

LILLY ELI & CO  
Form 10-Q  
October 30, 2009

**Table of Contents**

**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**Form 10-Q**  
**Quarterly Report Under Section 13 or 15(d) of the**  
**Securities Exchange Act of 1934**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 2009**  
**COMMISSION FILE NUMBER 001-6351**  
**ELI LILLY AND COMPANY**  
(Exact name of Registrant as specified in its charter)

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

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

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

Yes  No

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

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

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

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Class	Number of Shares Outstanding
Common	1,149,022,405

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

**Item 4. Controls and Procedures**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

**Item 6. Exhibits**

**SIGNATURES**

**INDEX TO EXHIBITS**

**EX-10**

**EX-11**

**EX-12**

**EX-31.1**

**EX-31.2**

**EX-32**

**EX-101 INSTANCE DOCUMENT**

**EX-101 SCHEMA DOCUMENT**

**EX-101 CALCULATION LINKBASE DOCUMENT**

**EX-101 LABELS LINKBASE DOCUMENT**

**EX-101 PRESENTATION LINKBASE DOCUMENT**

---

**Table of Contents****PART I. FINANCIAL INFORMATION***Item 1. Financial Statements*

## CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions, except per-share data)			
Net product sales	\$ 5,385.5	\$ 5,092.4	\$ 15,390.6	\$ 14,835.6
Collaboration and other revenue (Note 4)	176.5	117.1	511.2	331.9
Total revenue	5,562.0	5,209.5	15,901.8	15,167.5
Cost of sales	1,051.9	1,155.2	2,815.7	3,467.4
Research and development	1,122.1	953.0	3,109.8	2,781.6
Marketing, selling, and administrative	1,701.8	1,649.2	4,939.2	4,899.8
Acquired in-process research and development (Note 3)		28.0		150.0
Asset impairments, restructuring, and other special charges (Note 5)	549.8	1,659.4	654.8	1,894.0
Other - net, expense (income) (Note 13)	66.9	(2.5)	161.7	(55.1)
	4,492.5	5,442.3	11,681.2	13,137.7
Income (loss) before income taxes	1,069.5	(232.8)	4,220.6	2,029.8
Income taxes (Note 10)	127.7	232.8	807.2	472.3
Net income (loss)	\$ 941.8	\$ (465.6)	\$ 3,413.4	\$ 1,557.5
Earnings (loss) per share - basic and diluted (Note 9)	\$ .86	\$ (.43)	\$ 3.11	\$ 1.42
Dividends paid per share	\$ .49	\$ .47	\$ 1.47	\$ 1.41

See Notes to Consolidated Condensed Financial Statements.

**Table of Contents**

CONSOLIDATED CONDENSED BALANCE SHEETS  
Eli Lilly and Company and Subsidiaries

	September 30, 2009	December 31, 2008
	(Dollars in millions)	
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,848.2	\$ 5,496.7
Short-term investments (Note 6)	80.9	429.4
Accounts receivable, net of allowances of \$106.2 (2009) and \$97.4 (2008)	3,016.8	2,778.8
Other receivables	466.1	498.5
Inventories	3,128.2	2,493.2
Deferred income taxes	263.7	382.1
Prepaid expenses	1,006.1	374.6
<b>TOTAL CURRENT ASSETS</b>	<b>11,810.0</b>	<b>12,453.3</b>
<b>OTHER ASSETS</b>		
Investments (Note 6)	1,173.8	1,544.6
Goodwill and other intangibles - net (Note 3)	3,738.9	3,929.1
Sundry	2,172.5	2,659.3
	7,085.2	8,133.0
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	15,188.5	15,315.9
Less accumulated depreciation	(6,955.8)	(6,689.6)
	8,232.7	8,626.3
	\$27,127.9	\$ 29,212.6
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 622.5	\$ 5,846.3
Accounts payable	887.7	885.8
Employee compensation	730.6	771.0
Sales rebates and discounts	999.3	873.4
Dividends payable		536.8
Income taxes payable	275.9	229.2
Accrued marketing investigation charges (Note 12)	239.6	1,425.0
Other current liabilities	2,311.9	2,542.2
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,067.5</b>	<b>13,109.7</b>
Long-term debt	6,769.7	4,615.7

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

Accrued retirement benefit (Note 11)	2,009.3	2,387.6
Long-term income taxes payable (Note 10)	990.0	906.2
Deferred income taxes	101.8	74.7
Other noncurrent liabilities	1,284.6	1,381.0
	11,155.4	9,365.2
SHAREHOLDERS EQUITY (Notes 7 and 8)		
Common stock	718.7	711.1
Additional paid-in capital	4,560.2	3,976.6
Retained earnings	9,992.7	7,654.9
Employee benefit trust	(3,013.2)	(2,635.0)
Deferred costs-ESOP	(79.9)	(86.3)
Accumulated other comprehensive loss	(2,175.4)	(2,786.8)
Noncontrolling interests	0.4	2.4
	10,003.5	6,836.9
Less cost of common stock in treasury	98.5	99.2
	9,905.0	6,737.7
	\$27,127.9	\$ 29,212.6

See Notes to Consolidated Condensed Financial Statements.

**Table of Contents**

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

	Nine Months Ended September 30,	
	2009	2008
	(Dollars in millions)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 3,413.4	\$ 1,557.5
Adjustments to reconcile net income to cash flows from operating activities:		
Net marketing investigation charges accrued (paid)	(1,185.3)	1,477.0
Other changes in operating assets and liabilities, net of acquisitions	(1,768.0)	144.0
Depreciation and amortization	922.0	842.3
Stock-based compensation expense	264.4	192.7
Deferred income taxes	306.3	268.0
Acquired in-process research and development, net of tax		107.3
Other, net	364.1	326.3
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>2,316.9</b>	<b>4,915.1</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net purchases of property and equipment	(508.2)	(671.5)
Net change in short-term investments	563.2	(237.3)
Purchases of noncurrent investments	(329.3)	(1,295.4)
Proceeds from sales and maturities of noncurrent investments	742.2	653.5
Cash paid for acquisitions, net of cash acquired		(44.4)
Purchase of in-process research and development		(122.0)
Other, net	(70.8)	(85.4)
<b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>	<b>397.1</b>	<b>(1,802.5)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(1,612.4)	(1,541.5)
Net change in short-term borrowings	(4,829.4)	(392.2)
Proceeds from issuance of long-term debt	2,400.0	0.1
Repayment of long-term debt	(400.0)	(10.8)
Other, net	36.6	(6.8)
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(4,405.2)</b>	<b>(1,951.2)</b>
Effect of exchange rate changes on cash and cash equivalents	42.7	(28.3)
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,648.5)</b>	<b>1,133.1</b>

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

Cash and cash equivalents at January 1	5,496.7	3,220.5
<b>CASH AND CASH EQUIVALENTS AT SEPTEMBER 30</b>	<b>\$ 3,848.2</b>	<b>\$ 4,353.6</b>

See Notes to Consolidated Condensed Financial Statements.

