

LILLY ELI & CO  
Form 10-Q  
May 01, 2009

**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**Form 10-Q**  
**Quarterly Report Under Section 13 or 15(d) of the**  
**Securities Exchange Act of 1934**  
**FOR THE QUARTER ENDED MARCH 31, 2009**  
**COMMISSION FILE NUMBER 001-6351**  
**ELI LILLY AND COMPANY**  
(Exact name of Registrant as specified in its charter)

INDIANA  
(State or other jurisdiction of  
incorporation or organization)

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

LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285  
(Address of principal executive offices)

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

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

Yes  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 "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

Yes  No

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

Yes  No

The number of shares of common stock outstanding as of April 20, 2009:

Class	Number of Shares Outstanding
Common	1,149,015,506

PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## CONSOLIDATED CONDENSED STATEMENTS OF INCOME

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended March 31,	
	2009	2008
	(Dollars in millions, except per-share data)	
Net product sales	\$4,891.8	\$4,709.4
Collaboration and other revenue (Note 4)	155.2	98.2
Total revenue	5,047.0	4,807.6
Cost of sales	816.4	1,111.3
Research and development	947.3	877.1
Marketing, selling, and administrative	1,529.2	1,550.5
Acquired in-process research and development (Note 3)		87.0
Asset impairments, restructuring, and other special charges (Note 5)		145.7
Other net, expense (income) (Note 13)	70.7	(20.3)
	3,363.6	3,751.3
Income before income taxes	1,683.4	1,056.3
Income taxes (Note 10)	370.3	(8.0)
Net income	\$1,313.1	\$1,064.3
Earnings per share basic and diluted (Note 9)	\$ 1.20	\$ .97
Dividends paid per share	\$ .49	\$ .47

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS  
Eli Lilly and Company and Subsidiaries

	March 31, 2009	December 31, 2008
	(Dollars in millions)	
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,313.1	\$ 5,496.7
Short-term investments (Note 6)	195.2	429.4
Accounts receivable, net of allowances of \$99.1 (2009) and \$97.4 (2008)	2,676.4	2,778.8
Other receivables	483.5	498.5
Inventories	2,549.0	2,493.2
Deferred income taxes	391.2	382.1
Prepaid expenses	652.0	374.6
<b>TOTAL CURRENT ASSETS</b>	<b>10,260.4</b>	<b>12,453.3</b>
<b>OTHER ASSETS</b>		
Investments (Note 6)	1,363.8	1,544.6
Goodwill and other intangibles net (Note 3)	3,857.9	3,929.1
Sundry	2,664.5	2,659.3
	7,886.2	8,133.0
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	14,943.0	15,315.9
Less allowances for depreciation	(6,492.8)	(6,689.6)
	8,450.2	8,626.3
	\$26,596.8	\$ 29,212.6
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 1,602.8	\$ 5,846.3
Accounts payable	1,022.7	885.8
Employee compensation	472.4	771.0
Sales rebates and discounts	889.7	873.4
Dividends payable		536.8
Income taxes payable	709.6	229.2
Other current liabilities	2,660.5	3,967.2
<b>TOTAL CURRENT LIABILITIES</b>	<b>7,357.7</b>	<b>13,109.7</b>
Long-term debt	6,870.8	4,615.7
Accrued retirement benefit (Note 11)	2,308.9	2,387.6

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

Long-term income taxes payable (Note 10)	942.8	906.2
Deferred income taxes	72.1	74.7
Other noncurrent liabilities	1,319.7	1,381.0
	11,514.3	9,365.2
SHAREHOLDERS' EQUITY (Notes 7 and 8)		
Common stock	718.7	711.1
Additional paid-in capital	4,360.5	3,976.6
Retained earnings	8,967.9	7,654.9
Employee benefit trust	(3,013.2)	(2,635.0)
Deferred costs-ESOP	(84.1)	(86.3)
Accumulated other comprehensive loss	(3,130.3)	(2,786.8)
Noncontrolling interests	3.8	2.4
	7,823.3	6,836.9
Less cost of common stock in treasury	98.5	99.2
	7,724.8	6,737.7
	\$26,596.8	\$ 29,212.6

See Notes to Consolidated Condensed Financial Statements.

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

	Three Months Ended March 31,	
	2009	2008
	(Dollars in millions)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 1,313.1	\$ 1,064.3
Adjustments to reconcile net income to cash flows from operating activities:		
Payments related to the Eastern District of Pennsylvania settlement (Note 12)	(1,063.1)	
Other changes in operating assets and liabilities, net of acquisitions	(672.0)	70.2
Depreciation and amortization	306.3	277.5
Change in deferred taxes	129.1	111.9
Stock-based compensation expense	66.1	58.5
Acquired in-process research and development, net of tax		56.6
Other, net	8.4	63.6
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>87.9</b>	<b>1,702.6</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net purchases of property and equipment	(157.0)	(184.2)
Net change in short-term investments	286.2	(715.7)
Purchases of noncurrent investments	(67.7)	(41.5)
Proceeds from sales and maturities of noncurrent investments	184.8	36.0
Purchase of in-process research and development		(87.0)
Other, net	(19.0)	(41.6)
<b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>	<b>227.3</b>	<b>(1,034.0)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(536.8)	(513.6)
Net change in short-term borrowings	(4,243.6)	(342.5)
Proceeds from issuance of long-term debt	2,400.0	0.1
Other, net		(5.9)
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(2,380.4)</b>	<b>(861.9)</b>
Effect of exchange rate changes on cash and cash equivalents	(118.4)	118.2
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(2,183.6)</b>	<b>(75.1)</b>
Cash and cash equivalents at January 1	5,496.7	3,220.5

CASH AND CASH EQUIVALENTS AT MARCH 31	\$ 3,313.1	\$ 3,145.4
---------------------------------------	------------	------------

See Notes to Consolidated Condensed Financial Statements.

4

---

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

	Three Months Ended March 31,	
	2009	2008
	(Dollars in millions)	
Net income	\$1,313.1	\$1,064.3
Other comprehensive income (loss), net of tax <sup>1</sup>	(343.5)	193.8
Comprehensive income	\$ 969.6	\$1,258.1

<sup>1</sup> The significant component of other comprehensive income (loss) was a loss of \$403.7 million from foreign currency translation adjustments for the three months ended March 31, 2009, compared with a gain of \$259.9 million from foreign currency translation adjustments for the three months ended March 31, 2008.

See Notes to Consolidated Condensed Financial Statements.

## SEGMENT INFORMATION

We operate in one significant business segment — human pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as human pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the first quarters of 2009 and 2008 was \$35.7 million and \$26.9 million, respectively.

## REVENUE BY CATEGORY

Worldwide revenue by category was as follows:

	Three Months Ended March 31,	
	2009	2008
	(Dollars in millions)	
Net product sales to unaffiliated customers:		
Neurosciences	\$2,077.6	\$1,971.4
Endocrinology	1,326.2	1,316.0
Oncology	729.2	673.3
Cardiovascular	455.1	462.0
Animal health	264.1	235.3
Other pharmaceuticals	39.6	51.4
Net product sales	\$4,891.8	\$4,709.4
Collaboration and other revenue	155.2	98.2
Total revenue	\$5,047.0	\$4,807.6



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, 2008. Certain reclassifications have been made to the December 31, 2008 consolidated condensed financial statements to conform with the March 31, 2009 presentation.

