and the first six months of 2010 increased 15 percent and 4 percent to \$1.22 per share and \$2.35 per share, respectively, compared with the same periods of 2009. Net income for the second quarter and first six 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 \$60 million (pretax), or \$.04 per share, in the first quarter and approximately \$70 million (pretax), or \$.05 per share, in the second quarter, as a result of higher rebates. We also recorded a one-time non-cash charge in the first quarter of \$85.1 million, or \$.08 per share, associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan.

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

We recognized asset impairments, restructuring, and other special charges of \$26.2 million (pretax) and \$27.3 million (pretax) in the first and the second quarter, respectively, primarily related to severance and other related costs from previously announced strategic actions that we are taking to reduce our cost structure and global workforce, which decreased earnings per share by \$.02 in each quarter.

##### 2009

We incurred a pretax charge of \$105.0 million representing the currently probable and estimable exposures in connection with the claims of several states that did not

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participate in the EDPA settlement related to Zyprexa. This charge decreased earnings per share by \$.06 in the second quarter.

### 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

**Ramucirumab** a monoclonal antibody being investigated as a treatment for breast and gastric cancer

**Semagacestat** a gamma secretase inhibitor for the treatment of Alzheimer's disease

**Solanezumab** an a-beta antibody for the treatment of Alzheimer's disease

**Tasisulam** a small-molecule compound for the treatment of melanoma

**Teplizumab** a monoclonal antibody for the treatment of type 1 diabetes

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

**Arxxant** a potential treatment for diabetic retinopathy

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

**Liprotamase** a non-porcine pancreatic enzyme replacement therapy

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

#### Second Quarter

We signed a definitive merger agreement to acquire Alnara Pharmaceuticals, Inc., a privately-held company developing protein therapeutics for the treatment of metabolic diseases, for an upfront payment of \$180 million, subject to adjustment based on existing cash on hand at closing, and up to \$200 million in additional payments contingent upon potential future regulatory and commercial milestones. Alnara's lead product in development is liprotamase, a non-porcine pancreatic enzyme replacement therapy (PERT). Liprotamase is under review by the U.S. Food and Drug Administration (FDA) for the treatment of exocrine pancreatic insufficiency (EPI). We completed this acquisition in July 2010.

We, along with our partners Amylin and Alkermes, Inc., received a complete response letter from the FDA for Bydureon, the proposed brand name for exenatide once weekly, and submitted our response to the FDA's letter in April. The FDA classified the Bydureon complete response as a Class 2 resubmission and assigned a new Prescription Drug User Fee Act (PDUFA) action date of October 22, 2010.

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..

The FDA announced that it will hold an advisory committee meeting to discuss the supplemental New Drug Application (sNDA) for Cymbalta in chronic pain on August 19, 2010.

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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 sales force additions in high-growth emerging markets and Japan), 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 will consider other legal options, including seeking reconsideration by the full Federal Circuit. 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.

Trial was held May 2010 in the U.S. District Court for the District of New Jersey on the validity of our Strattera method-of-use patent, which expires in 2017. We are waiting for a decision. 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 that are currently provided for prescription drugs sold to Medicaid beneficiaries, which increase the minimum statutory rebate for branded drugs from 15.1 percent to 23.1 percent, are generally effective in the first quarter. This rebate has been expanded to managed-Medicaid, a program which provides for the delivery of Medicaid benefits via managed care organizations, under arrangements between these 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 subsidy paid by the government to employers 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 record this future tax liability as a one-time non-cash charge upon enactment of the tax law change. 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 Medicare prescription drug coverage). The doughnut hole will be phased out 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

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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.

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. In addition, the recently proposed

American Jobs and Closing Tax Loopholes Act of 2010 also proposes changes to the manner in which the U.S. would tax U.S.-based companies with foreign-source income. While it is uncertain how the U.S. Congress may address these matters, reform of U.S. taxation, including taxation of international income, continues to be a topic of discussion for the U.S. 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.