4

---



**Table of Contents**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Net income (loss)	\$ 941.8	\$ (465.6)	\$3,413.4	\$1,557.5
Other comprehensive income (loss), net of tax <sup>1</sup>	291.4	(610.0)	611.4	(409.1)
Comprehensive income (loss)	\$1,233.2	\$(1,075.6)	\$4,024.8	\$1,148.4

<sup>1</sup> The significant components of other comprehensive income (loss) were gains from foreign currency translation adjustments of \$189.1 million and \$381.8 million for the three months and nine months ended September 30, 2009, respectively. In addition, net unrealized gains on investment securities of \$72.4 million and \$169.4 million were included in other comprehensive income (loss) for the three months

and nine months  
ended  
September 30,  
2009,  
respectively.  
The significant  
components of  
other  
comprehensive  
income  
(loss) for the  
three months  
and nine months  
ended  
September 30,  
2008 were  
losses from  
foreign currency  
translation  
adjustments of  
\$640.4 million  
and  
\$376.7 million,  
respectively.

See Notes to Consolidated Condensed Financial Statements.

**Table of Contents****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 was \$59.3 million and \$47.6 million for the quarters ended September 30, 2009 and 2008, respectively, and \$142.6 million and \$102.9 million for the nine months ended September 30, 2009 and 2008, respectively.

**REVENUE BY CATEGORY**

Worldwide revenue by category was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Net sales to unaffiliated customers				
Neurosciences	\$2,252.1	\$2,160.4	\$ 6,515.5	\$ 6,258.5
Endocrinology	1,448.7	1,371.4	4,164.2	4,098.8
Oncology	816.0	754.0	2,307.6	2,142.5
Cardiovascular	509.9	477.4	1,419.1	1,416.1
Animal health	314.6	277.1	854.0	766.9
Other pharmaceuticals	44.2	52.1	130.2	152.8
Net product sales	5,385.5	5,092.4	15,390.6	14,835.6
Collaboration and other revenue	176.5	117.1	511.2	331.9
Total revenue	\$5,562.0	\$5,209.5	\$ 15,901.8	\$ 15,167.5

**Table of Contents**

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 September 30, 2009 presentation. We issued our financial statements by filing with the Securities and Exchange Commission on October 30, 2009. We have evaluated subsequent events up to the time of the filing.

Note 2: Implementation of New Financial Accounting Pronouncements

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

In June 2009, the Financial Accounting Standards Board (FASB) issued a Statement on Subsequent Events. This Statement provides authoritative accounting guidance and disclosure requirements for material events occurring subsequent to the balance sheet date and prior to the issuance of the financial statements. This Statement is effective for us for the periods ended on and after June 30, 2009. The implementation of this Statement had no effect on our consolidated financial position or results of operations.

In June 2009, the FASB issued a Statement on Transfers and Servicing, an amendment of previous authoritative guidance. The most significant amendments resulting from this Statement consist of the removal of the concept of a qualifying special-purpose entity (SPE) from previous authoritative guidance, and the elimination of the exception for qualifying SPEs from the Consolidation guidance regarding variable interest entities. This Statement is effective for us January 1, 2010 and is not expected to be material to our consolidated financial position or results of operations.

In June 2009, the FASB issued a Statement that amends the previous Consolidations guidance regarding variable interest entities and addresses the effects of eliminating the qualifying special-purpose entity concept from the guidance on Transfers and Servicing. This Statement responds to concerns about the application of certain key provisions of the previous guidance on Consolidations regarding variable interest entities, including concerns over the transparency of enterprises' involvement with variable interest entities. This Statement is effective for us January 1, 2010 and is not expected to be material to our consolidated financial position or results of operations.

**Table of Contents**

We adopted the provisions of a FASB Staff Position (FSP) relating to Fair Value Measurements and Disclosures, as of March 31, 2009. This FSP 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 a FSP on Financial Instruments, as of March 31, 2009. This FSP required 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.

The FASB Statement on Business Combinations was effective for us for business combinations with the acquisition date on or after January 1, 2009. This Statement changes the way in which the acquisition method is to be applied in a business combination. The primary revisions 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. This Statement significantly amends other authoritative guidance on Business Combinations as well, and now requires the capitalization of research and development assets acquired in a business combination at their acquisition-date fair values, separately from goodwill. The 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 the FASB Statement on Consolidations relating to the accounting for noncontrolling interests on January 1, 2009. This Statement amends previous authoritative guidance, 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 is 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 part of shareholders' equity in our consolidated condensed statements of financial position at September 30, 2009 and reclassified the December 31, 2008 balances accordingly. The net income attributed to the noncontrolling interest in a subsidiary for the third quarter and first nine months of 2009 and 2008 is not material and has not been separately disclosed in the consolidated condensed statements of operations.

We adopted the provisions of the FASB Statement on disclosures relating to Derivatives and Hedging on January 1, 2009. 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, 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 the EITF guidance related to Collaborative Arrangements on January 1, 2009. This guidance defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative

**Table of Contents**

arrangement and between participants in the arrangement and third parties. This guidance has been applied retrospectively to all prior periods presented for 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 the FSP relating to Investments on January 1, 2009. This FSP 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.

**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. Pursuant to the existing rules, 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 or second quarters of 2008 and \$28.0 million was incurred in the third 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 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.

**Table of Contents**

This strategic combination offers 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 was accounted for as a business combination under the purchase method of accounting, resulting in goodwill of \$425.9 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 was 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	425.9
Property and equipment	339.8
Debt assumed	(600.0)
Deferred taxes	(315.0)
Deferred income	(127.7)
Other assets and liabilities - net	(78.5)
Acquired in-process research and development	4,685.4
 Total purchase price	 \$ 6,506.9

1 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.



**Table of Contents**

This acquisition was 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 was 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. In July 2009, data from the Phase III clinical trials showed there were no statistically significant differences between dirucotide and placebo on the primary or secondary endpoints of the study, and ongoing clinical trials were discontinued. 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.

**Table of Contents**

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. The following table summarizes the revenue recognized with respect to Erbitux:

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
	(Dollars in millions)	
Net product sales	\$ 22.3	\$ 72.3
Collaboration and other revenue	79.6	223.5
Total revenue	\$101.9	\$ 295.8

***Bristol-Myers Squibb Company***

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

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties 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 operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in collaboration and other revenue. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.

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

***Merck KGaA***

A development and license agreement between ImClone and Merck KGaA (Merck) with respect to Erbitux granted Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and co-exclusive rights to market Erbitux with BMS and ImClone in Japan. Merck also has rights to manufacture Erbitux for supply in its territory. We manufacture and provide a portion of Merck's requirements for API, which is included in net product sales. We also receive a royalty on the sales of Erbitux outside of the U.S. and Canada, which is included in collaboration and other revenue as

**Table of Contents**

earned. Collaborative reimbursements received for supply of product; for research and development; and marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. Royalty expense paid to third parties, net of any royalty reimbursements received, is recorded as reductions 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® (exenatide injection) and other forms of exenatide such as exenatide once weekly. Byetta is presently approved as an adjunctive therapy to improve glycemic control in patients with type 2 diabetes who have not achieved adequate glycemic control using metformin, a sulfonylurea, and/or a thiazolidinediene (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. The following table summarizes the revenue recognized with respect to Byetta:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Net product sales	\$ 38.0	\$ 26.0	\$ 100.2	\$ 65.3
Collaboration and other revenue	77.8	83.2	228.0	227.9
Total revenue	\$ 115.8	\$ 109.2	\$ 328.2	\$ 293.2

We pay Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs are recorded in cost of sales. Under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide's gross margin, we also 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 operations. A New Drug Application has been submitted to the U.S. Food and Drug Administration (FDA) for exenatide once weekly. 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. We have also agreed to cooperate with Amylin in the development, manufacturing, and marketing of exenatide once weekly in a dual-chamber cartridge pen configuration. We will contribute 60 percent of the total initial capital costs of the project, our portion of which will be approximately \$130 million.