Note 2: Implementation of New Financial Accounting Pronouncements

Financial Accounting Standards Board (FASB) Statement No. 141, Business Combinations (SFAS 141(R)), is effective for us for business combinations for which the acquisition date is on or after January 1, 2009. SFAS 141(R) changes how the acquisition method is applied in accordance with SFAS 141. The primary revisions to this Statement require an acquirer in a business combination to measure assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, at their fair values as of that date, with limited exceptions specified in the Statement. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values (or other amounts determined in accordance with the Statement). Assets acquired and liabilities assumed arising from contractual contingencies as of the acquisition date are to be measured at their acquisition-date fair values, and assets or liabilities arising from all other contingencies as of the acquisition date are to be measured at their acquisition-date fair value, only if it is more likely than not that they meet the definition of an asset or a liability in FASB Concepts Statement No. 6, Elements of Financial Statements. This Statement significantly amends other Statements and authoritative guidance, including FASB Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, and now requires the capitalization of research and development assets acquired in a business combination at their acquisition-date fair values, separately from goodwill. FASB Statement No. 109, Accounting for Income Taxes, was also amended by this Statement to require the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances.

We adopted the provisions of FASB Statement No. 160, Accounting for Noncontrolling Interests (SFAS 160), on January 1, 2009. This Statement amends Accounting Research Bulletin No. 51, Consolidated Financial Statements (ARB 51), by requiring companies to report a noncontrolling interest in a subsidiary as equity in its consolidated financial statements. Disclosure of the amounts of consolidated net income attributable to the parent and the noncontrolling interest will be required. This Statement also clarifies that transactions that result in a change in a parent's ownership interest in a subsidiary that do not result in deconsolidation will be treated as equity transactions, while a gain or loss will be recognized by the parent when a subsidiary is deconsolidated. We now classify our noncontrolling interest in a subsidiary as equity in our consolidated condensed statements of financial position at March 31, 2009 and retroactively

reclassified the December 31, 2008 balances accordingly. The net income attributed to the noncontrolling interest in a subsidiary for the first quarters of 2009 and 2008 is not material and has not been separately disclosed in the consolidated condensed statements of income.

We adopted the provisions of FASB Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161), on January 1, 2009. SFAS 161 applies to all derivative instruments and related hedged items accounted for under FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133). This Statement requires entities to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. These disclosures are included in Note 6.

We adopted the provisions of Emerging Issues Task Force (EITF) Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1), on January 1, 2009. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This Issue has been applied retrospectively to all prior periods presented for all significant collaborative arrangements existing as of the effective date by classifying revenues into two separate components: net product sales and collaboration and other revenue. See Note 4 for additional information.

We adopted the provisions of FASB Staff Position 115-2, Recognition and Presentation of Other-Than-Temporary Impairments (FSP 115-2), on January 1, 2009. FSP 115-2 amends the other-than-temporary recognition guidance for debt securities and requires additional interim and annual disclosures of other-than-temporary impairments on debt and equity securities. Pursuant to the new guidance, an other-than-temporary impairment has occurred if a company does not expect to recover the entire amortized cost basis of the security. In this situation, if the company does not intend to sell the impaired security, and it is not more likely than not it will be required to sell the security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings is limited to the portion attributed to the credit loss. The remaining portion of the other-than-temporary impairment is then recorded in other comprehensive income. This FSP has been applied to existing and new securities as of January 1, 2009. The applicable disclosures are included in Note 6. The implementation of this FSP was not material to our consolidated financial position or results of operations and there was no cumulative effect adjustment.

We adopted the provisions of FASB Staff Position 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly (FSP 157-4), as of March 31, 2009. FSP 157-4 provides additional guidance on estimating fair value when the volume and level of activity for an asset or liability have significantly decreased in relation to normal market activity. The FSP also provides additional guidance on circumstances that may indicate that a transaction is not orderly and requires additional disclosures. The implementation of this FSP was not material to our consolidated financial position or results of operations.

We adopted the provisions of FASB Staff Position 107-1, Disclosures About Fair Value of Financial Instruments (FSP 107-1), as of March 31, 2009. FSP 107-1 requires disclosures about fair value of all financial instruments for interim reporting periods. The applicable disclosures are included in Note 6. The implementation of this FSP was not material to our consolidated financial position or results of operations.

#### Note 3: Acquisitions

During 2008 we acquired several businesses. These acquisitions were accounted for as business combinations under the purchase method of accounting. Under the purchase method of accounting, the assets acquired and liabilities assumed were recorded at their respective fair

values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions are included in our consolidated financial statements from the date of acquisition.

Most of these acquisitions included in-process research and development (IPR&D), which represented compounds, new indications, or line extensions under development that had not yet achieved regulatory approval for marketing. There are several methods that can be used to determine the estimated fair value of the IPR&D acquired in a business combination. We utilized the income method, which applies a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. In accordance with FASB Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, these acquired IPR&D intangible assets totaling \$4.71 billion in 2008 were expensed immediately subsequent to the acquisition because the products had no alternative future use. None of these charges were incurred during the first quarter of 2008. The ongoing activities with respect to each of these products in development are not material to our research and development expenses.

In addition to the acquisitions of businesses, we also acquired several products in development. The acquired IPR&D related to these products of \$122.0 million in 2008, including \$87.0 million in the first quarter of 2008, was also written off by a charge to income immediately upon acquisition because the products had no alternative future use.

#### *ImClone Acquisition*

On November 24, 2008, we acquired all of the outstanding shares of ImClone Systems Inc. (ImClone), a biopharmaceutical company focused on advancing oncology care, for a total purchase price of approximately \$6.5 billion, which was financed through borrowings. This strategic combination will offer both targeted therapies and oncolytic agents along with a pipeline spanning all phases of clinical development. The combination also expands our biotechnology capabilities.

The acquisition has been accounted for as a business combination under the purchase method of accounting, resulting in goodwill of \$419.5 million. No portion of this goodwill is expected to be deductible for tax purposes.

#### *Allocation of Purchase Price*

We are currently determining the fair values of a few of these net assets. The purchase price has been preliminarily allocated based on an estimate of the fair value of assets acquired and liabilities assumed as of the date of acquisition. The final determination of these fair values will be completed as soon as possible but no later than one year from the acquisition date. Although the final determination may result in asset and liability fair values that are different than the preliminary estimates of these amounts included herein, it is not expected that those differences will be material to our consolidated financial results.

	Estimated Fair Value at November 24, 2008
Cash and short-term investments	\$ 982.9
Inventories	136.2
Developed product technology (Erbitux®) <sup>1</sup>	1,057.9
Goodwill	419.5
Property and equipment	339.8
Debt assumed	(600.0)
Deferred taxes	(315.0)
Deferred income	(127.7)
Other assets and liabilities net	(72.1)
Acquired in-process research and development	4,685.4
 Total purchase price	 \$ 6,506.9

<sup>1</sup> This intangible asset will be amortized on a straight-line basis through 2023 in the U.S. and 2018 in the rest of the world.

All of the estimated fair value of the acquired IPR&D is attributable to oncology-related products in development, including \$1.33 billion to line extensions for Erbitux. A significant portion (81 percent) of the remaining value of acquired IPR&D is attributable to one compound in Phase III clinical testing and two compounds in Phase II clinical testing, all targeted to treat various forms of cancers. The discount rate we used in valuing the acquired IPR&D projects was 13.5 percent, and the charge for acquired IPR&D of \$4.69 billion recorded in the fourth quarter of 2008 was not deductible for tax purposes.

#### Posilac®

On October 1, 2008, we acquired the worldwide rights to the dairy cow supplement Posilac, as well as the product's supporting operations, from Monsanto Company (Monsanto). The acquisition of Posilac provides us with a product that complements those of our animal health business. Under the terms of the agreement, we acquired the rights to the Posilac brand, as well as the product's U.S. sales force and manufacturing facility, for an aggregate purchase price of \$403.9 million, which includes a \$300.0 million upfront payment, transaction costs, and an accrual for contingent consideration to Monsanto based on estimated future Posilac sales for which payment is considered likely beyond a reasonable doubt.

This acquisition has been accounted for as a business combination under the purchase method of accounting. We allocated \$204.3 million to identifiable intangible assets related to Posilac, \$167.6 million to inventories, and \$99.5 million of the purchase price to property and equipment. We also assumed \$67.5 million of liabilities. Substantially all of the identifiable intangible assets are being amortized over their estimated remaining useful lives of 20 years. The amount allocated to each of the intangible assets acquired is deductible for tax purposes.