Certain other federal and state health care reform 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 second quarter and the first six months of 2010 increased 9 percent to \$5.75 billion and \$11.23 billion, respectively, driven primarily by the increase in revenue related to the collective growth of Alimta, Cymbalta, Zyprexa, Cialis and Humalog. Revenue in the U.S. increased by \$246.7 million, or 8 percent, and \$408.6 million, or 7 percent, for the second quarter and first six months of 2010, respectively, compared with the same periods of 2009 due to higher prices offset in part by approximately \$70 million and approximately \$130 million in the second quarter and first six months of 2010, respectively, in higher rebates resulting from U.S. health care reform and, to a lesser extent, increased volume. Revenue outside the U.S. increased \$209.1 million, or 9 percent, and \$485.9 million, or 11 percent, for the second quarter and first six months of 2010, respectively, compared with the same periods of 2009 due to increased demand and, to a lesser extent, the positive impact of foreign exchange rates, partially offset by lower prices. For the second quarter, worldwide sales volume increased 5 percent; selling prices increased 2 percent; and the favorable impact of foreign exchange rates contributed 1 percent of revenue growth; (numbers do not add due to rounding). For the first six months of 2010, worldwide sales volume increased 5 percent; the favorable impact of foreign exchange rates contributed 2 percent of revenue growth; and selling prices increased 2 percent.

The following tables summarize our revenue activity for the three- and six-month periods ended June 30, 2010 and 2009:

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Product	Three Months Ended June 30, 2010 Outside			Three Months Ended June 30, 2009	Percent Change from 2009
	U.S. <sup>1</sup>	U.S.	Total <sup>2</sup>	Total	
(Dollars in millions)					
Zyprexa	\$ 638.2	\$ 624.7	\$ 1,262.9	\$ 1,203.2	5
Cymbalta	707.9	159.8	867.7	744.4	17
Alimta	253.6	298.3	551.8	385.3	43
Humalog	299.7	205.0	504.6	477.5	6
Cialis	165.2	253.5	418.7	363.6	15
Animal health products	185.0	139.1	324.2	275.4	18
Gemzar	189.8	103.6	293.4	353.2	(17)
Humulin®	115.3	150.0	265.2	248.1	7
Evista	175.6	83.9	259.5	251.3	3
Forteo®	131.4	78.2	209.6	203.3	3
Strattera	100.4	46.7	147.1	142.8	3
Other pharmaceutical products	179.7	304.5	484.6	465.2	4
Total net product sales	3,141.8	2,447.3	5,589.3	5,113.3	9
Collaboration and other revenue <sup>3</sup>	119.9	39.5	159.4	179.5	(11)
Total revenue	\$3,261.7	\$2,486.8	\$5,748.7	\$ 5,292.8	9

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Product	Six Months Ended June 30, 2010 Outside			Six Months Ended June 30, 2009	Percent Change from 2009
	U.S. <sup>1</sup>	U.S.	Total <sup>2</sup>	Total	
(Dollars in millions)					
Zyprexa	\$1,221.7	\$1,256.2	\$ 2,477.9	\$ 2,326.2	7
Cymbalta	1,358.5	312.4	1,670.9	1,453.7	15
Alimta	476.3	602.9	1,079.2	720.6	50
Humalog	609.5	401.5	1,011.0	928.0	9
Cialis	315.1	511.9	827.0	722.4	14
Animal health products	342.8	271.0	613.8	539.5	14
Gemzar	363.5	217.7	581.2	721.0	(19)
Humulin	229.8	293.2	523.0	488.7	7
Evista	333.9	167.2	501.1	508.2	(1)
Forteo	248.3	155.8	404.1	390.7	3
Strattera	203.3	90.2	293.5	301.7	(3)
Other pharmaceutical products	345.5	593.6	939.1	904.4	4
Total net product sales	6,048.2	4,873.6	10,921.8	10,005.1	9
Collaboration and other revenue <sup>3</sup>	247.3	65.1	312.4	334.7	(7)
Total revenue	\$6,295.5	\$4,938.7	\$11,234.2	\$ 10,339.8	9

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

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

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

**Product Highlights**

Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. In the second quarter and first six months of 2010, Zyprexa sales in the