**Cymbalta®**

*Boehringer Ingelheim*

**Table of Contents**

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 operations. 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 and receives a commission based upon net product sales. According to this agreement, Quintiles' obligation to promote Cymbalta expires in 2009, and we will pay a lower rate on net product sales for three years after completion of the promotion efforts specified in this agreement. The commissions paid to Quintiles are recorded in marketing, selling, and administrative expenses.

*Effient*

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote 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. Prasugrel was also approved for marketing by the FDA under the tradename Effient in July 2009, and the initial sales in the U.S. were recorded in the third quarter. Within this arrangement, we and D-S have agreed to co-promote under the same trademark in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. D-S has exclusive marketing rights in Japan. Under the agreement, we paid D-S an upfront license fee and agreed to pay future success milestones. The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. We record product sales in the exclusive and co-promotion territories. In our exclusive territories, we pay D-S a royalty specific to these territories. Profit share payments made to D-S are recorded as marketing, selling, and administrative expenses. All royalties paid to D-S and the third-party manufacturer are recorded in cost of sales. Worldwide Effient sales were \$22.6 million in the third quarter of 2009. The product is in the early phases of launch in both the U.S. and Europe.

*TPG-Axon Capital*

In 2008, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of a gamma-secretase inhibitor and an 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. We record reimbursements received from TPG for its portion of research and development costs as a reduction to research and development expenses on the consolidated condensed statements of operations. The reimbursement from TPG is not expected to be material in any period.

Summary of Collaboration Related Commissions and Profit Share Payments

**Table of Contents**

The aggregate amount of commissions and profit share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$80.8 million and \$81.0 million in the quarters ended September 30, 2009 and 2008, respectively, and \$243.0 million and \$223.5 million in the nine months ended September 30, 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 operations are described below.

We recognized asset impairment, restructuring, and other special charges of \$424.8 million in the third quarter of 2009 primarily due to the announced agreement to sell our Tippecanoe Laboratories manufacturing site to an affiliate of Evonik Industries AG (Evonik) by the end of 2009, subject to certain closing conditions. In connection with the sale of the site, we will enter into a nine-year supply and services agreement, whereby the Evonik affiliate will manufacture final and intermediate step active pharmaceutical ingredient (API) for certain of our human and animal health products. The decision to sell the site was based upon a projected decline in utilization of the site due to several factors, including upcoming patent expirations on certain medicines made at the site; our strategic decision to purchase, rather than manufacture, many late-stage chemical intermediates; and the evolution of our pipeline toward more biotechnology medicines. In addition to the sale of the Tippecanoe site, in the third quarter of 2009 we announced a voluntary exit program for certain U.S. sales employees. Components of the third-quarter restructuring charge include non-cash asset impairment charges and other charges of \$363.7 million, and \$61.1 million in severance related charges, substantially all of which is expected to be paid in cash by early 2010. The fair value of assets used in determining impairment charges is based on contracted sales prices.

In the second and third quarters of 2009, we incurred other special charges of \$105.0 million and \$125.0 million, respectively. We are in advanced discussions with the attorneys general for several states that were not part of the Eastern District of Pennsylvania settlement, seeking to resolve their Zyprexa<sup>®</sup>-related claims, and we have agreed to settlements with the states of Connecticut, Idaho, South Carolina, Utah, and West Virginia. The charge reflects the currently probable and estimable exposures in connection with the states' claims. See Note 12 for additional information.

In the third quarter of 2008, as a result of our previously announced agreements with Covance Inc. (Covance), Quintiles Transnational Corp. (Quintiles), and Ingenix Pharmaceutical Services, Inc., doing business as i3 Statprobe (i3), and as part of our efforts to transform into a more flexible organization, we recognized asset impairments, restructuring, and other special charges of \$182.4 million. We sold our Greenfield, Indiana, site to Covance, a global drug development services firm, and entered into a 10-year service agreement under which Covance will provide preclinical toxicology work and perform additional clinical trials for us as well as operate the site to meet our needs and those of other pharmaceutical industry clients. In addition, we signed agreements with Quintiles for clinical trial monitoring services and with i3 for clinical data management services. Components of the third-quarter 2008 restructuring charge include non-cash charges of \$148.3 million primarily related to the loss on sale of assets sold to Covance, severance costs of \$27.8 million, and exit costs of \$6.3 million. Substantially all of these costs were paid in 2008.

In the second quarter of 2008, we recognized restructuring and other special charges of \$88.9 million. In addition, we recognized non-cash charges of \$57.1 million for the write down of impaired manufacturing assets that had no future use, which were included in cost of sales. In April 2008, we announced a voluntary exit program that was offered to employees primarily in manufacturing. Components of the second-quarter restructuring charge include total severance costs of \$53.5 million related to these programs and \$35.4 million related to exit costs incurred during the second quarter in connection with previously announced strategic decisions made in prior periods. Substantially all of these costs were paid by the end of July 2008.

**Table of Contents**

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 includes 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, was 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

**Table of Contents**

currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other-net, expense (income). The purchased option contracts are used to hedge anticipated foreign currency transactions, primarily intercompany inventory activities expected to occur within the next year. These contracts are designated as cash flow hedges of those future transactions, and the impact on earnings is included in cost of sales. We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward and purchase option contracts generally have maturities not exceeding 12 months. At September 30, 2009, we did not hold any foreign currency option contracts. At September 30, 2009, we had outstanding foreign currency forward commitments to purchase 397 million British pounds and sell 438 million euro, and commitments to purchase 549 million U.S. dollars and sell 377 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 September 30, 2009, approximately 88 percent of our total debt was at a fixed rate. We have converted approximately 56 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 Operations

Both the losses on the hedged fixed-rate debt and the offsetting gains on the related interest rate swaps for the third quarter of 2009 were \$77.7 million. Both the gains on the hedged fixed-rate debt and the offsetting losses on the related interest rate swaps for the first nine months of 2009 were \$233.3 million. All of these amounts net to zero and were included in other-net, expense (income).

We expect to reclassify an estimated \$11.8 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.

Other-net, expense (income) for the third quarter and first nine months of 2009 includes the effective portion of losses on interest rate contracts in designated cash flow hedging relationships reclassified from accumulated other comprehensive loss into income of \$2.6 million and \$7.8 million, respectively, and the gains on foreign exchange contracts not designated as hedging instruments recognized in income of \$6.4 million and \$40.0 million, respectively. The effective portions of net gains on interest rate contracts in designated cash flow hedging relationships recorded in other comprehensive income for the first nine months of 2009 were \$37.8 million; no such amounts were recorded in the third quarter.

During the third quarter and first nine months of 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.