SGX Pharmaceuticals, Inc.

On August 20, 2008, we acquired all of the outstanding common stock of SGX Pharmaceuticals, Inc. (SGX), a collaboration partner since 2003. The acquisition allows us to integrate SGX's structure-guided drug discovery platform into our drug discovery efforts. It also gives us access to FAST™, SGX's fragment-based, protein structure guided drug discovery technology, and to a portfolio of preclinical oncology compounds focused on a number of kinase targets. Under the terms of the agreement, the outstanding shares of SGX common stock were redeemed for an aggregate purchase price of \$66.8 million.

The acquisition has been accounted for as a business combination under the purchase method of accounting. We allocated \$29.6 million of the purchase price to deferred tax assets and \$28.0

million to acquired IPR&D. The acquired IPR&D charge of \$28.0 million was recorded in the third quarter of 2008 and was not deductible for tax purposes.

#### Acquisitions of Products in Development

In June 2008, we entered into a licensing and development agreement with TransPharma Medical Ltd. (TransPharma) to acquire rights to its product and related drug delivery system for the treatment of osteoporosis. The product, which is administered transdermally using TransPharma's proprietary technology, was in Phase II clinical testing, and had no alternative future use. Under the arrangement, we also gained non-exclusive access to TransPharma's ViaDerm drug delivery system for the product. As with many development-phase products, launch of the product, if approved, was not expected in the near term. The charge of \$35.0 million for acquired IPR&D related to this arrangement was included as expense in the second quarter of 2008 and was deductible for tax purposes.

In January 2008, our agreement with BioMS Medical Corp. to acquire the rights to its compound for the treatment of multiple sclerosis became effective. At the inception of this agreement, this compound was in the development stage (Phase III clinical trials) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of \$87.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2008 and was deductible for tax purposes.

In connection with these arrangements, our partners are generally entitled to future milestones and royalties based on sales should these products be 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.

#### Erbitux

Prior to our acquisition, 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 of the rights with respect to Erbitux in the U.S. and Canada return to us. In the first quarter of 2009, we recognized total revenue of \$94.1 million for Erbitux, comprised of collaboration revenue of \$68.0 million related to the net royalties received from our collaboration partners, and product sales of \$26.1 million related to revenue from manufactured product.

#### *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

had 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 as determined pursuant to 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 income. 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 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 income. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.

*Exenatide*

We are in a collaborative arrangement with Amylin Pharmaceuticals (Amylin) for the joint development, marketing, and selling of Byetta® and other forms of exenatide such as exenatide once weekly. Byetta (exenatide injection) 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 and/or a thiazolidinedione (U.S. only), three common oral therapies for type 2 diabetes. 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. We recorded revenue of \$97.5 million and \$82.7 million in the quarters ended March 31, 2009 and 2008, respectively, for Byetta. 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 report 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 income.

Exenatide once weekly is presently in Phase III clinical trials and has not received regulatory approval. 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 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 beginning December 1, 2009; any borrowings have to be repaid by June 30, 2014.

Cymbalta®

*Boehringer Ingelheim*

We are in a collaborative arrangement with Boehringer Ingelheim (BI) to jointly market and promote Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, outside the U.S. Pursuant to the terms of the agreement, we generally share equally in development, marketing, and selling expenses, and pay 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 are recorded in the respective expense line items in the consolidated condensed statements of income. The commission paid to BI is recognized in marketing, selling, and administrative expenses.

*Quintiles*

We are in a collaborative arrangement with Quintiles Transnational Corp. (Quintiles) to jointly market and promote Cymbalta in the U.S. Pursuant to the terms of the agreement, Quintiles shares in the costs to co-promote Cymbalta with us. In exchange, Quintiles receives a commission based upon net product sales. According to the agreement, Quintiles' obligation to promote Cymbalta expires in 2009, and we will pay a lower rate on net product sales for three years after their promotion efforts. The commissions paid to Quintiles are recorded in marketing, selling, and administrative expenses.

Prasugrel

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote prasugrel, an antiplatelet agent for the treatment of patients with acute coronary syndromes (ACS) who are being managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). Prasugrel was approved for marketing by the European Commission under the tradename Efient® in February 2009, and the initial sales were recorded in the first quarter of 2009. We have submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and are currently awaiting its decision. Within this arrangement, we 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 agreed to pay future success milestones. Both parties share in the costs of the development and marketing in the co-promotion territories. D-S is responsible for supplying bulk product, but we will produce the finished product for our exclusive and co-promotion territories. Profits in the U.S. and other co-promotion territories will be shared according to the agreement. In our exclusive territories, we will pay D-S a royalty specific to those territories. Profit share payments made to D-S are recorded as marketing, selling, and administrative expenses. All royalties paid to D-S will be recorded in cost of sales.



#### TPG-Axon Capital

In 2008, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of our gamma-secretase inhibitor and our A-beta antibody, 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 million and could extend into 2014. In exchange for their funding, TPG may receive success-based milestones totaling \$330 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 income. The reimbursement from TPG is not expected to be material in any period.

#### Summary of Collaboration Related Commissions and Profit Share Payments

The aggregate amount of commissions and profit share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$77.6 million and \$66.6 million in the quarters ended March 31, 2009 and 2008, respectively.

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

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

In March 2008, we terminated development of our AIR<sup>®</sup> Insulin program, which was being conducted in collaboration with Alkermes, Inc. The program had been in Phase III clinical development as a potential treatment for type 1 and type 2 diabetes. This decision was not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies. As a result of this decision, we halted our ongoing clinical studies and transitioned the AIR Insulin patients in these studies to other appropriate therapies. We implemented a patient program in the U.S., and other regions of the world where allowed, to provide clinical trial participants with appropriate financial support to fund their medications and diagnostic supplies through the end of 2008.

We recognized asset impairment, restructuring, and other special charges of \$145.7 million in the first quarter of 2008. These charges were primarily related to the decision to terminate development of AIR Insulin. Components of these charges included non-cash charges of \$40.9 million for the write down of impaired manufacturing assets that had no use beyond the AIR Insulin program, as well as charges of \$91.7 million for estimated contractual obligations and wind-down costs associated with the termination of clinical trials and certain development activities, and costs associated with the patient program to transition participants from AIR Insulin. This amount included an estimate of Alkermes' wind-down costs for which we were contractually obligated. The wind-down activities and patient programs were substantially complete by the end of 2008. The remaining component of these charges, \$13.1 million, is related to exit costs incurred in the first quarter of 2008 in connection with previously announced strategic decisions made in prior periods.

#### Note 6: Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit review procedures and insurance. Major financial institutions represent the largest component of our investments in corporate debt securities. In accordance with documented corporate policies, we limit the

amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

#### Accounting Policy for Risk-Management Instruments

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

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of 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.

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 March 31, 2009, we did not hold any foreign currency option contracts. At March 31, 2009, we had outstanding foreign currency forward commitments to purchase 244 million British pounds and sell 264 million euro, and commitments to purchase 758 million U.S. dollars and sell 581 million euro, which will settle within 30 days.

In the normal course of business, our operations are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance. Interest rate swaps or collars that convert our fixed-rate debt or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. At March 31, 2009, approximately 78 percent of our total debt is at a fixed rate. We have converted approximately 34 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

#### The Effect of Risk-Management Instruments on the Statement of Income

The loss on the hedged fixed-rate debt and the offsetting gain on the related interest rate swaps for the three months ended March 31, 2009 were \$139.6 million and both were included in other-net, expense (income).

We expect to reclassify an estimated \$11.0 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on floating rate debt from accumulated other comprehensive loss to earnings during the next 12 months.