U.S. increased 10 percent and 9 percent, respectively, compared with the same periods of 2009, driven by higher prices, partially offset by lower demand in the second quarter. Sales outside the U.S. increased 1 percent and 4 percent for the second quarter and first six months of 2010, respectively, with the changes driven by the favorable impact of foreign exchange rates and increased demand, partially offset by lower prices. For the first six months of 2010, demand outside the U.S. was favorably affected by the withdrawal of generic competition in Germany in early 2009. U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, increased 14 percent and 12 percent during the second quarter and first six months of 2010, respectively, driven by higher prices and increased volume. Sales outside the U.S. increased 30 percent and 33 percent during the second quarter and first six months of 2010, respectively, compared to the same periods in 2009, driven primarily by increased demand, including the effect of recent launches in Japan and Canada.

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U.S. sales of Alimta, a treatment for various cancers, increased 28 percent during the second quarter and first six months of 2010, respectively, due to increased demand. Sales outside the U.S. increased 60 percent and 73 percent for the same periods, due to increased demand. Demand outside the U.S. was favorably affected by the approval in the second quarter of 2009 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, increased 3 percent and 5 percent during the second quarter and first six months of 2010, respectively, with the second quarter increase driven by increased volume, partially offset by lower net effective selling prices. The increase for the first six months of 2010 was due to increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 10 percent and 15 percent for the second quarter and first six months of 2010, respectively, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 11 percent and 6 percent during the second quarter and first six months of 2010, respectively, with the second quarter increase primarily driven by higher prices, and increased volume. The increase for the first six months was due to higher prices. Sales outside the U.S. increased 18 percent and 21 percent for the same periods, with the second quarter increase driven by increased demand. The increase for the first six 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, decreased 3 percent and remained essentially flat during the second quarter and first six months of 2010, respectively, with the second quarter decrease due to lower net effective selling prices. The results in the first six months of 2010 were driven by lower net effective selling prices offset by increased volume. Sales outside the U.S. decreased 34 percent and 39 percent for the second quarter and first six months of 2010, respectively, due to lower demand and lower prices as a result of the entry of generic competition in most major markets. 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 21 percent and 18 percent during the second quarter and first six months of 2010, respectively, driven by higher prices and, to a lesser extent, increased demand. Sales outside the U.S. decreased 2 percent and remained essentially flat for the second quarter and first six months of 2010, respectively, with the second quarter decrease driven by lower prices, partially offset by the favorable impact of foreign exchange rates. The favorable impact of foreign exchange rates for the first six months of 2010 was offset by lower prices and lower demand.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, increased 4 percent and 1 percent during the second quarter and first six months of 2010, respectively, due to higher prices, partially offset by decreased demand. Sales outside the U.S. increased 1 percent for the second quarter and decreased 5 percent for the first six months of 2010, respectively, with second quarter increases driven by the favorable impact of foreign exchange rates, partially offset by decreased demand. The decrease during the first six months of 2010 was due to decreased 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, remained essentially flat and decreased 2 percent during the second quarter and first six months of 2010, respectively, with higher net effective selling prices being offset by decreased demand in the second quarter. The decrease in the first six months of 2010 is due to decreased demand partially offset by higher prices. Sales outside the U.S. increased 10 percent and 14 percent for the second quarter and first six months of 2010, respectively, due to



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increased demand and, to a lesser extent for the first six months of 2010, the favorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 5 percent and 8 percent during the second quarter and first six months of 2010, respectively, due primarily to decreased demand. Sales outside the U.S. increased 26 percent and 12 percent for the second quarter and first six months of 2010, respectively, with the increase for the second quarter driven by increased demand. The increase in the first six months of 2010 was due to increased demand and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower prices.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, decreased 13 percent and 5 percent to \$178.8 million and \$366.8 million during the second quarter and first six months of 2010, respectively. The decrease in the second quarter was due to competitive pressures. 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 7 percent to \$106.9 million for the second quarter and increased 5 percent to \$222.7 million during first six 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 increased 4 percent and 1 percent to \$103.8 million and \$196.2 million during the second quarter and first six months of 2010, respectively.