**Table of Contents**

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 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:



**Table of Contents**

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>September 30, 2009</b>						
Short-term investments						
Corporate debt securities	\$ 58.0	\$ 58.3	\$	\$ 58.0	\$	\$ 58.0
U.S. government and agencies	17.0	17.2	17.0			17.0
Other securities	5.9	5.9		5.9		5.9
	\$ 80.9	\$ 81.4				
Noncurrent investments						
Corporate debt securities	\$ 212.3	\$ 226.0	\$	\$ 212.3	\$	\$ 212.3
Mortgage-backed	263.7	341.9		263.7		263.7
Asset-backed	91.2	109.4		91.2		91.2
U.S. government and agencies	77.3	77.0	77.3			77.3
Other debt securities	30.9	13.4		3.8	27.1	30.9
Marketable equity	361.7	183.5	361.7			361.7
Equity method and other investments	136.7	136.7				NA
	\$ 1,173.8	\$1,087.9				
Long-term debt, including current portion	\$(6,789.9)	NA	\$	\$(7,097.8)	\$	\$(7,097.8)
Risk-management instruments						
Interest rate contracts designated as hedging instruments						
Sundry	\$ 264.9	NA		\$ 264.9	\$	\$ 264.9
Foreign exchange contracts not designated as hedging instruments	4.8	NA		4.8		4.8

Prepaid expenses					
Other current liabilities	(10.0)	NA		(10.0)	(10.0)

**December 31, 2008**

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

**Table of Contents**

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)	
Corporate debt securities	\$ 466.4	\$ 542.2	\$	\$ 466.4	\$	\$ 466.4
Mortgage-backed	330.6	436.6		330.6		330.6
Asset-backed	204.0	240.1		204.0		204.0
U.S. government and agencies	179.2	176.8	179.2			179.2
Other debt securities	14.7	10.6		3.6	11.1	14.7
Marketable equity	221.9	175.1	221.9			221.9
Equity methods and other investments	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. Approximately \$300 million of our investments in debt securities will mature within five years.

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

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

	September 30, 2009	December 31, 2008
Unrealized gross gains	\$203.8	\$ 69.9
Unrealized gross losses	118.4	239.0
Fair value of securities in an unrealized gain position	688.2	767.5
Fair value of securities in an unrealized loss position	417.6	1,046.1
A summary of other-than-temporary impairment losses follows:		
	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
Recognized in the statement of operations	\$10.7	\$ 18.3
Recognized in other comprehensive income	(3.5)	10.1
Total other-than-temporary impairment losses	\$ 7.2	\$ 28.4

These charges relate to credit losses on certain mortgage-backed securities. The amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

**Table of Contents**

The securities in an unrealized loss position are comprised of fixed-rate debt securities and mortgage-backed 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 56 percent of the securities in a loss position are investment-grade debt securities. The majority of these securities first moved into an unrealized loss position during 2008. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of September 30, 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 September 30, 2009.

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

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
Proceeds from sales	\$426.6	\$ 1,027.2
Realized gross gains on sales	39.5	56.7
Realized gross losses on sales	4.5	5.5

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

Our stock-based compensation expense consists primarily of performance awards (PAs) and shareholder value awards (SVAs). We recognized pretax stock-based compensation expense of \$104.0 million and \$77.9 million in the third quarter of 2009 and 2008, respectively. In the first nine months of 2009 and 2008, we recognized pretax stock-based compensation expense of \$264.4 million and \$192.7 million, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings per share targets over a 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 September 30, 2009, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$149.1 million, which will be amortized over the weighted-average remaining requisite service period of approximately 11 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of September 30, 2009, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$58.4 million, which will be amortized over the weighted-average remaining requisite service period of approximately 23 months.

**Table of Contents****Note 8: Shareholders' Equity**

As of September 30, 2009, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first nine months 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 were seeking 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. In addition, the IRS administrative appeals matter from the 2001-2004 IRS audit was settled in the third quarter of 2009. Considering the current status of the 2005-2007 IRS examination and the settlement of the IRS administrative appeals matter from the 2001-2004 audit, gross unrecognized tax benefits have been reduced approximately \$190 million in the third quarter of 2009. As a result, our income tax expense was reduced by \$54.4 million. After utilization of all tax credit carryovers, a cash payment of \$52.8 million was paid in the third quarter of 2009 upon settlement of the IRS appeals matter. While the IRS is currently examining tax years 2005-2007, the resolution of all issues in this audit period will likely extend beyond the next 12 months.

**Note 11: Retirement Benefits**

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

	Defined Benefit Pension Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 59.3	\$ 61.4	\$ 179.0	\$ 186.8
Interest cost	104.6	102.7	312.0	308.5
Expected return on plan assets	(149.9)	(151.3)	(435.3)	(455.0)
Amortization of prior service cost	1.8	1.8	5.4	5.3
Recognized actuarial loss	21.2	19.2	63.0	57.8
Net periodic benefit cost	\$ 37.0	\$ 33.8	\$ 124.1	\$ 103.4

**Table of Contents**

	Retiree Health Benefit Plans			
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 13.4	\$ 15.5	\$ 40.1	\$ 46.6
Interest cost	29.2	26.5	87.7	79.4
Expected return on plan assets	(29.5)	(29.1)	(88.4)	(88.3)
Amortization of prior service cost	(9.0)	(9.0)	(27.0)	(27.0)
Recognized actuarial loss	17.2	15.7	51.5	47.1
Net periodic benefit cost	\$ 21.3	\$ 19.6	\$ 63.9	\$ 57.8

In 2009, we contributed approximately \$70 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we contributed approximately \$310 million of additional discretionary funding in 2009 to our defined benefit plans. We do not expect to contribute any significant additional amounts during the remainder of the year.

**Note 12: Contingencies**

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

**Patent Litigation**

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

**Cymbalta:** Sixteen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia, and one alleges the patent having claims directed to the active ingredient is unenforceable. Lawsuits have been filed in U.S. District Court for the Southern District of Indiana against Activis Elizabeth LLC; Anchen Pharmaceuticals, Inc.; 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®:** Mayne Pharma (USA) Inc. (Mayne), Sico Pharmaceuticals, Inc. (Sico), 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. Sandoz Inc. (Sandoz) has similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sico (February 2006), Mayne (October 2006 and January 2008), and Sandoz (October 2009), seeking rulings that our patents are valid and are being infringed. The trial against Sico was held in September 2009 and we are waiting for a ruling. Sico





**Table of Contents**

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. In August 2009, the District Court granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We plan to appeal this decision. This ruling has no bearing on the compound patent. The trial originally scheduled for December 2009 has been postponed while the court considers Sun's second summary judgment motion, related to the validity of our compound patent.

Alimta<sup>®</sup>: 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<sup>®</sup>: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. The trial against Teva was completed in March 2009. In September 2009, the court upheld our method-of-use patents (the last expires in 2014). Teva has appealed that ruling. In addition, the court held that our particle-size patent (expiring 2017) is invalid. We have appealed that ruling.

Strattera<sup>®</sup>: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. The defendants have filed various summary judgment motions on the issues of invalidity and noninfringement, which are currently pending, and Aurobindo has received tentative approval to market generic atomoxetine. Trial is anticipated as early as the first quarter of 2010.

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

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

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled in our infringement suit against Novopharm, finding our patent invalid. We plan to appeal this decision. If the decision is upheld, we could face liability for damages

related to delays in the launch of generic olanzapine products; however, we have concluded at this time that the damages are not probable or estimable.