For the three months ended March 31, 2009, the effective portion of losses on interest rate contracts in designated cash flow hedging relationships reclassified from accumulated other comprehensive loss into income of \$2.5 million and the gains on foreign exchange contracts not designated as hedging instruments recognized in income of \$36.6 million are reflected in other-net, expense (income). The effective portion of net gains on interest rate contracts in designated cash flow hedging relationships recorded in other comprehensive loss for the three months ended March 31, 2009 was \$37.8 million.

During the three months ended March 31, 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.

#### Fair Value of Financial Instruments

The following tables summarize certain fair value information at March 31, 2009 and December 31, 2008 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

Description	Carrying Amount	Amortized Cost	Fair Value Measurements Using			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>March 31, 2009</b>						
Short-term investments						
Corporate debt securities	\$ 106.8	\$ 112.8	\$	\$ 106.8	\$	\$ 106.8
U.S. government and agencies	55.4	55.3	55.4			55.4
Other securities	33.0	32.7		33.0		33.0
	\$ 195.2	\$ 200.8				
Noncurrent investments						
Corporate debt securities	\$ 461.9	\$ 535.7	\$	\$ 461.9	\$	\$ 461.9
Mortgage-backed	262.5	374.1		262.5		262.5
Asset-backed	166.6	202.2		166.6		166.6
U.S. government and agencies	90.7	87.8	90.7			90.7
Other debt securities	9.0	11.3		3.3	5.7	9.0
Marketable equity	240.2	180.8	240.2			240.2
Equity method and other investments	132.9	132.9				NA
	\$ 1,363.8	\$1,524.8				
Long-term debt, including current portion	\$(7,290.2)	NA	\$	\$(7,433.7)	\$	\$(7,433.7)
Risk-management instruments						
Interest rate contracts designated as hedging instruments						
Sundry	\$ 358.7	NA	\$	\$ 358.7	\$	\$ 358.7
Foreign exchange contracts not designated as hedging instruments						
Prepaid expenses	5.1	NA		5.1		5.1
Other current liabilities	(13.8)	NA		(13.8)		(13.8)

**December 31, 2008**

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

Short-term investments

Corporate debt securities	\$ 172.4	\$ 180.1	\$	\$ 172.4	\$	\$ 172.4
U.S. government and agencies	212.3	212.0	212.3			212.3
Other securities	44.7	41.8		44.7		44.7
	\$ 429.4	\$ 433.9				

Noncurrent investments

Corporate debt securities	\$ 466.4	\$ 542.2	\$	\$ 466.4	\$	\$ 466.4
---------------------------	----------	----------	----	----------	----	----------

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

Description	Carrying Amount	Amortized Cost	Fair Value Measurements Using			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Mortgage-backed Asset-backed	330.6	436.6		330.6		330.6
U.S. government and agencies	204.0	240.1		204.0		204.0
Other debt securities	179.2	176.8	179.2			179.2
Marketable equity	14.7	10.6		3.6	11.1	14.7
Equity methods and other investments	221.9	175.1	221.9			221.9
	127.8	127.8				NA
	\$ 1,544.6	\$ 1,709.2				
Long-term debt, including current portion	\$ (5,036.1)	NA	\$	\$ (5,180.1)	\$	\$ (5,180.1)
Risk-management instruments						
Interest rate contracts designated as hedging instruments						
Sundry	\$ 500.3	NA	\$	\$ 500.3	\$	\$ 500.3
Foreign exchange contracts not designated as hedging instruments						
Prepaid expenses	12.0	NA		12.0		12.0
Other current liabilities	(57.3)	NA		(57.3)		(57.3)

NA Not applicable

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.

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 loss follows:

	March 31, 2009	December 31, 2008
Unrealized gross gains	\$ 71.4	\$ 69.9
Unrealized gross losses	238.0	239.0
Fair value of securities in an unrealized gain position	579.5	767.5
Fair value of securities in an unrealized loss position	830.9	1,046.1

The total other-than-temporary impairment loss for the three months ended March 31, 2009 was \$17.9 million, of which \$12.6 million was recognized in other comprehensive loss resulting in a net charge of \$5.3 million, which relates 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 comprised 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. Approximately 80 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 March 31, 2009. The fair values of our auction rate securities and collateralized debt obligations were determined using Level 3 inputs. We did not hold securities issued by structured investment vehicles at March 31, 2009.

In March 2009, we issued \$2.40 billion of fixed-rate notes (\$1.00 billion at 3.55 percent due in 2012; \$1.00 billion at 4.20 percent due in 2014; and \$400.0 million at 5.95 percent due in 2037) with interest to be paid semi-annually.

#### Note 7: Stock-Based Compensation

In 2009 and 2008, our stock-based compensation expense consists primarily of performance awards (PAs) and shareholder value awards (SVAs). We recognized pretax stock-based compensation cost of \$66.1 million and \$58.5 million in the first quarter of 2009 and 2008, 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 one-year and a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of March 31, 2009, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$211.8 million, which will be amortized over the weighted-average remaining requisite service period of approximately 14 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of March 31, 2009, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$81.6 million, which will be amortized over the weighted-average remaining requisite service period of approximately 27 months.

#### Note 8: Shareholders' Equity

As of March 31, 2009, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first quarter of 2009, we did not acquire any shares pursuant to this program, nor do we expect any share repurchases under this program for the remainder of 2009. In the first quarter of 2009, we contributed an additional 10 million shares to the employee benefit trust, which resulted in a reclassification within equity from additional-paid-in capital of \$371.9 million and common stock of \$6.3 million to the employee benefit trust of \$378.2 million.

#### 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 United States (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 2002. During the first quarter of 2008, we completed and effectively settled our Internal Revenue Service (IRS) audit of tax years 2001-2004 except for one matter for which we will seek resolution through the IRS administrative appeals process. As a result of the IRS audit conclusion, gross unrecognized tax benefits were reduced by approximately \$618 million, and the consolidated results of operations were benefited by \$210.3 million through a reduction in income tax expense. The majority of the reduction in gross unrecognized tax benefits related to intercompany pricing positions that were agreed with the IRS in a prior audit cycle for which a prepayment of tax was made in 2005. Application of the prepayment and utilization of tax carryovers resulted in a refund of approximately \$50 million. The IRS began its examination of tax years 2005-2007 during the third quarter of 2008. We do not believe it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within the next 12 months.

#### Note 11: Retirement Benefits

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

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2009	2008	2009	2008
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 60.7	\$ 64.3	\$ 16.3	\$ 14.4
Interest cost	103.4	102.9	28.7	26.5
Expected return on plan assets	(142.3)	(151.5)	(29.5)	(29.4)
Amortization of prior service cost	1.8	1.8	(9.0)	(9.0)
Recognized actuarial loss	21.6	19.2	17.2	16.5
Net periodic benefit cost	\$ 45.2	\$ 36.7	\$ 23.7	\$ 19.0

As of March 31, 2009, approximately \$50 million of the total expected 2009 contributions of approximately \$70 million has been made to our defined benefit pension plans. We expect to make contributions during the remainder of 2009 of approximately \$15 million to satisfy minimum funding requirements and approximately \$5 million of additional discretionary funding to our defined benefit pension plans.

#### 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 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 eight allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the eight 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. Lawsuits have been filed in U.S. District Court for the Southern District of Indiana against Activis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; Sun Pharma Global, Inc.; and Wockhardt Limited, seeking rulings that the patents are valid, infringed, and enforceable. The cases have been consolidated and are proceeding.

Gemzar®: Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted an ANDA 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. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006 and January 2008), seeking rulings that these patents are valid and are being infringed. The suit against Sicor has been scheduled for trial in September 2009. Sicor's ANDAs have been approved by the FDA; however, Sicor must provide 90 days notice prior to marketing generic Gemzar to allow time for us to seek a preliminary injunction. Both suits against Mayne have been administratively closed, and the parties have agreed to be bound by the results of the Sicor suit. In November 2007, Sun filed a declaratory judgment action in the United States 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. This trial is scheduled for December 2009.