Animal health product sales in the U.S. increased 20 percent and 11 percent during the second quarter and first six months of 2010, respectively, primarily due to higher demand. Sales outside the U.S. increased 15 percent and 17 percent during the second quarter and first six months of 2010, respectively, driven primarily by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

### **Gross Margin, Costs, and Expenses**

For the second quarter of 2010, gross margins as a percent of total revenue were essentially flat at 82.2 percent. For the first six months of 2010, gross margins as a percentage of total revenue decreased by 2 percentage points, to 80.9 percent. This decrease was 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 six months of 2010, but substantially decreased cost of sales in the first six months of 2009.

Marketing, selling, and administrative expenses increased 3 percent to \$1.76 billion for the second quarter, and 4 percent to \$3.37 billion for the first six months of 2010. The increase for both periods was driven by higher marketing and selling expenses outside the U.S. and the impact of foreign exchange rates, partially offset by lower litigation and other administrative expenses. Research and development expenses were \$1.19 billion and \$2.23 billion for the second quarter and first six months of 2010, respectively. Compared with the same periods of 2009, research and development expenses grew 14 percent and 12 percent for the second quarter and first six months of 2010, respectively, due primarily to increased costs of late-stage clinical trials in both periods and associated development milestones in the second quarter.

Acquired IPR&D charges were \$50.0 million in the first six 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 second quarter or first six months of 2009. We incurred \$27.3 million and \$53.5 of asset impairments, restructuring, and other special charges in the second quarter and first six months of 2010, respectively, compared with \$105.0 million for the same periods in 2009. See Notes 3 and 5 to the consolidated condensed financial statements for additional information.

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Other - net, expense (income) improved \$5.7 million and \$150.9 million, to a net expense of \$18.4 million and a net income of \$56.1 million for the second quarter and first six months of 2010, respectively, primarily due to lower net interest expense in both periods, and 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 in the first six months.

The effective tax rate was 22.3 percent and 24.6 percent in the second quarter and first six months of 2010, respectively, compared with an effective tax rate of 21.1 percent and 21.6 percent in the second quarter and first six months of 2009, respectively. The increase in the effective tax rate was driven by a one-time 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 in the first six months, as well as the expiration of the research and development tax credit in the U.S. at the end of 2009, which affected both periods.

Earnings per share growth of 15 percent for the second quarter was higher than revenue growth of 9 percent for the same period primarily due to lower asset impairments, restructuring, and other special charges as well as lower administrative expenses. Earnings per share growth of 4 percent for the first six months of 2010 was lower than revenue growth of 9 percent for the same period due to cost of sales growing at a faster rate than revenue and the one-time 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.

**FINANCIAL CONDITION**

As of June 30, 2010, cash, cash equivalents, and short-term investments totaled \$5.20 billion compared with \$4.50 billion at December 31, 2009. The increase in cash is driven by cash flow from operations of \$2.87 billion, partially offset by dividends paid of \$1.08 billion, acquisitions of \$598.4 million and net purchases of property and equipment of \$279.3 million.

Total debt as of June 30, 2010 increased by \$226.8 million compared with December 31, 2009, to \$6.89 billion. Our current debt ratings from Standard & Poor's and Moody's remain at AA and A1, respectively.

As of the second quarter of 2010, the U.S. and global economic recoveries continue but face additional macroeconomic headwinds. U.S. consumer confidence remains fragile, though unemployment is expected to continue to decline through 2010 and 2011. The U.S. Federal Reserve continues to keep interest rates low to stimulate lending and economic growth. Although many economists believe that the U.S. economy will see moderate growth with low inflation through 2011, recent U.S. economic data has been below expectations, prompting renewed concern about the sustainability and pace of the economic recovery. 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. In addition, both private and public health care payers are facing heightened fiscal challenges due to the economic slowdown and are taking aggressive steps to reduce the costs of care, including pressures for increased pharmaceutical discounts and rebates and efforts to drive greater use of generic drugs. We continue to monitor the potential near-term impact of the economic slowdown 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 economic crisis, 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

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credit markets has not been adversely affected by the illiquidity in the markets because of 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 major European countries (September 2011) and the U.S. (October 2011); and for Humalog in major European countries (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 face an unexpected loss of 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.