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

**Table of Contents**

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 additional actions are now pending. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited (Dr. Reddy's) has challenged the validity of our Zyprexa 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 we expect a decision in late 2009 or early 2010.

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. In August 2009, the Court of Appeals agreed to review this decision en banc, thereby vacating the Court of Appeals decision.

Nevertheless, 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.

**Zyprexa Litigation**

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims) allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (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 110 lawsuits in the U.S. covering approximately 260 plaintiffs, of which about 80 cases covering about 105 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, with the

**Table of Contents**

earliest trial scheduled to begin in March 2010. We also have a trial scheduled in California in November 2009. In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures, and practices. In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued and paid \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We are in advanced discussions with the attorneys general for several of these states, seeking to resolve their Zyprexa-related claims, and we have agreed to settlements with the states of Connecticut, Idaho, South Carolina, Utah, and West Virginia. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the currently probable and estimable exposures in connection with these claims. The Pennsylvania case is set for trial in April 2010 in state court.

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 2010.

**Table of Contents**

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 product liability litigation pending in the U.S.

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

**Other Product Liability Litigation**

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

**Product Liability Insurance**

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

**Environmental Matters**

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

**Note 13: Other Net, Expense (Income)**

Other net, expense (income), consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Interest expense	\$ 59.2	\$ 44.0	\$ 211.1	\$ 146.4
Interest income	(15.2)	(53.2)	(61.4)	(156.8)
Other	22.9	6.7	12.0	(44.7)
	\$ 66.9	\$ (2.5)	\$ 161.7	\$ (55.1)

**Table of Contents**

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

**OPERATING RESULTS**

**Executive Overview**

**I. Financial Results**

Worldwide revenues increased 7 percent and 5 percent to \$5.56 billion and \$15.90 billion for the third quarter and first nine months of 2009, respectively, driven by the collective growth of Alimta, Cymbalta, Humalog®, and the inclusion of Erbitux revenue as a result of the ImClone acquisition in November 2008. Third quarter net income was \$941.8 million and earnings per share was \$.86 as compared to 2008 net loss of \$465.6 million and loss per share of \$.43. Net income and earnings per share increased 119 percent for the first nine months of 2009, to \$3.41 billion and \$3.11, respectively. Net income for the third quarter and first nine months of 2009 and 2008 was affected by the following significant items:

2009

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

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

2008

We recorded charges of \$1.48 billion (pretax) related to the pending Zyprexa investigations led by the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia, which decreased earnings per share by \$1.33 in the third quarter.

We recognized asset impairments, restructuring, and other special charges of \$182.4 million (pretax), primarily associated with previously-announced strategic exit activities related to our Greenfield, Indiana, site, which decreased earnings per share by \$.11 in the third quarter.

We incurred an in-process research and development (IPR&D) charge associated with the acquisition of SGX Pharmaceuticals, Inc. (SGX) of \$28.0 million (pretax), which decreased earnings per share by \$.03 in the third quarter.

We recognized restructuring and other special charges of \$88.9 million (pretax), primarily associated with previously-announced strategic exit activities related to manufacturing operations, which decreased earnings per share by \$.05 in the second quarter.

We recognized asset impairments associated with certain manufacturing operations (included in cost of sales) of \$57.1 million (pretax), which decreased earnings per share by \$.04 in the second quarter.

We incurred an IPR&D charge associated with the licensing arrangement with TransPharma Medical Ltd. of \$35.0 million (pretax), which decreased earnings per share by \$.02 in the second quarter.

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 in the first quarter.

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

We recognized asset impairments, restructuring, and other special charges of \$145.7 million (pretax), 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 in the first quarter.

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

**Table of Contents**

II. Late-Stage Pipeline Developments

Third Quarter

We announced that initial results from a Phase III clinical trial for arzoxifene met its primary endpoints of significantly reducing the risk of vertebral fracture and invasive breast cancer in postmenopausal women. However, the study failed to demonstrate a statistically significant difference in key secondary efficacy endpoints, and certain adverse events were reported more frequently in the arzoxifene group compared with placebo. After reviewing the overall clinical profile of arzoxifene in light of currently available treatments, including our own osteoporosis products, we decided not to submit the compound for regulatory review.

The U.S. Food and Drug Administration (FDA) approved a new use for Forteo® to treat osteoporosis associated with sustained, systemic glucocorticoid therapy in men and women at high risk of fracture.

We and our partner BioMS Medical Corp. discontinued Phase III clinical trials for dirucotide in patients with secondary progressive multiple sclerosis. Data showed that dirucotide did not meet the primary endpoint of delaying disease progression and there were no statistically significant differences between dirucotide and placebo on the secondary endpoints of the study.

Second Quarter

The FDA approved Effient (prasugrel) tablets for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndromes (ACS) who are managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). We and our partner, Daiichi Sankyo, Inc., launched Effient in the U.S. in early August.

The FDA approved Alimta as a maintenance therapy for locally advanced or metastatic non-small cell lung cancer (NSCLC), specifically for patients with a nonsquamous histology whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

The European Commission granted approval for the use of Alimta as monotherapy for maintenance treatment of patients with other than predominantly squamous cell histology in locally-advanced or metastatic NSCLC, whose disease has not progressed immediately following platinum-based chemotherapy.

Alimta received regulatory approval in Japan as both a first- and second-line treatment of NSCLC.

We and our partners Amylin Pharmaceuticals, Inc., and Alkermes, Inc. submitted a New Drug Application (NDA) to the FDA for exenatide once weekly. Exenatide once weekly is an investigational sustained release medication for type 2 diabetes that is injected subcutaneously and administered only once a week.

We resubmitted our supplemental New Drug Application (sNDA) for Cymbalta for the management of chronic pain to the FDA.

We began enrolling patients in two separate but identical Phase III clinical trials of solanezumab, an anti-amyloid beta monoclonal antibody being investigated as a potential treatment to delay the progression of mild to moderate Alzheimer's disease. The trials each include a treatment period that lasts 18 months and are expected to enroll a total of 2,000 patients age 55 and over from 16 countries.

First Quarter

The European Commission granted marketing authorization for Efient (prasugrel) for the prevention of atherothrombotic events in patients with ACS undergoing PCI.

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.

**Table of Contents**

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 September 2009, we set a goal to reduce our expected cost structure by \$1 billion by the end of 2011. We also plan to lower global headcount to 35,000 by the end of 2011, excluding strategic sales force additions in high-growth emerging markets and Japan.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. 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. We are in advanced discussions with the attorneys general for several states that were not part of the EDPA settlement, seeking to resolve their Zyprexa-related claims, and we have agreed to settlements with the states of Connecticut, Idaho, South Carolina, Utah, and West Virginia. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the currently probable and estimable exposures in connection with these claims. The Pennsylvania case is set for trial in April 2010 in state court.

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). Health care reform is currently the subject of intense debate in Congress. The impact of reform on the pharmaceutical industry is uncertain. Further reform proposals to expand coverage to the uninsured could include some form of price rebates or tax 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 that would increase the rebates we pay on sales to Medicaid patients or impose additional rebates on, or otherwise subsidize, sales to patients who receive their medicines through Medicare Part D or other government programs. Additionally, various proposals have been introduced 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. 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 budget submission to Congress in May 2009, 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, including taxation of international income, continues to be a topic of discussion for the U.S. Congress. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations.