Alimta®: Teva Parenteral Medicines, Inc. (Teva), APP Pharmaceuticals, LLC (APP), and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. 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®: Barr submitted an ANDA in 2002 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 November 2002, we filed a lawsuit against Barr 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 Barr. The lawsuit against Barr was administratively closed and, as a result, no trial date has been set.

In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a lawsuit, similar to the Barr lawsuit, against Teva in the U.S. District Court for the Southern District of Indiana. The trial against Teva was completed in March 2009. In April 2008, the FDA granted Teva tentative approval of its ANDA; however, Teva's ability to market a generic product is subject to a preliminary injunction that prevents Teva from launching its generic raloxifene product until the Court issues a final judgment. Teva has announced its intent to appeal the preliminary injunction.

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 compound and method-of-use 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. We sued Novopharm for patent infringement, and the trial was completed in April 2009. We anticipate a decision in the second half of 2009. In November 2007, Apotex filed an action seeking a declaration of the invalidity of our Zyprexa compound and method-of-use patents, and no trial date has been set. We are involved in similar actions against Pharmascience (August 2007), Sandoz (July 2007), Nu-Pharm (June 2008), Genpharm (June 2008) and Cobalt (January 2009). By agreement between the parties, or due to scheduling by the court, no substantive developments are expected in these suits prior to the decision in the Novopharm suit.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolab Ltd. challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007. We appealed the decision to the German Federal Supreme Court and following a hearing in December 2008, the Supreme Court reversed the Federal Patent Court and found the patent to be valid. Following the decision of the Supreme Court, the generic companies either agreed to withdraw from the market or were subject to preliminary injunction. We are pursuing these companies for damages arising from infringement.

We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), France, 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 further legal challenge is now pending before the Commercial Court in Madrid. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited has challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In October 2008, the Patents Court in the High Court, London ruled that our patent was valid. Dr. Reddy's appealed this decision, and a hearing date for the appeal has been set for November 2009.

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. While Ariad may request the Court of Appeals to reconsider its decision, or the United States Supreme Court to consider the matter, we believe that these allegations are without legal merit, that we

will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

#### Government Investigations and Related Litigation

In March 2004, the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA) advised us that it had commenced an investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac®, and Prozac Weekly. In addition, the State Medicaid Fraud Control Units of more than 30 states coordinated with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In January 2009, we announced that we reached resolution of this matter, and on January 30, 2009, the court approved the settlement. 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. In connection with the federal criminal and civil settlements, in the first quarter of 2009, we paid \$1.06 billion. We also agreed to make available a maximum amount of approximately \$362.0 million for payment to those states that agree to settle. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. 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 September 2006, we received a subpoena from the California Attorney General's Office seeking production of documents related to our efforts to obtain and maintain Zyprexa's status on California's formulary, marketing and promotional practices with respect to Zyprexa, and remuneration of health care providers. We expect this matter to be resolved if California participates in the state component of the EDPA resolution.

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.

#### Product Liability and Related 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 (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 120 lawsuits in the U.S. covering approximately 140 plaintiffs, of which about 90 cases covering about 100 plaintiffs are part of the MDL. No trials have been scheduled related to these claims.

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 has been certified for residents of Quebec, and a second has been certified in Ontario and includes all Canadian residents except for residents of Quebec and British Columbia. The allegations in the Canadian actions are similar to those in the litigation pending in the U.S.

Since the beginning of 2005, we have recorded aggregate net pretax charges of \$1.61 billion for Zyprexa product liability matters. The net charges, which take into account our actual insurance recoveries, covered the following:

The cost of the Zyprexa product liability settlements to date; and

Reserves for product liability exposures and defense costs regarding the known Zyprexa product liability claims and expected future claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York (EDNY). In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. We have been served with similar lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. 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. The following cases have been set for trial: Connecticut in the EDNY in November 2009, and South Carolina in September 2009 and Pennsylvania in April 2010, both in their respective states.

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. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. In 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. 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. The Pennsylvania case is set for trial in June 2009.

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.

In addition, we have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES) and thimerosal. The majority of these claims are covered by insurance, subject to deductibles and coverage limits.

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 few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

#### Environmental Matters

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

Note 13: Other Net, Expense (Income)

Other net, expense (income) comprised the following:

	Three Months Ended March 31,	
	2009	2008
	(Dollars in millions)	
Interest expense	\$ 87.6	\$ 59.8
Interest income	(27.4)	(56.3)
Other	10.5	(23.8)
	\$ 70.7	\$ (20.3)

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

### OPERATING RESULTS

#### Executive Overview

##### I. Financial Results

Our worldwide revenue for the quarter increased 5 percent, to \$5.05 billion, driven primarily by the collective growth of Cymbalta, Alimta, and Humalog, and the inclusion of Erbitux revenue as a result of the ImClone acquisition in November 2008. Net income and earnings per share for the first quarter of 2009 increased to \$1.31 billion and \$1.20, respectively, compared with \$1.06 billion and \$.97, respectively, for the first quarter of 2008. Net income for the first quarter of 2008 was affected by the following significant items:

We recognized a discrete income tax benefit of \$210.3 million as a result of the resolution of a substantial portion of the IRS audit of our federal income tax returns for years 2001 through 2004, which increased earnings per share by \$.19.

We recognized asset impairments, restructuring (exit costs), and other special charges of \$145.7 million (pre-tax), primarily associated with certain impairment, termination, and wind-down costs resulting from the termination of the AIR Insulin program, which decreased earnings per share by \$.09.

We incurred IPR&D charges associated with the licensing arrangement with BioMS Medical Corp. of \$87.0 million (pretax), which decreased earnings per share by \$.05.

## II. Late-Stage Pipeline Developments

The U.S. FDA Cardiovascular and Renal Drugs Advisory Committee voted 9 to 0 that prasugrel, an investigational antiplatelet agent, should be approved for the treatment of patients with acute coronary syndromes (ACS) managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). We are awaiting final FDA action on prasugrel.

The European Commission granted marketing authorization for Efient (prasugrel) for the prevention of atherothrombotic events in patients with ACS undergoing PCI. The product has now been launched in both Germany and the United Kingdom.

The FDA approved a new indication for Symbyax® for the acute treatment of treatment-resistant depression (TRD) in adults.

The FDA approved two new combination indications for Zyprexa (olanzapine) and fluoxetine for the acute treatment of bipolar depression and TRD in adults.

We received a complete response letter from the FDA for the first-line squamous cell carcinoma of the head and neck (SCCHN) supplemental Biologics License Application (sBLA) for Erbitux.

We submitted a reply to the FDA regarding the agency's complete response letter for Zyprexa long-acting injection. We also launched this product under the tradename Zypadhera™ in several countries within the European Union.

## III. Legal, Regulatory, and Other Matters

In March 2004, we were notified by the U.S. Attorney's office for the EDPA that it had commenced an investigation relating to our U.S. marketing and promotional practices for Zyprexa, Prozac, and Prozac Weekly. In October 2008, we announced that we were in advanced discussions to resolve the ongoing investigations led by the EDPA, and we recorded a charge of \$1.42 billion. In January 2009, we announced that the discussions had been successfully concluded, and that we settled the Zyprexa-related federal claims, as well as similar Medicaid-related claims of states which decided to participate in the settlement. In addition, 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, under which we paid \$62.0 million. However, we have been served with lawsuits brought by 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 and seeking 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 to treat Zyprexa-related illnesses. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. The cases in Connecticut and South Carolina have been set for trial in 2009; the trial in Pennsylvania is scheduled for 2010.