### **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 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, and one alleges the patent having claims directed to the active ingredient is unenforceable. 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 patents 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.

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Gemzar: Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); Actavis Elizabeth LLC and Actavis Totowa LLC (Actavis); and Sun Pharmaceutical Industries Inc. (Sun) each submitted one or more abbreviated marketing applications 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) and APP Pharmaceuticals, LLC (APP) 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), and Actavis (June 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. The status of these cases is as follows:

In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We appealed this decision, and on July 28, 2010, a panel of the Court of Appeals for the Federal Circuit affirmed the district court's ruling. We disagree with the decision and will consider other legal options, including seeking reconsideration by the full Federal Circuit. Nevertheless, some of the generic companies, including Sun and Teva, 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 on November 15, 2010.

The trial against Teva was held in September 2009. 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. Teva's ANDAs have been approved by the FDA.

Two suits against Hospira have been administratively closed, and the parties have agreed to be bound by the results of the Teva suit. The remaining suit is in the early stages.

APP filed a motion to dismiss our suit, based on the decision in the Sun case. APP's ANDA has received tentative approval from the FDA, but APP is prohibited from entering the market by a 30-month stay, which expires in May 2012.

The Fresenius and Actavis cases are in the early stages.

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. The trial against Teva was completed in March 2009. In September 2009, the court upheld our method-of-use patents (the last expires in 2014) and Teva has appealed that ruling. In addition, the court held that our particle-size



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patents (expiring 2017) are invalid, and we have appealed that ruling. 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. The court has ruled on all pending summary judgment motions, and granted our infringement motion. The remaining invalidity defenses were heard at trial in May 2010. We are waiting for a decision. Several companies have received tentative approval to market generic atomoxetine, but are prohibited from entering the market by a 30-month stay that expires in November 2010. An adverse court decision prior to November 2010 would terminate the stay and enable one or more companies to launch generic atomoxetine.

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. We appealed this decision, and in July 2010 the appeals court set aside the decision and remitted it 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 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.

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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.

*Xigris and Evista:* In June 2002, Ariad Pharmaceuticals, Inc. (Ariad), the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. Following jury and bench trials on separate issues, the U.S. District Court of Massachusetts entered final judgment in September 2007 that Ariad's claims were valid, infringed, and enforceable, and finding damages in the amount of \$65 million plus a 2.3 percent royalty on net U.S. sales of Xigris and Evista since the time of the jury decision. However, the court deferred the requirement to pay any damages until after all rights to appeal are exhausted. In April 2009, the Court of Appeals for the Federal Circuit overturned the District Court judgment, concluding that Ariad's asserted patent claims are invalid. The Court of Appeals reheard the case en banc in December 2009 and affirmed the panel decision in March 2010. No further appeals are possible.

### **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 32,670 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 145 lawsuits in the U.S. covering approximately 235 plaintiffs, of which about 120 cases covering about 130 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 October and December 2010. We also have trials scheduled in Texas state court in October and December 2010.

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

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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 and paid \$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 Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. 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. While the Second Circuit Court of Appeals heard oral arguments on the appeal in December 2009, no opinions have been rendered. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees who were prescribed Zyprexa on similar grounds as described in the New York cases. In December 2009, the court granted our summary judgment motion dismissing the case. The Pennsylvania Employees Trust Fund has agreed to dismiss its appeal.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits was certified for residents of Quebec, and a second was certified in Ontario and includes all Canadian residents except for residents of Quebec and British Columbia. The allegations in the Canadian actions were similar to those in the product liability litigation pending in the U.S. We have reached agreement to resolve all Zyprexa class-action litigation in Canada. No additional charges were recorded as a result of this agreement.



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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.

### **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 attain 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 \$4.44 to \$4.59, excluding potential restructuring charges primarily related to severance and other related costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce.