**Table of Contents**

In addition, the federal government is considering creating a regulatory pathway for biosimilars (copies of biological compounds) 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 or reimbursement for our products, or reduce the value of our intellectual property protection.

**Revenue**

Revenue for the third quarter and the first nine months of 2009 increased 7 percent and 5 percent to \$5.56 billion and \$15.90 billion, respectively, and was driven primarily by the increase in net product sales related to the collective growth of Alimta, Cymbalta, 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 \$377.1 million, or 14 percent, and \$1.04 billion, or 13 percent, for the third quarter and first nine months of 2009, respectively, compared with the same periods of 2008. Revenue outside the U.S. decreased \$24.7 million, or 1 percent, and \$302.5 million, or 4 percent, for the third quarter and first nine months of 2009, respectively. For the third quarter, worldwide sales volume increased 8 percent, while selling prices contributed 2 percent of revenue growth, partially offset by the unfavorable impact of foreign exchange rates of 3 percent. For the first nine months of 2009, worldwide sales volume increased 7 percent, while selling prices contributed 3 percent of revenue growth, partially offset by the unfavorable impact of foreign exchange rates of 5 percent.

**Table of Contents**

The following tables summarize our revenue activity for the three- and nine-month periods ended September 30, 2009 and 2008:

Product	Three Months Ended			Three Months Ended	Percent Change from 2008
	September 30, 2009			September 30, 2008	
	U.S. <sup>1</sup>	U.S.	Total <sup>3</sup>	Total	
	(Dollars in millions)				
Zyprexa	\$ 569.6	\$ 653.4	\$ 1,223.0	\$ 1,189.5	3
Cymbalta	652.7	137.5	790.2	716.4	10
Humalog	310.6	189.6	500.2	432.6	16
Alimta	215.5	246.4	461.9	313.9	47
Cialis®	158.7	238.5	397.2	376.6	5
Gemzar	191.0	140.8	331.8	440.2	(25)
Animal health products	176.8	137.8	314.6	277.1	14
Humulin®	105.8	154.6	260.4	271.6	(4)
Evista	174.4	85.1	259.5	265.7	(2)
Forteo	135.1	78.0	213.1	192.7	11
Strattera	106.8	38.7	145.5	149.5	(3)
Other pharmaceutical products	200.5	287.6	488.1	466.6	5
Total net product sales	2,997.5	2,388.0	5,385.5	5,092.4	6
Collaboration and other revenue <sup>2</sup>	148.5	28.0	176.5	117.1	51
Total revenue	\$ 3,146.0	\$ 2,416.0	\$ 5,562.0	\$ 5,209.5	7

**Table of Contents**

Product	Nine Months Ended			Nine Months	Percent
	September 30, 2009			Ended	
	Outside			September	Change
	U.S. <sup>1</sup>	U.S.	Total <sup>3</sup>	30,	from
				2008	2008
	(Dollars in millions)				
Zyprexa	\$ 1,687.2	\$ 1,862.0	\$ 3,549.2	\$ 3,549.5	
Cymbalta	1,871.0	372.9	2,243.9	1,975.9	14
Humalog	888.8	539.5	1,428.2	1,277.8	12
Alimta	586.9	595.6	1,182.5	836.0	41
Cialis	457.2	662.4	1,119.6	1,075.7	4
Gemzar	556.1	496.7	1,052.8	1,306.5	(19)
Animal health products	484.5	369.5	854.0	766.9	11
Evista	506.3	261.4	767.7	806.6	(5)
Humulin	299.9	449.2	749.1	800.8	(6)
Forteo	389.0	214.9	603.9	584.3	3
Strattera	328.2	119.0	447.2	432.7	3
Other pharmaceutical products	546.5	845.9	1,392.5	1,422.9	(2)
Total net product sales	8,601.6	6,789.0	15,390.6	14,835.6	4
Collaboration and other revenue <sup>2</sup>	431.4	79.8	511.2	331.9	54
Total revenue	\$ 9,033.0	\$ 6,868.8	\$ 15,901.8	\$ 15,167.5	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.

<sup>3</sup> Numbers may not add due to rounding.

**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 third quarter and first nine months of 2009, Zyprexa sales in the

U.S. increased 3 percent and 4 percent, respectively, compared with the same periods of 2008, due primarily to higher net effective selling prices, partially offset by lower demand. Sales outside the U.S. increased 3 percent for the third quarter and decreased 4 percent for the first nine months of 2009, respectively, with third quarter increases due to increased demand partially offset by the unfavorable impact of foreign exchange rates. The decrease during the first nine months of 2009 was due to the unfavorable impact of foreign exchange rates partially offset by increased demand. Demand outside the U.S. was favorably affected 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 9 percent and 13 percent during the third quarter and first nine months of 2009, respectively, driven primarily by increased demand and higher net effective selling prices. Sales outside the U.S. increased 15 percent for both the third quarter and first nine months of 2009, compared with the same periods in 2008, driven primarily by increased demand, partially offset by the unfavorable impact of foreign exchange rates and lower selling prices.

**Table of Contents**

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 27 percent and 21 percent for the third quarter and first nine months of 2009, respectively, driven primarily by higher net effective selling prices and increased demand. Sales outside the U.S. increased 1 percent for the third quarter and decreased 1 percent for the first nine months of 2009, with third quarter increases due to increased demand, partially offset by the unfavorable impact of foreign exchange rates. The decrease during the first nine months of 2009 was due to the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased demand.

U.S. sales of Alimta, a treatment for various cancers, increased 44 percent and 46 percent during the third quarter and first nine months of 2009, respectively, due to increased demand and, to a lesser extent, higher prices. Alimta sales outside the U.S. increased 50 percent and 37 percent for the same periods, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates. Demand outside the U.S. benefited from the addition of the non-small cell lung cancer indication in Japan.

U.S. sales of Cialis, a treatment for erectile dysfunction, increased 13 percent and 17 percent during the third quarter and first nine months of 2009, respectively, due to increased demand and higher net effective selling prices. Sales outside the U.S. increased 1 percent for the third quarter and decreased 3 percent during the first nine months of 2009, with third quarter increases due primarily to increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates. The decrease during the first nine months of 2009 was due to the unfavorable impact of foreign exchange rates, partially offset by increases in both demand and prices.