In the third quarter of 2008, we initiated a strategic review of our Tippecanoe manufacturing facility in Lafayette, Indiana. Options being considered for this site include continuing operations with a revised site mission, exploring opportunities to sell the facility, and ceasing operations altogether. The review is expected to last up to 12 months. No final decisions



have been made at this time; however, depending on the decision, we could record significant charges. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) continues to provide an effective prescription drug benefit under the Medicare program (known as Medicare Part D). Uncertainty exists surrounding the new administration and Congress and the impact any government decisions or programs will have on the pharmaceutical industry. Various measures have been discussed and/or passed in both the U.S. House of Representatives and U.S. Senate that would impose additional pricing pressures on our products, including proposals to legalize the importation of prescription drugs and either allow, or require, the Secretary of Health and Human Services to negotiate drug prices within Medicare Part D directly with pharmaceutical manufacturers. Additionally, various proposals have been introduced that would increase the rebates we pay on sales to Medicaid patients or impose additional rebates on sales to patients who receive their medicines through Medicare Part D or other government programs. Further, proposals to expand coverage to the uninsured could include some form of price rebates or tax on the pharmaceutical industry. In addition, many U.S. states are facing substantial budget difficulties due to the downturn in the economy and are expected to seek aggressive cuts or other offsets in healthcare spending. We expect pricing pressures at the federal and state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

In its preliminary budget submission to Congress, the new administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. While it is uncertain how the U.S. Congress may address this issue, reform of U.S. taxation of international income continues to be a topic of discussion for the U.S. legislature. A significant change to the U.S. tax system that would change the taxation of international income could have a material adverse effect on our consolidated results of operations.

In addition, the federal government is considering creating a regulatory pathway for biosimilars (copies) for the majority of biologic products in the U.S.; the proposals vary as to which biologic products would be eligible, how quickly a biosimilar might reach the market, and the ability to interchange the biosimilar and the original biologic product at the pharmacy.

International operations also are generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls, limit access to reimbursement for our products, or reduce the value of our intellectual property protection.

#### Revenue

Revenue increased 5 percent, to \$5.05 billion, driven primarily by the increase in net product sales related to the collective growth of Cymbalta, Alimta, and Humalog, and the increase in collaboration and other revenue due to the inclusion of Erbitux revenue as a result of the ImClone acquisition. Revenue in the U.S. increased by \$325.3 million, or 13 percent, for the first quarter of 2009 compared with the first quarter of 2008. Revenue outside the U.S. decreased \$85.9 million, or 4 percent, for the first quarter of 2009 due to the negative impact of foreign exchange rates.

Worldwide volume increased 7 percent, while selling prices contributed 3 percent of sales growth, partially offset by the unfavorable impact of foreign exchange rates of 6 percent (numbers do not add due to rounding).

The following table summarizes our revenue activity for the three months ended March 31, 2009 and 2008:

Product	Three Months Ended March 31, 2009			Three Months Ended March 31, 2008	Percent Change from 2008
	U.S. <sup>1</sup>	U.S. Outside	Total	Total	
	(Dollars in millions)				
Zyprexa	\$ 535.4	\$ 587.6	\$ 1,123.0	\$ 1,120.2	0
Cymbalta	597.1	112.2	709.3	605.1	17
Humalog <sup>®</sup>	286.2	164.4	450.6	407.4	11
Gemzar	169.4	198.4	367.8	426.2	(14)
Cialis <sup>®</sup>	149.1	209.7	358.8	336.9	6
Alimta	172.8	162.5	335.3	247.2	36
Animal health products	153.6	110.5	264.1	235.3	12
Evista	163.8	93.1	256.9	261.1	(2)
Humulin <sup>®</sup>	99.0	141.6	240.6	257.7	(7)
Forteo <sup>®</sup>	121.8	65.7	187.5	185.0	1
Strattera <sup>®</sup>	115.6	43.3	158.9	148.0	7
Other pharmaceutical products	173.0	266.0	439.0	479.3	(8)
Total net product sales	2,736.8	2,155.0	4,891.8	4,709.4	4
Collaboration and other revenue <sup>2</sup>	135.1	20.1	155.2	98.2	58
Total revenue	\$ 2,871.9	\$ 2,175.1	\$ 5,047.0	\$ 4,807.6	5

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

<sup>2</sup> Collaboration and other revenue is primarily comprised 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 first quarter of 2009, Zyprexa sales in the U.S. increased 7 percent compared with the first quarter of 2008, driven by higher prices and the favorable impact of wholesaler buying patterns, partially offset by decreased demand. Sales outside the U.S. decreased 5 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by increased demand. Demand outside the U.S. was favorably

impacted by the withdrawal of generic competition in Germany.

U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, increased 17 percent during the first quarter of 2009, driven by increased demand, higher prices, and the favorable impact of wholesaler buying patterns. Sales outside the U.S. increased 19 percent, driven primarily by increased demand, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 20 percent during the first quarter of 2009, driven by higher prices and increased

demand. Sales outside the U.S. decreased 3 percent during the first quarter driven by the unfavorable impact of foreign exchange rates, partially offset by increased demand.

U.S. sales of Gemzar, a product approved to fight various cancers, decreased 4 percent during the first quarter of 2009, due to the unfavorable impact of wholesaler buying patterns and lower net effective selling prices, partially offset by increased demand. Sales outside the U.S. decreased 21 percent as a result of the unfavorable impact of foreign exchange rates, lower prices and the entry of generic competition in most major markets.

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 21 percent during the first quarter of 2009, driven by higher prices, increased demand, and the favorable impact of wholesaler buying patterns. Sales outside the U.S. decreased 2 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by increased demand and higher prices.

U.S. sales of Alimta, a treatment for various cancers, increased 42 percent during the first quarter of 2009, due primarily to increased demand, and to a lesser extent, higher prices. Sales outside the U.S. increased 30 percent, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for risk reduction of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 4 percent during the first quarter of 2009, as a result of decreased demand, partially offset by higher prices. Sales outside the U.S. increased 4 percent due to the favorable impact of buying patterns in Japan, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 6 percent during the first quarter of 2009, due to higher net effective selling prices and increased demand. Sales outside the U.S. decreased 14 percent driven by the unfavorable impact of foreign exchange rates, and to a lesser extent, lower prices.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, increased 3 percent during the first quarter of 2009, due to higher net effective selling prices, partially offset by decreased demand. Sales outside the U.S. decreased 1 percent, due to the unfavorable impact of foreign exchange rates, partially offset by increased demand.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, were essentially flat during the first quarter of 2009, due to higher net effective selling prices offset by decreased demand. Sales outside the U.S. increased 33 percent, driven by a one-time benefit from the resolution of pricing discussions in Canada, and to a lesser extent, increased demand, partially offset by the unfavorable impact of foreign exchange rates.

We market Byetta, an injectable product for the treatment of type 2 diabetes, with Amylin. For the first quarter of 2009, we recognized total revenue of \$97.5 million for Byetta, an increase of 18 percent, comprised of collaboration revenue of \$70.2 million related to our 50 percent share of Byetta's gross margin in the U.S., and product sales of \$27.3 million related to sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. Worldwide sales of Byetta increased 7 percent to \$181.4 million during the first quarter of 2009, driven by growth in international markets. U.S. sales of Byetta of \$157.7 million were essentially flat in the first quarter while sales of Byetta outside the U.S. were \$23.7 million.

For the first quarter, we recognized total revenue of \$94.1 million for Erbitux, a product approved to fight cancers, comprised of collaboration revenue of \$68.0 million related to the net royalties

received from our collaboration partners, and product sales of \$26.1 million related to revenue from manufactured product.

Animal health product sales in the U.S. increased 43 percent, primarily due to the inclusion of Posilac sales from the acquisition of the product in October 2008. Sales outside the U.S. decreased 13 percent, driven primarily by the unfavorable impact of foreign exchange rates, and to a lesser extent, decreased demand and lower prices.

#### Gross Margin, Costs, and Expenses

For the first quarter of 2009, gross margins as a percent of total revenue increased 6.9 percentage points, to 83.8 percent. This increase was due to the impact on international inventories from the decline in foreign currencies compared to the U.S. dollar, resulting in a benefit to cost of sales.