We also have revised certain other elements of our full-year 2010 financial guidance. We still expect volume-driven revenue growth in the mid-single digits, driven primarily by Alimta, Cymbalta, Humalog, Cialis and Effient. We now anticipate that gross margin as a percent of revenue will be flat to increasing. Marketing, selling, and administrative expenses are now 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 still expected to be a net expense of between \$50.0 million and \$100.0 million. Cash flows are still expected to be sufficient to fund capital expenditures now estimated at less than \$900 million, as well as anticipated business development activity, and our dividend.

We caution investors that any forward-looking statements or projections made by us, including those above, are based on management's belief at the time they are made. However, they are subject to risks and uncertainties. Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the implementation of U.S. health care reform; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired IPR&D charges; foreign exchange rates and global macroeconomic conditions; changes in effective tax rates; wholesaler inventory changes; other regulatory developments, litigation, patent disputes, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2009 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

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### **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>.

#### ***Item 4. Controls and Procedures***

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

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

(b) *Changes in Internal Controls.* During the second 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, Strattera, and Xigris

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) and vaccines containing the preservative thimerosal. In the DES litigation, we have been named as a defendant in approximately 40 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

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have been named as a defendant in approximately 200 suits involving approximately 270 claimants. In addition, we have been named a defendant in approximately 60 lawsuits involving approximately 285 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 30 additional claimants who have not yet filed suit.

*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 may seek a 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*

In 2007, the company received two demands from shareholders that the board of directors cause the company to take legal action against current and former directors and others for allegedly causing damage to the company through improper marketing of Evista, Prozac, and Zyprexa. In accordance with procedures established under the Indiana Business Corporation Law (Ind. Code § 23-1-32), the board appointed a committee of independent persons to consider the demands and determine what action, if any, the company should take in response. 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; *Staehr, 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. Two of these lawsuits were filed by the shareholders who served the demands described above. 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. The *Zemprelli* suit also claims that certain defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

We have reached an agreement with plaintiffs' counsel to settle this litigation subject to final approval by the relevant 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. In light of the proposed settlement, in March 2010, Judge Weinstein dismissed the three derivative actions pending in the Eastern District of New York (*Waldman, Robbins, and Taylor*). In July 2010, the U.S. District Court approved the settlement and proposed fees in the *Lambrecht* and *Zemprelli* cases. No additional charges were recorded as a result of this settlement. The settlement and fee award are also pending in the Marion County Superior Court in the *Staehr* and *Solomon* cases.

*Other Matters*

Merck KGaA (Merck) is disputing royalties under a development and license agreement between Merck and ImClone with respect to sales of Erbitux outside the U.S. and Canada. In February 2010, this matter was heard by a panel of arbitrators and in June 2010, the panel issued an interim award, the contents of which are confidential. This interim award makes minor adjustments to Merck's obligation to reimburse ImClone for third-party royalties and will not have a material effect on our results of operations.

During 2004 we, along with several other pharmaceutical companies, were named in a consolidated lawsuit in California state court brought on behalf of consumers alleging that the conduct of pharmaceutical companies in preventing commercial importation of prescription drugs from outside the United States violated antitrust laws. The case sought restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative

conduct. Summary judgment was granted to us and the other defendants. In July 2008, the California Court of Appeals affirmed that decision. In July 2010, the California Supreme Court overturned the lower court decision and remanded the case to the state court.

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; Cautionary Statement Regarding Forward Looking Statements*

*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 June 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)
April 2010		\$		\$ 419.2
May 2010	10	34.89		419.2
June 2010	1	32.58		419.2
Total	11			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of June 30, 2010, we have purchased \$2.58 billion related to this program. During the first six 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 11.	Statement re: Computation of Earnings per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer
	Section 1350 Certification

EXHIBIT  
32.

EXHIBIT      Interactive Data File  
101.

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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: July 30, 2010

s/ James B. Lootens

James B. Lootens  
Corporate Secretary

Date: July 30, 2010

s/ Arnold C. Hanish

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

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INDEX TO EXHIBITS

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EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data File