U.S. sales of Gemzar, a product approved to treat various cancers, increased 1 percent for both the third quarter and first nine months of 2009, due primarily to higher net effective selling prices, partially offset by lower demand. Sales outside the U.S. decreased 44 percent and 34 percent during the third quarter and first nine months of 2009, respectively, due to reduced demand and lower prices as a result of the entry of generic competition in most major markets, as well as 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, increased 2 percent for the third quarter and decreased 3 percent during the first nine months of 2009, with third quarter increases due to higher net effective selling prices, partially offset by lower demand. The decrease during the first nine months of 2009 was due to lower demand, partially offset by higher net effective selling prices. Evista sales outside the U.S. decreased 10 percent and 9 percent, respectively, for the same periods, driven by the outlicensing of Evista in most European markets.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased by 11 percent and 7 percent for the third quarter and first nine months of 2009, respectively, due primarily to higher net effective selling prices. Product demand in the U.S. continues to decline. Humulin sales outside the U.S. decreased 12 percent and 14 percent during the third quarter and first nine months of 2009, respectively, due primarily to the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased demand.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, increased 15 percent and 7 percent during the third quarter and first nine months of 2009, respectively, with third quarter increases due primarily to higher prices and the impact of wholesaler buying patterns. The increase during the first nine months of 2009 was due to higher prices, partially offset by reduced demand. Forteo sales outside the U.S. increased 3 percent for the third quarter and decreased 2 percent during the first nine months of 2009, respectively, with third quarter increases due to increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates. The decrease during the first nine

**Table of Contents**

months of 2009 was due to the unfavorable impact of foreign exchange rates, partially offset by increased demand and prices.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 2 percent for the third quarter and increased 1 percent during the first nine months of 2009, with third quarter decreases due primarily to lower volume, partially offset by higher net effective selling prices. The increase during the first nine months of 2009 was due to higher net effective selling prices, partially offset by lower demand. Strattera sales outside the U.S. decreased 3 percent for the third quarter and increased 12 percent during the first nine months of 2009, with third quarter decreases due to lower prices and the unfavorable impact of foreign exchange rates, partially offset by increased demand. The increase during the first nine months of 2009 was due to higher prices and increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Animal health product sales in the U.S. increased 38 percent for both the third quarter and first nine months of 2009, primarily due to the inclusion of Posilac sales following the acquisition of the product from Monsanto in October 2008. Sales outside the U.S. decreased 8 percent and 11 percent, respectively, compared with the same periods in 2008, driven primarily by the unfavorable impact of foreign exchange rates and lower volume.

We market Byetta, an injectable product for the treatment of type 2 diabetes, with Amylin. For the third quarter and first nine months of 2009, we recognized revenue for Byetta comprised of collaboration revenue related to our 50 percent share of Byetta's gross margin in the U.S., and product sales related to sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
Net product sales	\$ 38.0	\$ 26.0	\$100.2	\$ 65.3
Collaboration and other revenue	77.8	83.2	228.0	227.9
Total revenue	\$115.8	\$109.2	\$328.2	\$293.2

Worldwide sales of Byetta increased 2 percent and 5 percent to \$205.7 million and \$592.9 million during the third quarter and first nine months of 2009, respectively, driven by growth in international markets. U.S. sales of Byetta declined 5 percent and 2 percent to \$171.1 million and \$503.9 million during the third quarter and first nine months of 2009, respectively. Sales outside the U.S. during the third quarter and first nine months of 2009, respectively, were \$34.6 million and \$89.0 million.

For the third quarter and first nine months of 2009, we recognized revenue for Erbitux, a product approved to fight cancers, comprised of collaboration revenue related to the net royalties received from our collaboration partners, and product sales related to revenue from manufactured product as follows:

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
	(Dollars in millions)	
Net product sales	\$ 22.3	\$ 72.3
Collaboration and other revenue	79.6	223.5
Total revenue	\$101.9	\$ 295.8





**Table of Contents****Gross Margin, Costs, and Expenses**

For the third quarter of 2009, gross margins as a percent of total revenue increased by 3.3 percentage points, to 81.1 percent. For the first nine months of 2009, gross margins as a percentage of total revenue increased by 5.2 percentage points, to 82.3 percent. These increases were due primarily to the impact of the decline in foreign currencies compared to the U.S. dollar on international inventories sold during the periods, resulting in a benefit to cost of sales as compared with the same periods of 2008.

Operating expenses (the aggregate of research and development, marketing, selling, and administrative expenses) increased 9 percent and 5 percent for the third quarter and first nine months of 2009 compared with the third quarter and first nine months of 2008, respectively. Marketing, selling, and administrative expenses increased 3 percent to \$1.70 billion for the third quarter, and 1 percent to \$4.94 billion for the first nine months of 2009. The increase was driven by the impact of the ImClone acquisition and higher incentive compensation, partially offset by the movement of foreign exchange rates and a reduction in advertising expenses in the U.S. market. Research and development expenses were \$1.12 billion and \$3.11 billion for the third quarter and first nine months of 2009, respectively.

Compared with the same periods of 2008, research and development expenses grew 18 percent and 12 percent for the third quarter and first nine months of 2009, respectively, due primarily to the ImClone acquisition, increased late-stage clinical trial costs, and estimated costs to terminate arzoxifene clinical trials.

We did not have any acquired IPR&D charges in either the third quarter or first nine months of 2009, compared with \$28.0 million and \$150.0 million for the same periods in 2008, respectively. We incurred \$549.8 million and \$654.8 million of asset impairments, restructuring, and other special charges in the third quarter and first nine months of 2009, respectively, compared with \$1.66 billion and \$1.89 billion for the same periods in 2008, respectively. See Notes 3 and 5 to the consolidated condensed financial statements for additional information.

Other-net, expense (income) decreased \$69.4 million and \$216.8 million, to a net expense of \$66.9 million and \$161.7 million for the third quarter and first nine months of 2009, respectively, primarily due to lower interest income and higher interest expense associated with the ImClone acquisition.

We incurred income tax expense of \$127.7 million for the third quarter of 2009 resulting in an effective tax rate of 11.9 percent. We recorded income tax expense of \$232.8 million for the third quarter of 2008 despite a net loss before income taxes, due to the uncertainty of the tax treatment of Zyprexa charges in that period. We incurred income tax expense of \$807.2 million for the first nine months of 2009 resulting in an effective tax rate of 19.1 percent, a decrease from 23.3 percent for the comparable period in 2008. The effective tax rate for the third quarter and first nine months of 2009 was reduced due to the tax benefit of asset impairment and restructuring charges associated with the sale of the Tippecanoe site as well as a reduction in our forecasted effective tax rate for the year, which is driven primarily by a projected change in the mix of income among taxing jurisdictions, and, to a lesser extent, by the final resolution of the 2001-2004 IRS audit.

**FINANCIAL CONDITION**

As of September 30, 2009, cash, cash equivalents, and short-term investments totaled \$3.93 billion compared with \$5.93 billion at December 31, 2008. The decrease in cash is driven by a reduction in short-term borrowings of \$5.23 billion and dividends paid of \$1.61 billion, partially offset by proceeds of long-term debt issuances of \$2.40 billion and cash from operations of \$2.32 billion (which included payments related to the EDPA settlement of \$1.39 billion).

Total debt at September 30, 2009, was \$7.39 billion, a decrease of \$3.07 billion from December 31, 2008 reflecting the pay-down of our commercial paper that was issued to finance our acquisition of ImClone, 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.

**Table of Contents**

In the past year, 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 to stimulate 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 to 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 evolving healthcare debate, 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 markets 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 Zyprexa legal 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, 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 nine allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia, and one alleges the patent having claims directed to the active ingredient is unenforceable. Lawsuits have been filed in U.S. District Court for the Southern District of Indiana against Activis Elizabeth LLC; Anchen Pharmaceuticals, Inc.; 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.