Operating expenses (the aggregate of research and development and marketing, selling, and administrative expenses) increased 2 percent for the first quarter of 2009 compared with the first quarter of 2008. Marketing, selling, and administrative expenses declined 1 percent to \$1.53 billion, due to the impact of foreign exchange rates and a reduction in expenses related to U.S. marketing programs, partially offset by the impact of the ImClone acquisition and increased prasugrel pre-launch activities. Research and development expenses increased 8 percent to \$947.3 million, due primarily to the ImClone acquisition and increased late-stage clinical trial and discovery research costs, partially offset by the impact of foreign exchanges rates.

Acquired IPR&D charges were \$87.0 million in the first quarter of 2008. We incurred asset impairments, restructuring (exit costs), and other special charges of \$145.7 in the first quarter of 2008. See Notes 3 and 5 to the consolidated condensed financial statements for additional information.

Other net, expense (income) decreased \$91.0 million, to a net expense of \$70.7 million, primarily due to lower interest income and higher interest expense associated with the ImClone acquisition, as well as lower business development income.

We incurred tax expense of \$370.3 million for the first quarter of 2009. The effective tax rate was 22.0 percent. In the first quarter of 2008, we reported an aggregate income tax benefit of \$8.0 million due to the recognition of \$210.3 million discrete benefit as a result of the resolution of a substantial portion of the IRS audit of our federal income tax returns for years 2001 through 2004.

#### FINANCIAL CONDITION

As of March 31, 2009, cash, cash equivalents, and short-term investments totaled \$3.51 billion compared with \$5.93 billion at December 31, 2008. The decrease in cash is driven by a net reduction in short-term borrowings of \$4.24 billion and dividends paid of \$536.8 million, partially offset by proceeds of long-term debt issuances of \$2.40 billion. Cash flow from operations was \$87.9 million, which included payments related to the EDPA settlement of \$1.06 billion.

Total debt as of March 31, 2009 decreased by \$1.99 billion, to \$8.47 billion, reflecting the pay down of our commercial paper that was issued to finance our acquisition of ImClone and to fund payments required in connection with the EDPA settlements, partially offset by \$2.40 billion of long-term debt we issued in March 2009. Our current debt ratings from Standard & Poor's and Moody's remain at AA and A1, respectively.

In the past several months, global economic conditions have deteriorated, triggered by the liquidity crisis in the capital markets, resulting in higher unemployment and declines in real consumer spending. In addition, many financial institutions tightened lines of credit, reducing funding available for near-term economic growth. Pharmaceutical consumption has traditionally been relatively unaffected by economic downturns; however, an extended downturn could lead to a decline in overall prescriptions corresponding with the growth of the

uninsured and underinsured population in the U.S. 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 prescription trends, the creditworthiness of our wholesalers and other customers and suppliers, the decline of health insurance coverage in the overall population, and the federal government's involvement in the economic crisis.

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, costs associated with litigation and government investigations, and dividends in 2009. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. Our access to credit markets has not been adversely affected by the illiquidity in the market because of the high credit quality of our short- and long-term debt. In the remainder of 2009, we intend to fund the remaining payments required in connection with the EDPA settlements, and to further reduce outstanding commercial paper with cash and cash equivalents on hand, and cash generated from operations. We currently have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program. Various risks and uncertainties, including those discussed in the Financial Expectations for 2009 section, may affect our operating results and cash generated from operations.

#### 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 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 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 eight allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the eight 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. Lawsuits have been filed in U.S. District Court for the Southern District of Indiana against Activis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; Sun Pharma Global, Inc.; and Wockhardt Limited, seeking rulings that the patents are valid, infringed, and enforceable. The cases have been consolidated and are proceeding.

**Gemzar:** Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted an ANDA 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. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006 and January 2008), seeking rulings that these patents are valid and are being infringed. The suit against Sicor has been scheduled for trial in September 2009. Sicor's ANDAs have been approved by the FDA; however, Sicor must provide 90 days notice prior to marketing generic Gemzar to allow time for us to seek a preliminary injunction. Both suits against Mayne have been administratively closed, and the parties have agreed to be bound by the results of the Sicor suit. In November 2007, Sun filed a declaratory judgment action in the United States 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. This trial is scheduled for December 2009.

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

Alimta: Teva Parenteral Medicines, Inc. (Teva), APP Pharmaceuticals, LLC (APP), and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. 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: Barr submitted an ANDA in 2002 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 November 2002, we filed a lawsuit against Barr 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 Barr. The lawsuit against Barr was administratively closed and, as a result, no trial date has been set. In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a lawsuit, similar to the Barr lawsuit, against Teva in the U.S. District Court for the Southern District of Indiana. The trial against Teva was completed in March 2009. In April 2008, the FDA granted Teva tentative approval of its ANDA; however, Teva's ability to market a generic product is subject to a preliminary injunction that prevents Teva from launching its generic raloxifene product until the Court issues a final judgment. Teva has announced its intent to appeal the preliminary injunction.

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 compound and method-of-use 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. We sued Novopharm for patent infringement, and the trial was completed in April 2009. We anticipate a decision in the second half of 2009. In November 2007, Apotex filed an action seeking a declaration of the invalidity of our Zyprexa compound and method-of-use patents, and no trial date has been set. We are involved in similar actions against Pharmascience (August 2007), Sandoz (July 2007), Nu-Pharm (June 2008), Genpharm (June 2008) and Cobalt (January 2009). By agreement between the parties, or due to scheduling by the court, no substantive developments are expected in these suits prior to the decision in the Novopharm suit.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolab Ltd. challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007. We appealed the decision to the German Federal Supreme Court and following a hearing in December 2008, the Supreme Court reversed the Federal Patent Court and found the patent to be valid. Following the decision of the Supreme Court, the generic companies either



agreed to withdraw from the market or were subject to preliminary injunction. We are pursuing these companies for damages arising from infringement.

We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), France, 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 further legal challenge is now pending before the Commercial Court in Madrid. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited has challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In October 2008, the Patents Court in the High Court, London ruled that our patent was valid. Dr. Reddy's appealed this decision, and a hearing date for the appeal has been set for November 2009.

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. While Ariad may request the Court of Appeals to reconsider its decision, or the United States Supreme Court to consider the matter, we believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

#### Government Investigations and Related Litigation

In March 2004, the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA) advised us that it had commenced an investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. In addition, the State Medicaid Fraud Control Units of more than 30 states coordinated with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In January 2009, we announced that we reached resolution of this matter, and on January 30, 2009, the court approved the settlement. 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. In connection with the federal criminal and civil settlements, in the first quarter of 2009, we paid \$1.06 billion. We also agreed to make

available a maximum amount of approximately \$362.0 million for payment to those states that agree to settle. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. 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 September 2006, we received a subpoena from the California Attorney General's Office seeking production of documents related to our efforts to obtain and maintain Zyprexa's status on California's formulary, marketing and promotional practices with respect to Zyprexa, and remuneration of health care providers. We expect this matter to be resolved if California participates in the state component of the EDPA resolution.

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.

#### Product Liability and Related 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 (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 120 lawsuits in the U.S. covering approximately 140 plaintiffs, of which about 90 cases covering about 100 plaintiffs are part of the MDL. No trials have been scheduled related to these claims.

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 has been certified for residents of Quebec, and a second has been certified in Ontario and includes all Canadian residents except for residents of Quebec and British Columbia. The allegations in the Canadian actions are similar to those in the litigation pending in the U.S.

Since the beginning of 2005, we have recorded aggregate net pretax charges of \$1.61 billion for Zyprexa product liability matters. The net charges, which take into account our actual insurance recoveries, covered the following:

The cost of the Zyprexa product liability settlements to date; and

Reserves for product liability exposures and defense costs regarding the known Zyprexa product liability claims and expected future claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York (EDNY). In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. We have been served with similar lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. 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. The following cases have been set for trial: Connecticut in the EDNY in November 2009, and South Carolina in September 2009 and Pennsylvania in April 2010, both in their respective states.

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. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. In 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. 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. The Pennsylvania case is set for trial in June 2009.

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.

In addition, we have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES) and thimerosal. The majority of these claims are covered by insurance, subject to deductibles and coverage limits.

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 few years, we have experienced difficulties in obtaining 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 2009

We reconfirm our 2009 financial guidance, as set forth in our Management's Discussion and Analysis in our 2008 Form 10-K. For the full year of 2009, we expect earnings per share to be in the range of \$4.00 to \$4.25. We expect mid-single digit sales growth. We expect gross margin as a percent of net sales to increase substantially, driven by the strengthening dollar. This increase could be more pronounced in the first half of 2009. Marketing, selling, and administrative expenses are expected to show flat to low-single digit growth. Research and development expenses are projected to grow in the low-double digits. Other net expense (income) is expected to be a net loss of between \$200.0 million and \$250.0 million. Capital expenditures are expected to remain level at approximately \$1.1 billion, and we expect continued strong operating cash flow.

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 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, 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 2008 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

#### AVAILABLE INFORMATION ON OUR WEBSITE

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The website link to our SEC filings is <http://investor.lilly.com/edgar.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, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of March 31, 2009, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the first quarter of 2009, 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 Cymbalta, Gemzar, Alimta, Evista, and Xigris

The patent litigation outside the U.S. involving Zyprexa

The investigation by the U.S. Attorney for the Eastern District of Pennsylvania and various state attorneys general relating to our U.S. sales, marketing, and promotional practices

The Zyprexa product liability and related litigation, including claims brought on behalf of state Medicaid agencies and private healthcare payors, as well as product liability litigation related to DES and thimerosal

That information is incorporated into this Item by reference.

#### *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

has appealed this ruling. We believe these claims are without legal merit and expect to prevail in any appeal of this litigation; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

*Other Product Liability Litigation*

We refer to Part I, Item 3, of our Form 10-K annual report for 2008 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 50 suits involving approximately 75 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 210 suits involving approximately 285 claimants.

*Other Marketing Practices Litigation*

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

*Employee Litigation*

In April 2006, three former employees and one current employee filed a putative class action against the company in the U.S. District Court for the Southern District of Indiana (*Welch, et al. v. Eli Lilly and Company*, filed April 20, 2006) alleging racial discrimination. Plaintiffs have since amended their complaint twice, adding to the lawsuit a total of 154 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). We believe this lawsuit is without merit and are prepared to defend against it vigorously.

*Other Environmental Matters*

We have been named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals. We have also been named in approximately 50 lawsuits filed in the same court by individual former employees making similar claims. We have also been named, along with several other companies, in a lawsuit filed by certain of these individuals in U.S. District Court for Southern District of Indiana on April 21, 2009, alleging possible harm caused by exposure to pesticides related to our former agricultural chemical manufacturing facility in Cosmopolis, Brazil. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended March 31, 2009:

Period	Total	Average	Total	Approximate
	Number of	Price	Number	Dollar Value
	Shares	Paid per	of Shares	of
	Purchased	Share	Purchased	Shares that
	(a)	(b)	as	May Yet Be
	(in	(c)	Part of	
	thousands)	(in	Publicly	
		thousands)	Announced	Purchased
			Plans or	Under the
			Programs	Plans
			(c)	or Programs
			(in	(d)
			thousands)	(in millions)
January 2009	44	\$ 39.55		\$ 419.2
February 2009	79	36.84		419.2
March 2009	2	33.17		419.2
Total	125			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of March 31, 2009, we have purchased \$2.58 billion related to this program. During the first three months of 2009, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2009.

On February 10, 2009, the company issued and sold 10 million shares of its common stock to National City Bank, not in its individual or corporate capacity, but solely in its capacity as Trustee of the Eli Lilly Compensation Trust (the Trust). The Trust is an employee benefit trust that provides a source of funds to assist the company in meeting its obligations under various employee compensation and benefit plans. The shares were sold in exchange for a promissory note from the Trustee in its capacity as Trustee of the Trust in the aggregate principal amount of \$378.2 million (the Note). The Note bears interest at 2 percent above the prime rate of interest charged by JPMorgan Chase bank, and is compounded annually. The Note is repayable on the earliest of (i) demand by the company, (ii) early termination of the Trust, or (iii) April 17, 2025, the final termination date of the Trust.

This funding of the Trust had no net impact on shareholders' equity as we consolidate the Trust. Any dividends paid on the shares in the Trust are used to repay indebtedness under the Note and are therefore eliminated. Lilly common stock held by the Trust is not considered outstanding in the computation of earnings per share. The sale of common stock was exempt from the registration requirements of the Securities Act of 1933 by virtue of the exemption provided by Section 4(2) as a transaction by an issuer not involving a public offering.

*Item 4. Submission of Matters to a Vote of Security Holders*

We held our annual meeting of shareholders on April 20, 2009. The following is a summary of the matters voted on at the meeting:

(a) The four nominees for director were elected to serve three-year terms ending in 2012, as follows:

Nominee	For	Withhold Vote
Martin S. Feldstein, Ph.D.	731,639,675	299,782,047
J. Erik Fyrwald	736,330,112	295,091,610
Ellen R. Marram	728,714,901	302,706,821
Douglas R. Oberhelman	1,009,116,635	22,305,087

(b) The appointment of Ernst & Young LLP as our principal independent auditors was ratified by the following shareholder vote:

For:	1,008,276,202
Against:	21,198,961
Abstain:	1,946,559

(c) By the following vote, the shareholders did not approve the proposal (proposal required the vote of 80 percent of outstanding shares) to amend the company's articles of incorporation to provide for annual election of directors:

For:	880,365,852
Against:	148,740,940
Abstain:	2,314,930

(d) By the following vote, the shareholders approved the material terms of the performance goals for the Eli Lilly and Company Bonus Plan:

For:	989,036,659
Against:	35,587,130
Abstain:	6,797,933

(e) By the following vote, the shareholders approved a shareholder proposal regarding amending the company's articles of incorporation to eliminate all supermajority voting provisions from the company's articles of incorporation and bylaws:

For:	590,218,045
Against:	337,521,044
Abstain:	4,058,929
Broker Nonvote:	99,623,704

(f) By the following vote, the shareholders did not approve a shareholder proposal regarding amending the company's articles of incorporation to allow shareholders to amend the bylaws by majority vote:

For:	458,189,802
Against:	469,363,190
Abstain:	4,245,026
Broker Nonvote:	99,623,704

(g) By the following vote, the shareholders did not approve a shareholder proposal regarding adopting a policy of asking shareholders to ratify the compensation of named executive officers at the annual meeting of shareholders:

For:	277,048,295
Against:	648,463,646
Abstain:	6,286,077



Broker Nonvote:

99,623,704

40

---

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT        The Eli Lilly and Company Bonus Plan, as amended effective January 1, 2009  
10.

EXHIBIT        Statement re: Computation of Earnings per Share  
11.

EXHIBIT        Statement re: Computation of Ratio of Earnings to Fixed Charges  
12.

EXHIBIT        Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer  
31.1

EXHIBIT        Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer  
31.2

EXHIBIT        Section 1350 Certification  
32.

SIGNATURES

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

ELI LILLY AND COMPANY

(Registrant)

Date: April 30, 2009

s/ James B. Lootens  
James B. Lootens  
Secretary and Deputy General Counsel

Date: April 30, 2009

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

42

---

INDEX TO EXHIBITS

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

Exhibit

- |                 |  |
|-----------------|--|
| EXHIBIT<br>10.  | The Eli Lilly and Company Bonus Plan, as amended effective January 1, 2009                           |
| EXHIBIT<br>11.  | Statement re: Computation of Earnings per Share  |
| EXHIBIT<br>12.  | Statement re: Computation of Ratio of Earnings to Fixed Charges                                      |
| EXHIBIT<br>31.1 | Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer |
| EXHIBIT<br>31.2 | Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer    |
| EXHIBIT<br>32.  | Section 1350 Certification   |