**Table of Contents**

Gemzar: Mayne Pharma (USA) Inc. (Mayne), Sicor Pharmaceuticals, Inc. (Sicor), 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. Sandoz Inc. (Sandoz) has similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006), Mayne (October 2006 and January 2008), and Sandoz (October 2009), seeking rulings that our patents are valid and are being infringed. The trial against Sicor was held in September 2009 and we are waiting for a ruling. 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. In August 2009, the District Court granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We plan to appeal this decision. This ruling has no bearing on the compound patent. The trial originally scheduled for December 2009 has been postponed while the court considers Sun's second summary judgment motion, related to the validity of our compound patent.

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: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. The trial against Teva was completed in March 2009. In September 2009, the court upheld our method-of-use patents (the last expires in 2014). Teva has appealed that ruling. In addition, the court held that our particle-size patent (expiring 2017) is invalid. We have appealed that ruling.

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. The defendants have filed various summary judgment motions on the issues of invalidity and noninfringement, which are currently pending, and Aurobindo has received tentative approval to market generic atomoxetine. Trial is anticipated as early as the first quarter of 2010.

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

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

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled in our infringement suit against Novopharm, finding our patent invalid. We plan to appeal this decision. If the decision is upheld, we could face liability for damages related to delays in the launch of generic

**Table of Contents**

olanzapine products; however, we have concluded at this time that the damages are not probable or estimable.

In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to withdraw from the market or were subject to injunction. We 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 additional actions are now pending. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited (Dr. Reddy's) has challenged the validity of our Zyprexa 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 we expect a decision in late 2009 or early 2010.

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. In August 2009, the Court of Appeals agreed to review this decision en banc, thereby vacating the Court of Appeals decision. Nevertheless, 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.

**Zyprexa Litigation**

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims) allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (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:

**Table of Contents**

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 110 lawsuits in the U.S. covering approximately 260 plaintiffs, of which about 80 cases covering about 105 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, with the earliest trial scheduled to begin in March 2010. We also have a trial scheduled in California in November 2009.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures, and practices.

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

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We are in advanced discussions with the attorneys general for several of these states, seeking to resolve their Zyprexa-related claims, and we have agreed to settlements with the states of Connecticut, Idaho, South Carolina, Utah, and West Virginia. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the currently probable and estimable exposures in connection with these claims. The Pennsylvania case is set for trial in April 2010 in state court.

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

**Table of Contents**

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 2010.

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 product liability litigation pending in the U.S.

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

**Other Product Liability Litigation**

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

**Product Liability Insurance**

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

**Environmental Matters**

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



**Table of Contents**

**FINANCIAL EXPECTATIONS FOR 2009**

We revised our earnings per share guidance for the full year of 2009 and we now expect reported earnings per share to be in the range of \$3.90 to \$4.00. We expect mid-single digit revenue growth. We expect gross margin as a percent of total revenue to increase for the full year, driven by the beneficial foreign exchange impact in the first nine months of 2009 compared to the first nine months of 2008. For the fourth quarter of 2009, we expect a significant decrease in gross margin as a percent of total revenue compared to the fourth quarter of 2008. 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. The effective tax rate is now expected to be approximately 20 percent. Capital expenditures are now expected to be less than \$1.0 billion. 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/sec.cfm>.

*Item 4. Controls and Procedures*

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

Our management, with the participation of John C. Lechleiter, chairman, president, and chief executive officer, and Derica W. Rice, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2009, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the third 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.

**Table of Contents**

**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, Strattera, 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.

That information is incorporated into this Item by reference.

*Other Product Liability Litigation*

We refer to Part I, Item 3, of our Form 10-K annual report for 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 35 suits involving approximately 65 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 210 suits involving approximately 285 claimants. In addition, we have been named a defendant in approximately 35 40 lawsuits involving approximately 165 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. In June 2009, a lawsuit was filed in Louisiana State Court (Ralph Jackson v. Eli Lilly and company, et al.) seeking to assert similar product liability claims on behalf of Louisiana residents who were prescribed Byetta; however, the plaintiff dropped the class action allegations in a recently-filed amended complaint.

*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; the lawsuit currently involves 145 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). The plaintiffs are now seeking leave of court to amend their complaint a third time to name the NAACP and 51 individual plaintiffs, dropping the remaining plaintiffs previously named and dropping their request for class action status. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

**Table of Contents**

We have also been named as a defendant in a lawsuit filed in the U.S. District Court for the Northern District of New York (*Schaefer-LaRose, et al., v. Eli Lilly and Company*, filed November 14, 2006) claiming that our pharmaceutical sales representatives should have been categorized as non-exempt rather than exempt employees, and claiming that the company owes them back wages for overtime worked, as well as penalties, interest, and attorneys' fees. Other pharmaceutical industry participants face identical lawsuits. The case was transferred to the U.S. District Court for the Southern District of Indiana in August 2007. In February 2008, the Indianapolis court conditionally certified a nationwide opt-in collective action under the Fair Labor Standards Act of all current and former employees who served as a Lilly pharmaceutical sales representative at any time from November 2003 to the present. As of the close of the opt-in period, fewer than 400 of the over 7,500 potential plaintiffs elected to participate in the lawsuit. In September 2009, the District Court granted our motion for summary judgment with regard to Ms. Schaefer-LaRose's claims and ordered the plaintiffs to demonstrate why the entire collective action should not be decertified within 30 days. We expect plaintiffs will appeal this decision to the 7th Circuit Court of Appeals. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

In September, one of the opt-in plaintiffs in *Schaefer-LaRose, et al., v. Eli Lilly and Company* filed an action in the Superior Court for Alameda County, California, alleging on behalf of a putative class that the company violated California's Business and Professions Code by failing to pay sales representatives overtime and by not providing them with rest and meal breaks under California law. We believe the lawsuit is without merit and are prepared to defend against it vigorously.

*Other Matters:*

During routine inspections in 2006 and 2007, the U.S. Environmental Protection Agency (EPA) identified potential gaps in our leak detection and repair program (LDAR). In addition, in 2006 we voluntarily reported to the state and city environmental agencies that we had exceeded an annual limit for air emissions. In response to these events, we have implemented numerous corrective actions and enhancements to our LDAR program. We are currently working with the EPA towards resolution of this matter, which will likely require the payment of a fine. We do not believe the amount of the fine will be material.

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.

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2009:

Period	Total Number of Shares Purchased (a) (in thousands)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c) (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d) (in millions)
July 2009		\$		\$ 419.2
August 2009	1	32.88		419.2
September 2009				419.2
Total	1			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of September 30, 2009, we have purchased \$2.58 billion related to this program. During the first nine 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.

*Item 6. Exhibits*

The following documents are filed as exhibits to this Report:

- EXHIBIT 10. The Lilly Directors' Deferral Plan as amended through October 19, 2009
- EXHIBIT 11. Statement re: Computation of Earnings per Share
- EXHIBIT 12. Statement re: Computation of Ratio of Earnings to Fixed Charges
- EXHIBIT 31.1 Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer
- EXHIBIT 31.2 Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer
- EXHIBIT 32. Section 1350 Certification
- EXHIBIT 101. Interactive Data File



**Table of Contents**

SIGNATURES

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

**ELI LILLY AND COMPANY**

(Registrant)

Date October 30, 2009

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

Date October 30, 2009

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

46

---

**Table of Contents**

INDEX TO EXHIBITS

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

Exhibit

EXHIBIT 10.	The Lilly Directors' Deferral Plan as amended through October 19, 2009
EXHIBIT 11.	Statement re: Computation of Earnings per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data File